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#### **CORRIGENDUM**

This document corrects document SWD(2016) 127 final of 21.4.2016

Incorrect data sets in A.1.3, A.1.28, and A.1.30. of Annex 1 have been replaced and the Table of Contents amended accordingly.

The text shall read as follows:

#### COMMISSION STAFF WORKING DOCUMENT

on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells

{COM(2016) 223 final} {SWD(2016) 128 final}

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#### **ABBREVIATIONS**

ART = assisted reproductive technologies

ATMP = advanced therapies medicinal products

CMV = cytomegalovirus

DBM = demineralised bone matrix

EBV = Epstein–Barr virus

EBMT = European Group for Blood and Marrow Transplantation

EC = European Commission

ECDC = European Centre for Disease Prevention and Control

EEA = European Economic Area

EU = European Union

GMP = good manufacturing practices

GTP = good tissue practices HBV = hepatitis B virus HCV = hepatitis C virus

HSC = haematopoietic stem cells HIV = human immunodeficiency virus

HFEA = Human Fertility and Embryology Authority

HLA = human leukocyte antigen HTA = Human Tissue Authority

HTLV = human T-cell lymphotropic virus

IgM = immunoglobulin M

ISO = International Organization for Standardization JACIE = Joint Accreditation Committee-ISCT & EBMT

NAT = nucleic acid amplification test PBSC = peripheral blood stem cells RATC = Rapid Alerts for Tissues and Cells

SAE = serious adverse event SAR = serious adverse reaction

SARE = serious adverse reactions and events SOP = standard operating procedures

Member State and country codes: <a href="http://publications.europa.eu/code/en/en-370100.htm">http://publications.europa.eu/code/en/en-370100.htm</a>

#### 1. Introduction

This Staff Working Document accompanying the Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells summarises the results of a Commission survey on the implementation of the EU tissue and cell legislation conducted in 2013. The data reported was from 2011.

The implementation survey was answered by all Member States except Greece, and also by two EEA countries, Liechtenstein and Norway. The individual country responses are included in Annex 1 to this document. Only Greece did not provide any information. Overall the cooperation with the Member States was satisfactory reflecting the very good interaction between the Commission services and the Member States in this area.

This document addresses only the implementation of the EU tissues and cells legislation, whereas the outcome of the verification of completeness of transposition performed by the Commission is summarised in the overall Report on the implementation of the EU tissue and cell legislation. Information on the application of the principle of voluntary and unpaid donation (VUD) is presented in a separate Staff Working Document also accompanying the abovementioned Report.

The implementation section of this document follows the structure of Directive 2004/23/EC, and includes three main chapters which address the obligations of Member States' authorities, donor selection and evaluation, and quality and safety of tissues and cells.

#### 2. IMPLEMENTATION OF THE EU TISSUES AND CELLS LEGISLATION

The implementation survey covers a broad range of topics: 1. designation of competent authorities, 2. obligations of Member States' authorities, 3. donor selection and evaluation, and 4. quality and safety of tissues and cells. Each sub-section ends with comments summarising the main findings.

Overall, the implementation of the EU tissues and cells legislation by Member States is considered adequate. However, a number of Member States reported difficulties in the interpretation, implementation or enforcement of some of its requirements.

As the EU legislation in the tissue and cell sector does not provide for full harmonisation, Member States had various approaches when implementing its provisions. These differences facilitate successful integration of the requirements into national legislation but in some cases they may limit the mutual acceptance of authorisations with consequences on the cross-border movement of tissues and cells

In a number of cases clarification requests were sent to Member States, as replies were incomplete or difficult to reconcile with other information available to the Commission. It is important to note that the hyperlinks contain the original replies of Member States, whilst the report reflects the updated information provided by Member States. This can lead to certain discrepancies. In such cases this report contains the correct information.

# 2.1. Designation of Competent Authority or Authorities Responsible for the Implementation of Directive $2004/23/E\mathrm{C}$

In the 2010 Communication on the application of Directive 2004/23/EC<sup>2</sup> it was stated that all Member States had designated a competent authority in accordance with the provision laid down in Article 4(1), with 21 Member States having one competent authority responsible for all types of tissues and cells and five Member States (EL, FI, FR, PT, UK) with a specific competent authority for reproductive tissues and cells.

The 2013 survey revealed some organisational changes in the Member States (Table I, Figure 1):

- In 15 Member States (AT, BE, BG, DE, DK, EE, FI, HR, HU, IE, LU, LV, MT, SI, SK) and Liechtenstein, there is only one competent authority;
- Four Member States (CZ, ES, RO, UK) reported that two competent authorities were designated in their countries. In the Czech Republic, while the main competent authority is responsible for tissue establishments' authorisation and inspection, as well as vigilance, a second competent authority is in charge of granting import and export licences, European affairs and various aspects related to the national legislation. In the United Kingdom one competent authority is overseeing the traditional tissues and cells, and the other is responsible for the supervision in the Assisted Reproductive Technologies (ART) sector. In Romania one authority is mainly responsible for the accreditation of the tissue establishments, while a second one is in charge of inspections and vigilance. In Spain, the organisation is similar to the one in the United Kingdom, but the national ART competent authority has only a consultative role, whereas the authorisation, inspection and vigilance tasks were delegated to the regions;
- Six Member States (FR, LT, NL, PL, PT, SE) and Norway reported that three competent authorities were designated to oversee the tissues and cells field at national level;
- In France, Portugal and UK one of the competent authorities is responsible only for the oversight of the ART sector;
- Five Member States declared having regional competent authorities, namely DE, ES, FR, IT and SK. These authorities have been entrusted with tasks like accreditation/authorisation/designation/licensing of tissue establishments, inspection and/or vigilance. In Italy regional authorities are responsible only for authorising the tissue

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establishments.

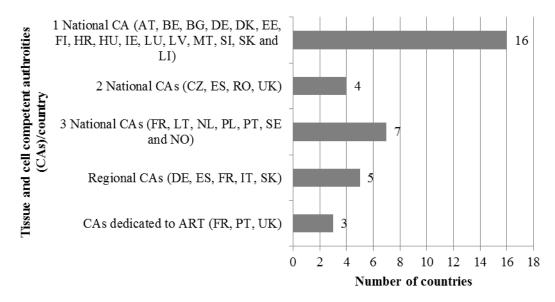


Fig. 1. Tissues and cells competent authorities in the reporting EU Member States and EEA countries

In two Member States the designated competent authorities do not cover all the categories of tissues and cells as requested by the Directives. This is the case of Poland<sup>3</sup> and Lithuania, where, due to an inappropriate transposition of the EU legislation in the ART sector, no competent authorities responsible for this particular field were reported.

In addition to the oversight of the tissues and cells sector, in most of the Member States, the tissues and cells competent authorities are also supervising other sectors/activities (Figure 2).

<sup>&</sup>lt;sup>3</sup> In 2015 Poland has adopted new legislation for the ART sector and is in process of implementing it.

Country	National competent authority 1	National competent authority 2	National competent authority 3
AT	Federal Office for Safety in Health Care (BASG) / AGES Austrian Agency for Health and Food		
BE	FAMHP: Federal Agency for Medicines and Health Products		
BG	Bulgarian Executive Agency for Transplantation		
CY	Ministry of Health, Cyprus		
CZ	State Institute for Drug Control	Ministry of Health of the Czech Republic	
DE	Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel		
DK	Danish Health & Medicines Authority		
EE	State Agency of Medicines		
EL	no data reported		
ES	Organizacion Nacional de Transplantes		
FI	Finnish Medicines Agency		
FR	Ministry of Health	Agence nationale de sécurité du médicament et des produits de santé (ANSM)	Agence de la biomédecine (ABM)
HR	Ministry of Health	,	
HU	National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)		
IE .	Irish Medicines Board (IMB)		
IT	Ministry of Health - National Transplant Centre	National Blood Centre	
LT	National Transplants Bureau under the Ministry of Health of the Republic of Lithuania	Ministry of Health of the Republic of Lithuania	State Health Care Accreditation Agency under the Ministry of Health
LU	Ministère de la Santé		
LV	State Agency of Medicines of the Republic of Latvia		
MT	Superintendence of Public Health, Ministry for Health, Malta		
NL	Ministry of Health, Welfare and Sport (Ministerie voor Volksgezondheid, Welzijn en Sport, VWS)	Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ)	Dutch Transplantation Foundation (Nederlandse Transplantatie Stichting, NTS)
PL	National Centre for Tissue and Cell Banking	Polish Transplant Coordinating Center Poltransplant	Department of Mother and Child, Ministry of Health
PT	Instituto Português do Sangue e da Transplantação, IP (IPST)	Direção-Geral de Saúde	Conselho Nacional de Procriação Medicamente Assistida (CNPMA)
RO	National Transplant Agency	Ministry of Health - Public Health and Control in Public Health Directorate	
SE	Health and Social Care Inspectorate / Inspektionen för vård och Omsorg (IVO)	Medical Products Agency	The National Board of Health and Welfare
SI	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke / Agency for Medicinal Products and Medical Devices of the Republic of Slovenia		
SK	Ministry of Health of the Slovak Republic		
UK	Human Tissue Authority (HTA)	Human Fertilisation and Embryology Authority (HFEA)	
11	Amt file Gagundhait		
NO NO	Amt für Gesundheit Norwegian directorate of health	Norwegian board of health supervision	Norwegian medicines agency

Table I. Tissues and cells national competent authorities

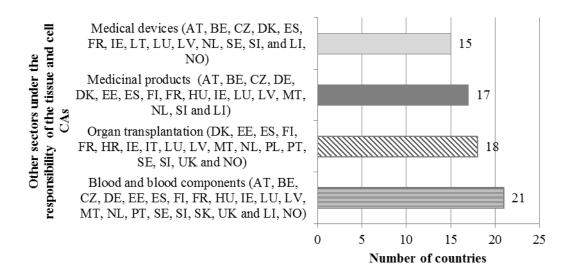


Fig. 2. Other responsibilities of tissues and cells competent authorities

Several Member States provided clarifications on the tasks and responsibilities of their national competent authorities. Germany and Ireland specified that they are also responsible for advanced therapy medicinal products and xenogenic medicinal products. Furthermore, some Member States reported that their competent authorities are also responsible for: cosmetic products, veterinary products (France, Ireland); tattoo inks, biocides, ancillary products, human breast milk (France); clinical trials approval, protection of animals (Ireland); data collection and traceability (Italy); licensing of import-export activities (Czech Republic, Poland); licensing organisations that remove, store, and use human tissue for purposes outside direct patient treatment (United Kingdom/HTA); public health regulation (Malta); policy development and implementation (Denmark, Ireland, United Kingdom); providing training programmes, international cooperation, relation with the media, research projects, transplant registries, promotion and education (Spain, Italy); enforcement (Ireland).

Certainly the designation of the competent authority or authorities in the field of human tissues and cells for human application is a prerogative of the Member States and EEA countries. As demonstrated by the reported data, many national competent authorities are ministries or agencies or delegated bodies in the health sector. In some countries the nominated organisations also work on research, education or labour issues. Some countries with federal organisations have entrusted some important responsibilities (e.g. authorisation and inspection of tissue establishments) to the regional authorities. Whereas some Member States preferred to pool national capability in one large national competent authority usually responsible for several/all healthcare sectors, other countries chose to develop expertise by creating/maintaining distinct organisations dedicated to oversee the human tissues and cells sector or a specific area of this sector (e.g. ART). Irrespective of organisational structure, the bi-annual meetings of the tissues and cells competent authorities allow for sharing best practices, with specialised authorities giving significant input in their particular area of expertise and the others contributing with integrative standpoints within the broader context of the healthcare sector, especially when analysing borderline issues like those with the medical devices and medicinal products sectors.

#### **Comments**

All Member States have appointed competent authorities for tissues and cells, which can be considered satisfactory. In some Member States more than one authority is responsible for the oversight of the tissue and cell sector. In these cases the division of tasks is based on the tissue types concerned (e.g. separate authority for the ART sector), geographic competences (federal/regional/local) or instruments used (e.g. authorisation/inspection). In some Member States the authorities for tissues and cells are also responsible for the oversight of other sectors (e.g. organs, blood, medicinal products), which can be beneficial from an efficiency point of view. Ultimately it is for the Member States to decide on the organisational set-up of their competent authorities. However, Member States need to ensure adequate coordination and communication between all authorities involved, e.g. to discuss borderline issues or ensure adequate follow-up in case of shortcomings.

Irrespective of the organisational set-up it is important that all authorities have adequate resources at their disposal and are independent from industry, from the professional sector and other influences. In this respect it could be problematic if one and the same person works for a national competent authority and – at the same time – for a national tissue establishment.

# 2.2 Obligations of Member States Authorities

Directive 2004/23/EC contains a number of obligations for competent authorities. They relate to (1) the supervision of procurement, (2) the authorisation of tissue establishments, (3) inspections and control measures, (4) traceability, (5) imports and exports, (6) reporting obligations and (7) notification of serious adverse events and reactions. The implementation of these obligations is set out in this section.

### 2.2.1 Supervision of human tissue and cell procurement

Under Article 5 of the Directive 2004/23/EC, the competent authority or authorities must ensure that tissue and cell procurement and testing are carried out in conditions accredited, designated, authorised or licensed for this purpose and that it complies with the requirements laid down in Directive 2006/17/EC.

The survey showed that all reporting Member States authorise the conditions of procurement, as follows:

- Twelve Member States (BG, CY, CZ, DE, ES, FI, HR, HU, IE, LU, MT, SI) and Liechtenstein authorise the conditions of procurement by inspecting all procurement centres:
- Seven Member States (AT, DK, IT, PL, PT, SE, UK) reported inspecting some procurement centres;
- Nineteen Member States (AT, BE, BG, CY, DE, DK, EE, HR, HU, IT, LT, LU, LV, MT, NL, PL, PT, SE, UK) and Norway evaluate the documentation associated with the procurement made available by the tissue establishment working with procurement centres.

Additionally, Member States reported other practices:

• Procurement sites have to be listed on the tissue establishment's licence and inspected during routine inspections (Finland);

- Procurement activities are evaluated during the product evaluation, where documentation has to include a description of the procurement conditions (France);
- Procurement centres which operate through a third party agreement with a licensed establishment are not inspected by the national competent authority (United Kingdom).

Estonia specified that only tissue establishments and healthcare professionals having contracts with tissue establishments are allowed to procure tissues. Ireland reported that when procurement occurs in Ireland, the activity is inspected and the site requires a tissue establishment authorisation; if the procurement occurs outside Ireland, the relevant documentation is inspected onsite at the Irish tissue establishment. Similar to Ireland, in Belgium procurement can be carried out only by authorised tissue establishments. Romania reported that one competent authority is responsible for evaluating the documentation of all the procurement centres, while the other authority is responsible for their inspection. Spain informed that the task of supervising human tissue and cell procurement was entrusted to the regional competent authorities.

In 2011, 20 Member States and Liechtenstein and Norway, granted 640 authorisations for the conditions of procurement (Figure 3). Six Member States (FI, IE, LU, LV, PT, SE) did not grant any authorisation and in two Member States (Greece and Italy) such data were not available.

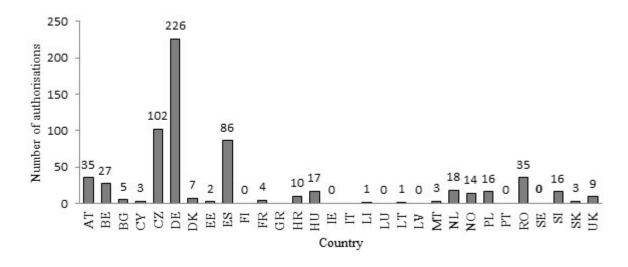


Fig. 3. Number of authorisations for conditions of procurement granted in 2011

Most of the Member States provided the number of centres carrying out procurement activities in 2011. Of the 4825 procurement organisations carrying out procurement activities, most of them are dedicated to the collection of haematopoietic stem cells, followed by procurement of replacement tissues and reproductive cells (Figure 4). It has to be underlined that a number of 332 procurement organisations harvesting cells or tissues to be used for advanced therapy medicinal product (ATMP) manufacturing were also reported. A detailed analysis of the procurement organisations per Member State and type of tissues procured is presented in Figures 5 - 8.

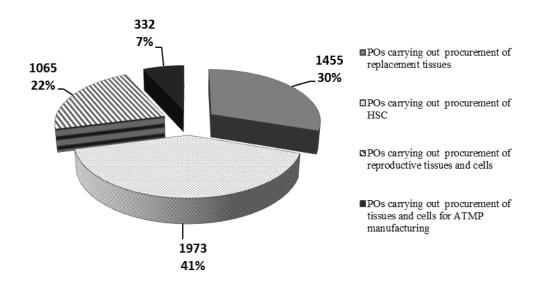


Fig. 4. Number of procurement organisations reported by the EU and EEA countries (2011 data)

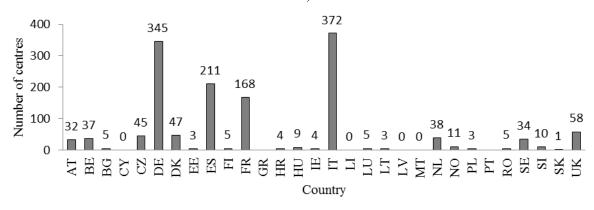


Fig. 5. Number of centres carrying out procurement of replacement tissues (e.g. musculoskeletal, cardiovascular, ocular tissue, skin) in 2011

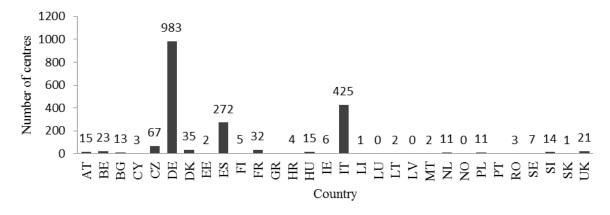


Fig. 6. Number of centres carrying out procurement of HSC (e.g. bone marrow, peripheral blood stem cells, cord blood) in 2011

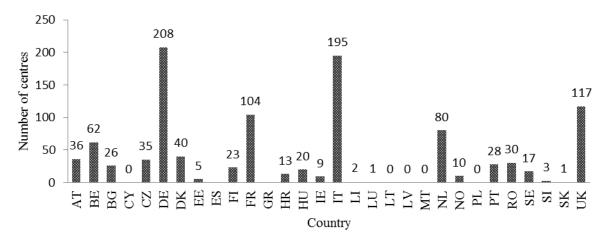


Fig. 7. Number of centres carrying out procurement of reproductive tissues and cells in 2011

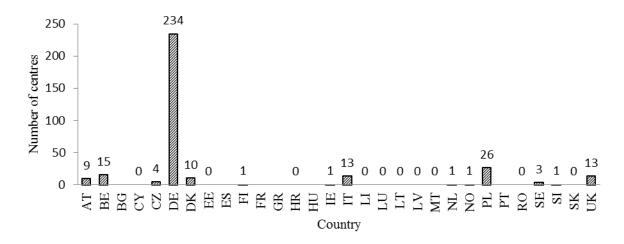


Fig. 8. Number of centres carrying out procurement of tissues and/or cells for ATMP manufacturing in 2011

The survey revealed that all reporting Member States ensure that centres carrying out procurement of human tissues and cells centres comply with the requirements of Article 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC. Their approaches vary, with Member States only inspecting the site/centre, others only analysing the mandatory documentation (Belgium, Denmark), and most of them performing both inspections and analysis of the mandatory documentation (Fig 9).

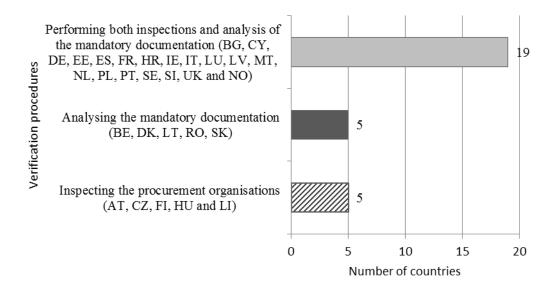


Fig. 9. Member States' approaches for ensuring that centres carrying out procurement of human tissues and cells comply with the EU legal requirements

Additional procedures were also reported. In Sweden tissue establishments perform audits of the procurement centre(s) and the audit reports are examined during the inspection of the tissue establishment. The competent authority in the United Kingdom (HTA) reported investigating allegations about non-compliance with procurement standards; moreover, to ensure continued compliance, correspondence is circulated to the sector (e.g. newsletter) and regular workshops are organised for updating the tissue establishments on the latest regulatory requirements.

According to Article 5(1) of Directive 2004/23/EC Member States have to ensure that testing is carried out in conditions accredited, designated, authorised or licensed for this purpose. The survey showed that only in 10 Member States (CZ, DE, DK, HR, LU, MT, NL, RO, UK) and Liechtenstein and Norway, the tissues and cells competent authorities are also responsible for the accreditation/designation/authorisation or licensing of testing laboratories. In all the other Member States this is the competence of other authorities (Table II), as follows:

- Ministry of Health (Cyprus, Slovenia);
- Regional authorities (DE, ES, FI, HU, IT);
- National accreditation organisations.

Country	Name of the national accreditation organisation
BE	Scientific Institute for Public Health
BG	Bulgarian Service for Accreditation
EE	Estonian Accreditation Centre
FI	National Institute for Health and Welfare
FR	Comité Français d'Accréditation
IE	Irish National Accreditation Board
LV	Latvian National Accreditation Bureau
PL	National Chamber of Diagnostic Laboratories
PT	Direcao-General de Saude
SE	The Swedish Board for Accreditation and Conformity Assessment
SK	Slovak National Accreditation Service
UK	Clinical Pathology Accreditation (private organisation, providing a voluntary national accreditation service)

Table II. National accreditation organisation responsible for the accreditation/designation/authorisation or licensing of testing laboratories

Additionally, Malta, Romania and Liechtenstein reported that in their countries the tissues and cells competent authorities are responsible for the laboratories' accreditation, without being responsible for inspecting them. Austria reported having no national provisions on accreditation of testing laboratories.

The Member States' approaches for ensuring that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed in conformity with Article 5(2) of Directive 2004/23/EC are shown in Figure 10.

Concerning the inspection of the testing laboratories, while in the Czech Republic, Denmark and the United Kingdom the tissues and cells competent authorities are also responsible for the laboratories' accreditation, in Hungary, Portugal and Spain this task is not in their remit.

Eleven Member States also provided the number of qualified laboratories in their countries (2011 data) (Figure 11).

Overall, the answers to this section of the questionnaire showed that Member States pay strict attention to the procurement of human tissues and cells. This is underlined by the fact that several countries allow procurement to be performed only by tissue establishments (BE, DE, EE, IT, SE) or authorise the conditions of procurement by inspecting all procurement centres (BG, CY, CZ, DE, ES, FI, HR, HU, IE, LU, MT, SI and LI). Additionally, in most of the responding countries, the documentation associated with the procurement is analysed during tissue establishments' inspections.

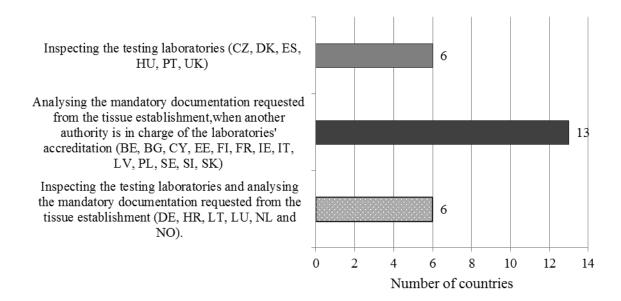


Fig. 10. Member States approaches for ensuring that donors' testing is carried out in conformity with Article 5.2 of the Directive 2004/23/EC

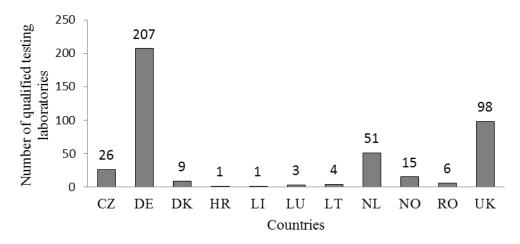


Fig. 11. Number of qualified testing laboratories/Member State (Total number = 421 - 2011 data)

#### **Comments**

The high number of procurement organisations shows that this activity is well developed across the Union, particularly in the larger Member States with tradition in this field (e.g. DE, FR, IT, UK). Furthermore, beside procurement of replacement tissues, haematopoietic stem cells and reproductive cells, some Member States also reported a significant number of centres carrying out procurement of tissue and cells for ATMP manufacturing.

Concerning testing, the survey showed that in most of the reporting countries accreditation/designation/authorisation or licensing of testing laboratories is not under the competence of tissues and cells authorities. In most of the cases the national accreditation organisations are also responsible for the inspection of the testing laboratories. However, only the countries in which tissues and cells competent authorities are also responsible for the

accreditation/designation/authorisation or licensing of testing laboratories provided data on the number of qualified laboratories on their territory. Wherever accreditation and inspections are undertaken by different authorities, a good communication and coordination between respective authorities needs to be ensured.

# 2.2.2. Accreditation/designation/authorisation/licensing of tissue establishments and tissue and cell preparation processes

Under Article 6(1) of Directive 2004/23/EC, Member States must have in place an appropriate mechanism to ensure that all tissue establishments where activities of testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

All Member States reported that for replacement tissues and cells (e.g. musculoskeletal tissue, cardiovascular tissues, ocular tissues, skin, haematopoietic stem cells) an accreditation/designation/authorisation/licensing system of tissue establishments is in place. In the ART sector, 25 Member States reported having an accreditation, designation, authorisation, licensing system also for the ART tissue establishments, while two Member States (Lithuania, Poland) are still in the process of organising their national oversight system for this area.

As reported by the Member States, inspections play a key role in the accreditation/designation/authorisation/licensing process which varies from prior compulsory on-site inspections to desk-based review of documentation and routine inspections (Figure 12). In five Member States (ES-ART sector, FR, SE, SK, UK) and Norway inspection is not a prerequisite for the designation, authorisation, accreditation, or licensing of tissue establishments.

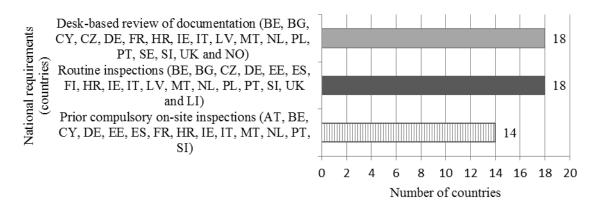


Fig. 12. National requirements for accrediting/designating/authorising/licensing of tissue establishments

Under Article 6(2), the competent authority or authorities must authorise the tissue and cell preparation processes which the tissue establishment is entitled to carry out.

Compared with the 2008 data when only three Member States were conducting inspections solely for the purpose of authorising preparation processes, this second survey reveals that 14

Member States are now organising such inspections (Figure 13). In the other Member States, in the absence of specific authorisation systems, tissue and cell preparation processes are either authorised by reviewing applications of the submitted documentation or during a general inspection for the purpose of authorising a tissue establishment.

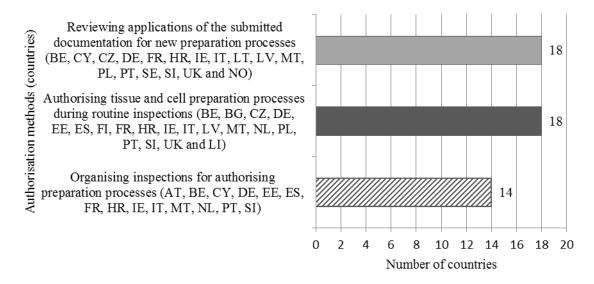


Fig. 13. National systems for authorising tissue and cell preparation processes

Two Member States, Croatia and the Netherlands, reported that a certification of the tissue establishment to a quality system standard provided by an external entity is also required. In other Member States (Cyprus, France and Spain), the certification by an external entity is optional, but recommended. In Italy there are different approaches depending on the type of tissues/cells: whereas haematopoietic stem cells centres are inspected in collaboration with JACIE and cord blood banks require ISO certification, for the other types of tissues and cells, no certification is required by law.

Compared to 2008 when 1716 tissue establishments were accredited/designated/authorised/licensed, the current survey showed that at 31/12/2011 a total of 2047 tissue establishments were accredited, designated, authorised or licensed in the EU (Figures 14 and 15).

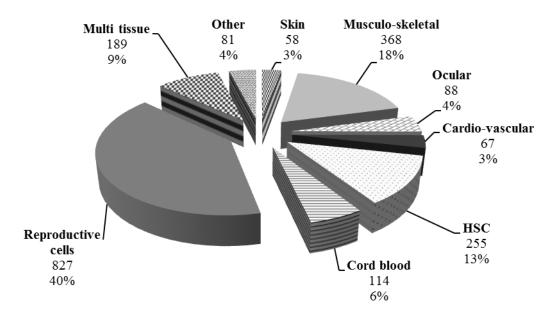


Fig. 14. Number of accredited/designated/authorised/licensed tissue establishments per type of human tissues and cells (2011 data)

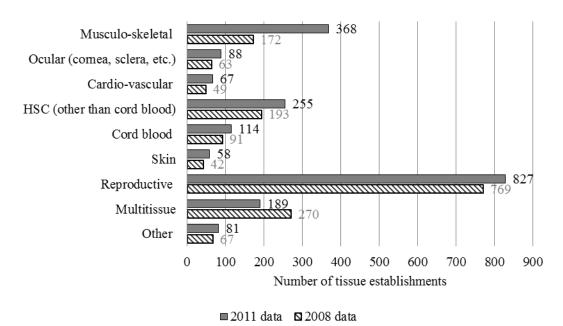


Fig. 15. Number of accredited/designated/authorised/licensed tissue establishments per type of human tissues and cells (comparative data)

The numbers of accredited/designated/authorised/licensed tissue establishments per country are presented in Figure 16. Only one Member State, namely Malta, reported having no authorised tissue establishments on their territory. Norway provided no information on the number of tissue establishments.

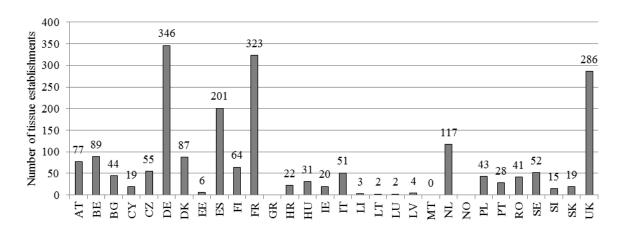


Fig. 16. The number of accredited/designated/authorised/licensed tissue establishments/country (2011 data)

Additionally in 2011, 1674 tissue establishments were authorised/re-authorised by competent authorities in 26 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK) and Liechtenstein. Eighteen Member States (AT, BE, BG, CY, CZ, DE, FR, HR, HU, IE, IT, LV, MT, PL, RO, SI, SK, UK) and Liechtenstein indicated that 528 tissue establishments were pending approval of authorisation/re-authorisation at 31/12/2011.

Information on the status of the tissue establishments (public vs. private) was provided by 25 Member States and Liechtenstein. The situation is summarised in Figures 17 and 18. Two other countries, Spain and Norway, indicated that such data are not available.

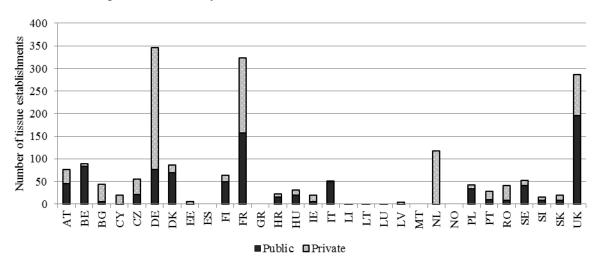


Fig. 17. Tissue establishments' status (public vs. private)/country (2011 data)

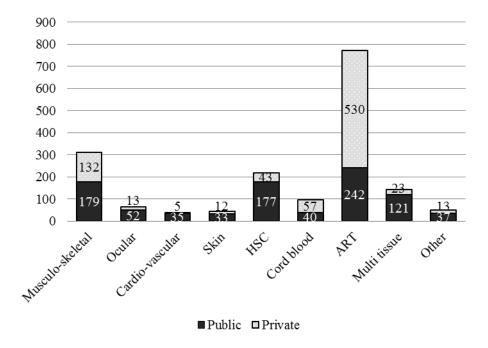


Fig. 18. Tissue establishments' status (public vs. private)/type of tissue (2011 data)

Overall, 916 public and 828 private accredited/designated/authorised/licensed tissue establishments were reported. As shown in Figure 18, only in the ART field and the cord blood sector the number of private tissue establishments exceeds the number of the public ones (69% and 59% respectively). Some interesting mixed models have emerged such as the tissue sector in Italy, where the private sector role is limited to that of a third party for processing or storage, with all donation, promotion and distribution activities remaining in public hands.

Under Article 6(5), competent authorities may agree to the direct distribution of tissues and cells for immediate transplantation to a recipient. Six Member States (CY, DE, DK, LT, FR, PT) indicated that in 2011 tissues and/or cells were distributed under the direct agreement of an competent authorities. In most of the cases, these were HSC (bone marrow, PBSC, cord blood, donor lymphocyte infusion), but also ocular tissues (Denmark, Portugal), heart valves (Portugal), musculoskeletal tissue (Lithuania, Portugal) and amniotic membrane (Portugal).

### **Comments**

The importance of the tissue and cell sector was demonstrated by its development in the last three years, with an almost 20% increase in the number of authorised tissue establishments compared with the previous survey. In two areas (musculoskeletal tissues and reproductive cells) a significant rise in the tissue establishments' number was noted, whereas for other types of tissues and cells the number of authorised tissue establishments slightly decreased. Additionally, if for most types of tissues and cells the public sector prevails, in the field of ART approximately 60% of the ART establishments belong to the private sector. The development of the private sector is more significant in some Member States (e.g. the Netherlands), while in others (e.g. BG, CZ, DE, RO) is due to the expansion of private ART establishments and cord blood banks.

Summing up, the answers concerning the accreditation/designation/authorisation/licensing of tissue establishments and tissue and cell preparation processes showed that this core responsibility is well implemented across the Union. However, when the survey was launched, two Member States were still in the process of transposing into national legislation the requirements for safety and quality in the ART field, and one Member State had no operational competent authority and submitted no replies to the implementation questionnaire.

The survey showed that the authorisation process is quite heterogeneous, which may hinder the process of mutual acceptance of authorisations between EU Member States. Even though half of the responding Member States require a prior on-site inspection, most of the countries grant a tissue establishment authorisation/accreditation/licence based on a desk-based review of the documentation. Additionally, depending on the Member State's approach, tissue establishments' authorisations/accreditations/licences are granted for a limited or unlimited time interval.

A combination of approaches was also reported for authorising tissue and cell preparation processes. Numerous recent technological developments which generated new processing methodologies, unheard of a decade ago (e.g. pre-cutting of corneas with the transplant of only the anterior or posterior segment to one patient, decellularisation of skin and heart valves, new pathogen inactivation or sterilisation techniques) have increased the importance of robust preparation process authorisation. As suggested by some Member States, a more harmonised procedure and/or establishing an EU authorisation template for preparation process authorisation may contribute to reaching mutual acceptance between Member States.

While it is for Member States to decide which terminology to use for the initial permission to operate as a tissue establishment, it should be transparent and mutually clear for competent authorities that the requirements of the EU legislation have been met in every Member State. The differences in terminology used might create some confusion, in particular as some of these terms (e.g., accreditation) are also used to describe reviews by private, non-governmental entities.

Overall, the survey shows that it is important that all Member States continue improving their practices on authorisation, accreditation, licensing and designation according to the EU legislation.

#### 2.2.3. Inspections and control measures

Under Article 7(1) of Directive 2004/23/EC, Member States must ensure that the competent authority or authorities organise inspections and that the tissue establishments carry out appropriate control measures.

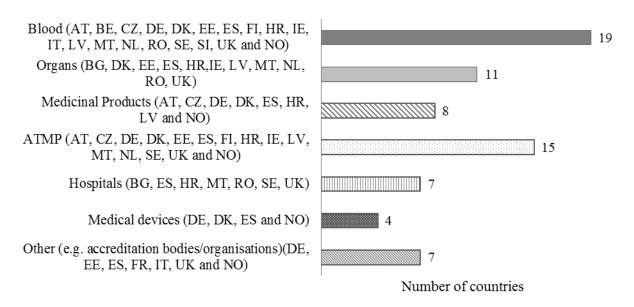
As reported in the first implementation survey, most of the countries have comprehensive inspection systems place. Twenty-four Member States (AT, BE, BG, CY, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, PL, PT, RO, SE, SI, UK) and Liechtenstein and Norway confirmed the existence of such systems (Table III).

	<del>-</del>	
AT	Austrian Agency for Health and Food Safety (AGES)	
BE	Directorate General Inspection of FAMHP	
BG	National Transplant Agency - Department "Registers, information, control and development of transplant"	
CY	Ministry of Health	
CZ	Clinical Practice and Surveillance over Biological Material Processing (part of Inspection Division)	
DE	Regional competent authorities in the German Länder supported by the Paul-Ehrlich-Institute.	
DK	DK Danish Medicines and Medicines Authority	
EE	State Agency of Medicines, Department of Biologicals within the structure of the agency.	
ES	Regional competent authorities.	
FI	Fimea's Inspectorate unit within the "Supervision and licenses Department"	
FR	ANSM (INSBIO Department) - for non-reproductive tissues and cells. Regional agencies - for ART establishments	
HR	Ministry of Health - Service for Blood, Tissues and Cells Inspection	
HU	Officers of the National Public Health and Medical Officer Service - Office of the Chief Medical Officer, Department of Health Administration	
IE	Irish Medicines Board - Compliance department	
IT	CNT - Tissue and Cell section. For HPC and cord blood banks inspections are carried out in collaboration with CNS.	
LI	Arzneimittelkontrolle, for coordination and the Swissmedic inspectorate by agreement.	
LT	Legal and Supervisory Division of the National Transplant Bureau under the Ministry of Health of Lithuania	
LU	Ministère de la santé - Division de la médecine curative.	
LV	State Agency of Medicines - Pharmaceutical activities compliance evaluation department	
MT	Superintendence of Public Health	
NL	Health Care Inspectorate	
NO	Norwegian Board of Health Supervision	
PL	National Centre for Tissue and Cell Banking	
PT	DGS - Departamento da Qualidade na Saúde, for non-reproductive tissues. Ministry of Health' administrative body for Health Inspections (IGAS) in collaboration with CNPMA, for ART establishments.	
RO	Ministry of Health - State Sanitary Inspectorate	
SE	The Health and Social Care Inspectorate	
SI	Agency for Medicinal Products and Medical Devices	
SK	In preparation	
UK	HTA - Regulation directorate for tissue establishments handling non-reproductive tissues and cells and reproductive tissues. HFEA - Directorate of Compliance - for ART establishments	

Table III. Competent authorities responsible for inspections (2011 data)

One Member State, Slovakia, is currently developing/revising the inspection system at national level.

Most Member States reported that tissue establishment inspection schemes overlap or interact with inspections performed in other sectors (mostly blood, organs, medicinal products/advanced therapies (Figure 19). Only seven Member States (CY, HU, LT, LU, PL, PT, SK) and Liechtenstein indicated having in place national inspection schemes dedicated only to tissue establishments.



19. Overlaps of the tissue establishment inspection schemes

Twenty-five Member States provided data on the staffing of inspection departments within the national competent authorities (Figure 20) and the number of inspections performed in 2011 (Figures 21a and 22a), as well as their outcome (Figures 21b and 22b).

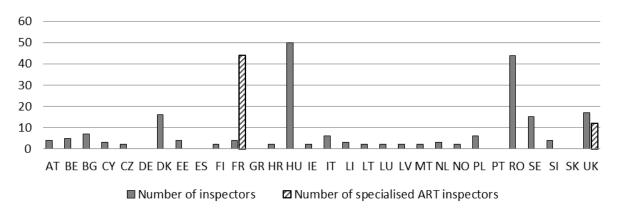


Fig. 20. Number of inspectors/Member State (numbers provided by FR, HU, RO and SE include also the inspectors in the regional authorities)

For Spain, where inspection was entrusted to the competent authorities in the autonomous regions, no data on either staffing or the number of inspections performed in 2011 were provided. Germany indicated that inspections are carried out by the regional competent authorities of the German *Länder*, supported by the national competent authority and provided data only on the number of inspections performed in 2011. Additionally, France specified that for the ART sector the regional agencies were given the task of inspecting the ART establishments, but the national authority is responsible for ensuring the appropriate training of the ART inspectors and for publishing an annual report on these inspections. Several Member States pointed out that inspections are carried out by inspectors of the national competent authority together with inspectors from the regional competent authorities (e.g. HU, IT, RO). Sweden reported that inspections are performed by the national competent authority together with inspectors from the regional offices. No information was received from Slovakia. Two Member States, France and the United Kingdom, provided data on the number of specialised inspectors for the ART establishments.

Regarding staffing, 13 Member States (BE, DK, EE, HR, IE, LU, LV, MT, PL, PT, RO, SE, SI) and Liechtenstein specified that inspectors responsible for the inspection of tissue establishments are also in charge of performing inspections in other sectors (e.g. blood, organs, medicinal products, sanitary inspections).

Regarding the number of inspections carried out in 2011, a number of 542 inspections of tissue establishments for non-reproductive tissues and cells was reported, as follows:

- 506 routine inspections;
- Four inspections following the communication of a serious adverse reaction (SAR) or event (SAE), and;
- 32 other inspections (enforcement inspections; inspections for new preparation processes; suspicion of illegal activities; verification of traceability and new activities; verification of corrective actions following a previous inspection; inspections due to a whistle-blower; inspection following moving to new premises).

Regarding the outcome of these inspections, in 48 cases (9%) no shortcomings were noted, minor or major shortcomings were identified in 331 (61%) cases and 150 cases (28%) respectively, whereas in five cases inspections were followed by either suspension (four cases) or revocation of authorisation and closure of the tissue establishment (one case) (Figure 21b).

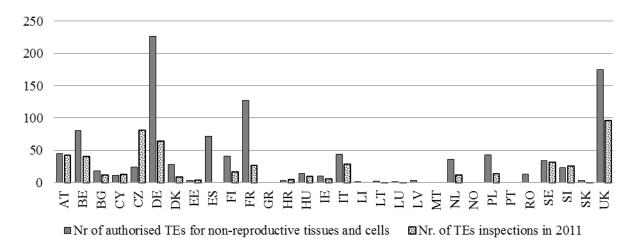


Fig. 21a. Number of authorised tissue establishments for non-reproductive tissues and cells and the number of inspections carried out in 2011

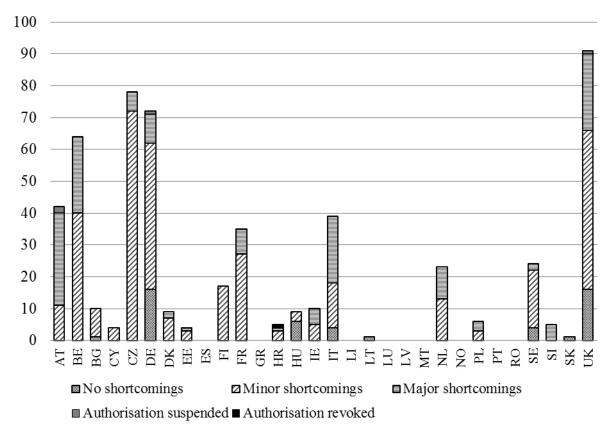


Fig. 21b. Outcome of the 2011 inspections of authorised tissue establishments for nonreproductive tissues and cells

For the ART sector, 338 inspections were carried out in 2011 in 23 Member States as well as in Liechtenstein and Norway (Figure 22a). These included:

- 305 routine inspections;
- 8 inspections following the communication of a serious adverse reaction (SAR) or event (SAE) and;
- 25 other inspections (e.g. following major organisational changes).

The outcome of these inspections was as follows: in 63 cases no shortcomings were noted, minor or major shortcomings were identified in 243 cases and 131 cases respectively, whereas in six cases inspections were followed by either suspension (three cases) or revocation of authorisation and closure of the tissue establishments (three cases) (Figure 22b).

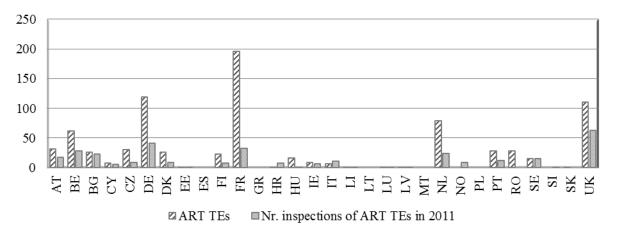


Fig. 22a. Number of authorised ART establishments and the number of inspections carried out in 2011

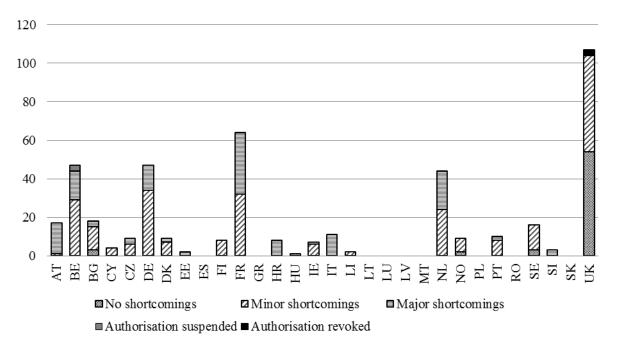


Fig. 22b. Outcome of the 2011 inspections of authorised ART establishments

Besides the abovementioned inspections, in 2011 inspections of procurement organisations outside the tissue establishments took place in 13 Member States (AT, BE, BG, CZ, DE, DK, FI, LU, MT, PL, PT, RO, SI) and Liechtenstein.

Additionally, inspections of third parties were performed by 12 Member States (BE, BG, CZ, DE, FR, HR, IT, MT, NL, PL, RO, SI). Most of the Member States indicated a variety of reasons for which third party inspections were not performed (e.g. no legal obligation, lack of inspection capacity, few or no third party agreements, third parties are limited to testing laboratories which are licensed and inspected by other authorities, tissue establishments have to audit the third parties and the audit report is reviewed during routine inspections).

Concerning the implementation of Article 7(2), 23 Member States confirmed respecting the required time interval between two inspections (two years). Moreover, Hungary informed that tissue establishments are inspected every year. Sweden indicated that all tissue establishments were authorised in 2010, and inspected for the first time in 2010 and 2011; thereafter the time interval between inspections has not exceeded two years. Four Member States (DK, HR, IT (only for the HPC and ART establishments) and NL) reported difficulties to fulfil this requirement mainly due to staffing problems within the national inspectorates.

In response to the requirement of Article 7(5) of Directive 2004/23/EC, in August 2010, the Commission published the Operational manual for competent authorities on inspection of tissue and cell procurement and tissue establishments – Guidelines for inspection (Commission Decision 2010/453/EU<sup>4</sup>). The Manual was translated in all the official languages<sup>5</sup>. Even though the Manual is not legally binding, 22 Member States (AT, BE, BG, CY, CZ, DK, EE, ES, FI, HR, HU, IE, IT, LU, LV, MT, NL, PL, PT, RO, SI, SK), and Liechtenstein and Norway reported using this Manual at national level. DE reported that according to the national legislation, the manual is not mandatory, but it is recommended as a guideline. Four Member States (DE, LT, SE, UK) reported that national guidelines were developed and are currently used at national level.

Twenty-five Member States (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SI SK, UK), and Liechtenstein and Norway, sent their inspectors to the training courses organised by the EU-funded projects EUSTITE<sup>6</sup> and SOHO V&S<sup>7</sup> and rated their usefulness and efficacy from good (three countries), to very good (ten countries) and essential (14 countries).

Regarding inspections of procurement sites in third countries from where tissue and cell preparations were imported into the EU, only Germany and France indicated organising such inspections. Germany reported that the inspection in the third country was a requirement pursuant to section 72b of the German Medicinal Products Act, whereas France specified that, in some cases, the national competent authority was asked to verify the accuracy of the data provided by the exporting procurement centre to the French tissue establishments.

As laid down in Article 7(6) and in agreement with the national competent authorities in three Member States (Bulgaria, Czech Republic, and Spain), joint inspections with other Member

http://ec.europa.eu/eahc/projects/database.html?prjno=20091110

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:213:0048:0050:EN:PDF

http://ec.europa.eu/health/blood\_tissues\_organs/docs/manual\_en.pdf

http://ec.europa.eu/eahc/projects/database.html?prjno=2005204

States' competent authorities were organised. Bulgaria reported that a joint inspection was performed with the French competent authorities. Spain reported that the inspectors of the HTA inspected the Transplant Service Foundation (Spain) in relation to distribution of skin to the United Kingdom. Additionally, the United Kingdom reported a case where a Regulation Manager observed an inspection in Germany in 2012 following allegations made against a German tissue establishment about procurement without consent.

In line with the provisions in Article 7(7) of Directive 2004/23/EC, four Member States (CZ, FR, NL, UK) requested or organised inspections of a tissue establishment located in another EU country, in collaboration with the competent authority(ies) from that Member State. The Czech Republic indicated that the purpose of the inspection was to exchange information and regulatory approaches, whereas for France's and Netherlands' competent authorities the objective was to substantiate the data provided by the tissue supplier in that Member State.

Most of the Member States and Norway indicated an interest in developing joint inspections. Lack of resources and personnel are seen as the main obstacles for the five countries (CY, DK, FI, LU and LI) who declared having no interest in organising such inspections.

#### Comments

The analysis of the replies concerning inspections of tissue establishments indicates a good implementation of the Directives' requirements. If in most cases minor or major shortcomings were recorded, only a few suspensions and revocations of authorisations were reported, showing that tissue establishments are striving to comply with the EU quality and safety requirements. Besides suggesting a high degree of compliance, which would be welcomed, the small number of suspensions/revocations may also indicate under-enforcement (e.g. in countries which have never reported any shortcomings). No data on the number of tissue establishments that voluntarily ceased operations or were forced to cease operations for other reasons (e.g. economic) were provided.

Concerning the time interval between inspections, several Member States underlined the difficulty of performing inspections every two years. It was also suggested that instead of a fixed time interval, a risk-based approach may be equally valuable. The development of a risk assessment tool to prioritise inspections based on factors like the size of establishment, range of activity, experience of designated individuals responsible for oversight of the licence and compliance history was reported by some Member States.

The heterogeneous practices reported (desk-based vs. on-site inspections, routine vs. non-routine inspections), the discrepancies in the number of inspectors and their training/expertise, or the impossibility to provide the number of staff in charge of inspections in the regional competent authorities may explain why an agreement on the mutual acceptance of inspections was not yet reached. Even though most of the Member States reported using the non-binding "Operational manual for competent authorities on inspection of tissue and cell procurement and tissue establishments" published by the Commission in 2010, it was suggested that the current practices in the Member States should be further analysed and addressed, so that shortcomings identified during inspections in different Member States (e.g. classification of minor, major and critical deficiencies) result in similar consequences for the inspected establishment (e.g. indications for a revocation or suspension for similar deficiencies).

Concerning joint inspections, their outcome was in general satisfying and in particular allowed bringing expertise where this might be missing within their own Member State.

#### 2.2.4 Traceability

Member States must ensure that all tissue and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. Additionally, Member States are required to implement a donor identification system which assigns a unique code to each donation and to each of the products associated with it (Article 8 of Directive 2004/23/EC and Article 9 and 10 of Directive 2006/86/EC).

Twenty-three Member States (BE, BG, CY, CZ, DE, DK, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK) reported that a donor identification system was implemented in their countries. In most Member States, the unique code for each donation is assigned by the tissue establishment (BE, BG, CY, CZ, DK, EE, FI, FR, HR, HU, IE, LT, LU, LV, PL, PT), while in others by the procurement centre (DE, MT, SI, UK).

Other approaches were also notified:

- Portugal reported that the donation identification system in the ART sector underwent changes since the last reporting exercise. Since the 1<sup>st</sup> of January 2013, the unique code for each donation has been allocated centrally by the ART competent authority (Conselho Nacional de Procriação Medicamente Assistida);
- Slovenia and Portugal (for the ART sector) specified that a national database was put in place, providing for an automatic allocation of donation numbers;
- Norway indicated that the donor identification is based on the national unique personal number identification system.

Two Member States, Austria and Spain, as well as Liechtenstein, indicated having difficulties in implementing the provisions related to the donor identification system. Romania notified that the unique national donor identification system is under construction. Austria reported that the Federal Ministry of Health deferred the implementation of ISBT128 due to difficulties encountered during implementation, whereas in Spain and Liechtenstein, the requirements of Article 8 have been partially implemented (Art. 8.1), awaiting final guidance from the Commission regarding the implementation of the Single European Code.

Article 8 also requires tissue establishments to keep the data ensuring full traceability for a minimum of 30 years. This requirement is fulfilled by all the Member States which reported to the Commission. In 25 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK, UK-HTA) and Norway it is mandatory to retain both paper and electronic records. For the ART sector, the UK (HFEA) indicated that records can be electronic or paper records. In Latvia, Slovenia and Liechtenstein this requirement is fulfilled only by keeping paper records.

Member States have different approaches for ensuring the implementation of the provisions in Article 9 of Directive 86/2006/EC (e.g. data storage for 30 years). Most of the Member States (AT, BE, BG, CY, DE, DK, EE, FI, FR, IE, IT, LU, LV, MT, NL, PL, PT, SE, UK) and Liechtenstein and Norway reported verifying this requirement during routine inspections. In the United Kingdom, this requirement is also checked at the initial licence application stage. Austria, Croatia and the Czech Republic ask the tissue establishments to include appropriate procedures in their SOP. Spain specified that this requirement was not implemented in the ART sector.

#### **Comments**

The survey showed that a donor identification system was implemented by most Member States, with the unique code for each donation being assigned predominantly by the tissue establishments. It has to be underlined that countries which reported difficulties in implementing the donation identification system were either developing a central allocation system or were waiting for the adoption of the implementing legislation introducing a Single European Code for tissues and cells. Moreover, most of the Member States reported that detailed coding requirements and a harmonised implementation of the Single European Code for tissues and cells is desirable and actively supported the development by the Commission of the new coding requirements, adopted in 2015<sup>8</sup>. Regarding data storage, almost all Member States and EEA countries comply with the 30 years rule, by requesting both paper and electronic records and by verifying this requirement during routine inspections.

# 2.2.5 Import/export of human tissues and cells

Under Article 9(1) of Directive 2004/23/EC, Member States must take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised, licensed for the purpose of those activities and that imported tissues and cells can be traced from the donor to the recipient and vice versa. In 2008, only 11 Member States reported having clearly identified tissue establishments authorised to import tissues and cells.

The current survey revealed that 16 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, PT, RO, SE, SI, UK), as well as Norway, have a register of tissue establishments that are explicitly authorised to perform import/export of tissues and cells from third countries and provided data on their number. According to the data provided by these countries for 2011, 297 tissue establishments were authorised to import and 306 were authorised to export tissues and cells from/to third countries. Compared to the previous report (2008 data) when 16 Members States reported importing tissues and/or cells, the current survey shows that more countries (22) were importing tissues and/or cells in 2011 (Figure 23).

<sup>&</sup>lt;sup>8</sup> Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells, OJ L 93, 9.4.2015, p. 43–55

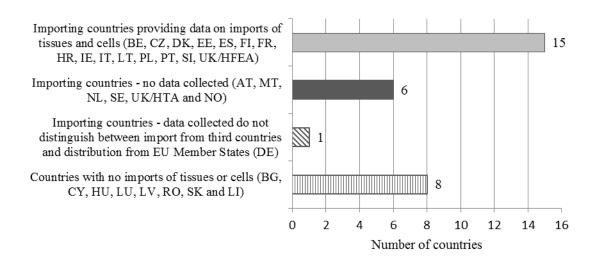


Fig. 23. Countries importing human tissues and cells for human application (2011 data)

Twenty-two countries indicated that imports from third countries were carried out in 2011, but only 15 provided data on the type and volume of the imported tissues and cells (Figures 24 and 25). Only nine Member States also collect data on the source of imports (BE, CZ, EE, ES, FI, HR, IT, SI, UK/HFEA). According to the reported data, most of the imports were from USA, Australia, Canada, Israel, and Switzerland. Other countries mentioned were China/Hong Kong, Taiwan, Russia, Uruguay and Bosnia Herzegovina. Six Member States acknowledged importing tissues and cells, but could not provide data on the amount and type of tissues or cells imported, and one Member State (Germany) is collecting data without distinguishing between tissues and cells imported from third countries and those distributed from other EU Member States. Seven Member States (BG, CY, HU, LU, LV, RO, SK) and Liechtenstein reported that no imports of tissues and cells were carried out in 2011.

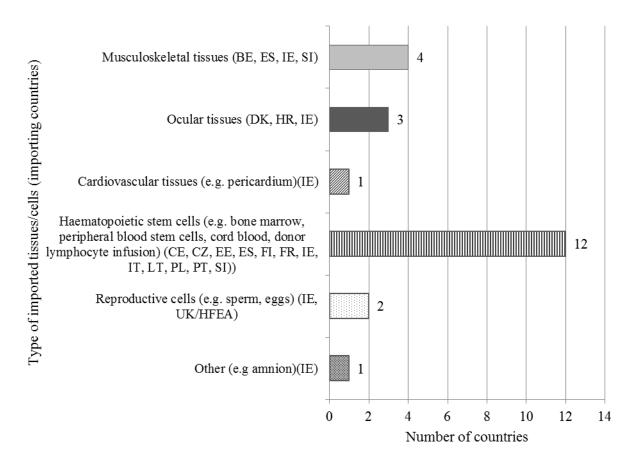


Fig. 24. Type of tissues and cells imported (data reported for 2011 by 15 countries)

Additionally, Germany reported that according to section 8d of the German Transplantation Act (TPG), all tissues entering Germany (both from third countries and EU Member States) must be notified to the Paul Ehrlich Institute, irrespective of their source (e.g. an EU Member State or a third country). In 2011, 45,073 units of tissues and cells entered Germany: 550 ocular tissue (cornea), 2,550 cardiovascular tissues (heart valves, vessels, and pericardium), 41, 648 musculoskeletal tissues (bone, cartilage, soft tissues), 325 reproductive cells (sperm), as well as 3,436,004 cm<sup>2</sup> of skin.

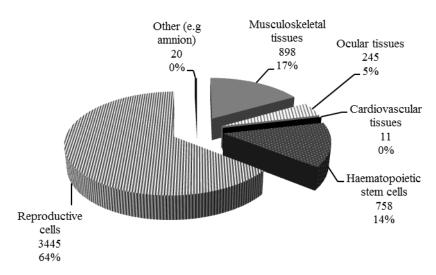


Fig. 25. Volume of tissues and cells imported (units of tissues or cells; 2011 data)

Due to the heterogeneous approach in recording data for the import of human tissues and cells it is still difficult to quantify the amount of imports into the Union.

Under Article 9(2), Member States must also take all necessary measures to ensure that all **exports of tissues and cells to third countries** are undertaken by tissue establishments accredited, designated, authorised or licensed for that purpose. Eighteen Member States (AT, BE, DE, DK, EE, ES, FI, FR, HR, IE, IT, MT, NL, PL, PT, SE, SI, UK) and Norway have a register of tissue establishments authorised to export tissues and cells to third countries.

Fourteen Member States (AT, BG, CZ, EE, FI, HR, HU, LT, LU, LV, MT, RO, SI, SK) and Liechtenstein and Norway reported that no exports of tissues and cells occurred in 2011 (Figure 26).

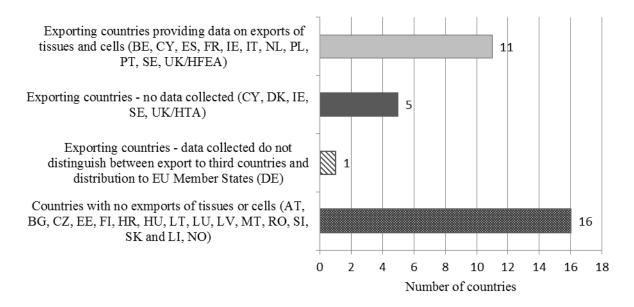


Fig. 26. Tissue and cell exporting countries (2011 data)

Overall 12,152 units of tissues and cells were reported as exported to third countries. Of the 11 countries exporting human tissue and/or cells in 2011, four specified that information on the country of destination is not collected by the national competent authority (CY, IE, SE, UK/HTA). The exporting countries, as well as the type and volume (in units) of tissues and cells exported, are shown in Figures 27 and 28.

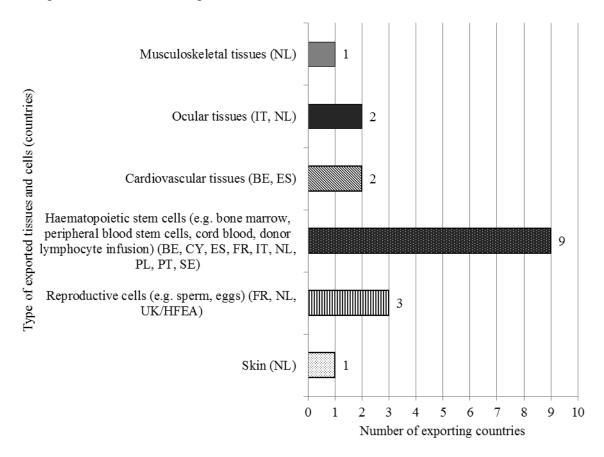


Fig. 27. Exporting countries - type of tissues and cells (data reported for 2011 by 11 countries)

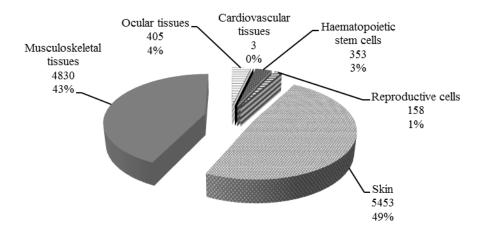


Fig. 28. Volume of tissues and cells exported (units of tissues or cells; 2011 data)

Similarly to the data reported for imports, Germany specified that according to section 8d of the German Transplantation Act (TPG) there is no distinction between export to third countries and distribution to EU Member States, therefore all tissues and cells leaving Germany are reported to the Paul Ehrlich Institute on an annual basis. In 2011, 148,285 units were reported as sent to healthcare facilities outside Germany, as following: 188 ocular tissue (cornea, limbal cells), 2,131 cardiovascular tissues (pericardium), 144,373 musculoskeletal tissues (bone, cartilage, soft tissues), 130 other (amniotic membrane), 1,463 reproductive cells (sperm). Additionally, 2,825,092 cm<sup>2</sup> of skin was also sent outside Germany.

The competent authority or authorities may also authorise the import or export of tissues and cells in case of an emergency (Art 9.3b). Nine Member States (CY, DE, DK, HR, MT, NL, RO, SI, UK) and Norway, indicated that direct distribution of tissues and cells to a specific recipient was authorised in 2011 for haematopoietic stem cells and ocular tissues.

Concerning the relation with self-sufficiency, the Member States approaches are different for import and export activities:

- For exporting tissues and/or cells:
  - o BG, DK, ES, HR, IT, PL, PT, RO, SK reported that export of tissues and cells is authorised only after checking if local and/or national needs are fulfilled;
  - o Bulgaria and Latvia indicated that exportation is authorised based on estimations performed on an annual basis;
  - o BE, CZ, DK, EE, HU, IT, PL, SE, SI, UK indicated that exportation of tissues and/or cells is authorised irrespective of national needs.
- For importing tissues and/or cells:
  - o BG, DK, ES, HR, IE, IT, RO, and Norway reported that imports are authorised only after checking that local/national needs are not fulfilled;
  - BG, IE, PL, PT, SE and Norway specified that imports of tissues/cells are authorised based on estimations showing that there is chronic deficiency of those tissues/cells.

Some Member States (Italy, Poland) acknowledged having a strict approach regarding tissues and cells coming from other EU Member States, which are treated like those imported from third countries. The United Kingdom informed that the Human Tissue Authority (HTA) provides specific online guidance for tissue establishments on import and export.

#### Comments

These data show that it would be useful for competent authorities to collect more comprehensive data on imports and exports of human tissues and cells through the tissue establishments' compulsory annual reports in accordance with Article 10(1), however, at this stage the reporting format is not harmonised.

The data provided, even though incomplete and sometimes ill-defined, confirm that more and more human tissues and cells - such as skin, bones, ocular tissues, heart valves, and haematopoietic stem cells - are imported from third countries or are exported for the benefit of patients outside the European Union. It has to be noted that it is difficult to draw conclusions

regarding the volume of imports and exports of human tissues and cells due the absence of a harmonised framework for data collection in the Member States. It should be underlined that some level of harmonisation exists for such data due to the Eurocet<sup>9</sup> project. However the fact that some countries do not distinguish between distribution within the European Union and import/export from/to third countries may be considered an important hurdle against data collection and analysis. In some countries the differences between the legal framework under which the tissue and cell legislation was transposed (e.g. transplantation vs. medicinal products legislation) may also contribute to the different datasets collected at national level.

Furthermore, mostly due to their more stringent quality and safety requirements, some countries treat tissues and cells distributed by EU Member States and those imported from third countries in the same way. It is expected that the recently adopted legal requirements regarding the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells<sup>10</sup> will streamline the tissue and cells imports, and the collection of related data, guaranteeing the appropriate level of safety and quality across the Union.

## 2.2.6. Register of tissue establishments and reporting obligations

Under Article 10(1) of Directive 2004/23/EC, tissue establishments must keep a record of their activities and submit an annual report to the competent authority or authorities, which should be publicly available.

Twenty Member States (AT, BE, BG, DE, EE, ES, FI, HR, HU, IE, IT, LT, MT, PL, PT, RO, SE, SI, SK, UK) and Liechtenstein and Norway, have created an annual report model on the activities of tissue establishments that makes the reporting of the yearly activities by tissue establishments easier.

All the reporting Member States receive annual reports from their tissue establishments corresponding to activities in the previous year(s). An overview of the number of tissue establishments providing data to the national competent authorities is presented in Figure 29.

<sup>-</sup>

<sup>&</sup>lt;sup>9</sup> European Registry for Organs, Tissues and Cells, <a href="http://www.eurocet.org/">http://www.eurocet.org/</a>

<sup>&</sup>lt;sup>10</sup> Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells Text with EEA relevance. OJ L 93, 9.4.2015, p. 56–68

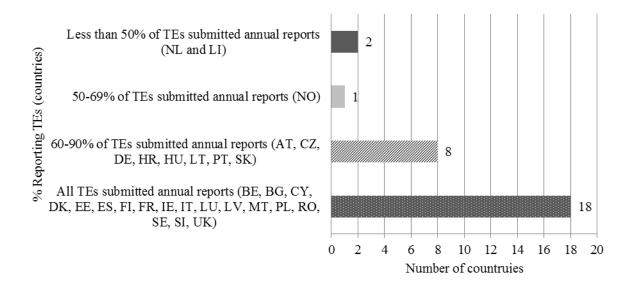


Fig. 29. Annual reporting by the tissue establishments (2011 data)

It should be emphasised that the annual reports submitted by the tissue establishments are essential in providing a suitable indication of the activities carried out in the field as well as reference data for assessing the needs and risks in the tissue and cell transplantation field.

Only nine Member States (BE, BG, CZ, ES, IT, MT, PL, RO, SE) and Norway, had made the tissue establishments' reports publicly available in 2012. For the Member States which did not make the tissue establishments' reports available, the main reasons were that at the moment of submitting their replies to the implementation survey, legal provisions in their national legislation were absent (inappropriate transposition of Art. 10(1)) or there was an insufficient capacity at competent authority level.

Under Article 10(2) of Directive 2004/23/EC, the competent authorities are responsible for maintaining a publicly accessible register of tissue establishments specifying the activities for which they have been accredited/designated/authorised/licensed. Twenty-five Member States and Norway indicated that they have a public register available (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, UK). In most cases the annual reports and the register are accessible through the competent authorities' web pages (Table IV). Liechtenstein reported that there are no legal requirements in their national legislation concerning the publicly accessible register of tissue establishments. Luxembourg informed that the information is given on demand. In Slovakia, this register is under preparation.

Country	Link to the national register of tissue establishments
AT	http://www.basg.gv.at/arzneimittel/gewebe/register-29-gsg/
BE	www.fagg-afmps.be
BG	http://www.bgtransplant.bg/iat/transplantation.php?target_f
CY	www.moh.gov.cy
CZ	www.sukl.cz/Rewievs and Lists/List of subjects from human tissues, cells and blood branch/List of
	holders of licence according the law on human TC
DE	http://www.pei.de/DE/infos/meldepflichtige/meldung-gewebe-8d-transplantationsgesetz/berichte-
	pei/berichte-meldung-8d-transplantationsgesetz-tpg-node.html
DK	http://laegemiddelstyrelsen.dk/da/service-menu/produktomraader/vaev-og-celler/register-over-
	godkendte-vaevscentre_
	<u> </u>
EE	http://www.ravimiamet.ee/en/list-licensed-handlers-cells-tissues-and-organs-tissue-establishments
ES	https://reports.ont.es/Autorizaciones.aspx
	For ART http://www.cnrha.msssi.gob.es/registros/centros/home.htm
FI	http://www.fimea.fi/download/23600 FI Lista Suomessa toimivista kudoslaitoksista 10-7-2013.pdf
FR	http://ansm.sante.fr/var/ansm_site/storage/original/application/b9b896c06d8367834865273951775d4b.p
	df; http://www.agence.biomedecine.fr/Autorisation-des-centres; http:
	//www.agence.biomedecine.fr/Les-etablissements-autorises.73
HR	Non-reproductive tissues and cells:
	http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republici_hrvatskoj/ustanove_s_odobren
	jem_za_obavljanje_djelatnosti_uzimanja_pohranjivanja_i_presadivanja_tkiva_i_stanica
	ART:
	http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republici_hrvatskoj/ustanove_s_odobren
	jem_za_obavljanje_djelatnosti_medicinski_pomognute_oplodnje
HU	https://www.antsz.hu/bal_menu/igazgatas/sejt_es_szovetbank_nyt.html
IE	http://www.imb.ie/EN/Blood-TissuesCells/BloodTissue-Establishments-
	_aspx?page=1&name=&orderby=name&orderascending=True&type=3&sitestatus=1&withdrawdate=
IT	http://www.trapianti.salute.gov.it/cnt/cntHomeSezione.jsp?id=10&area=cnt-
	tessuti&menu=menuPrincipale
LI	No register
LT	www.transplantacija.lt
LU	No register. Information available on demand.
LV	http://www.zva.gov.lv/doc_upl/audu-sunu-20130726.pdf
МГ	https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/tissues_cells_organs.asp
NL	X   http://www.farmatec.nl/doc/pdf/Internetoverzicht%20Wvkl-erkenningen%20en%20-
1111	vergunningen%20afgegeven%20vanaf%201%20juni%202007 18122.pdf
	Tel Barring Crive Control Cont
NO	http://www.helsedirektoratet.no/kvalitet-planlegging/bio-genteknologi/celler-og-
	vev/Sider/default.aspx
PL	http://www.kcbtik.pl/?Banki_Tkanek_
PT	http://www.dgs.pt/ms/8/default.aspx?pl=&id=5521&acess=0 (DGS); CNPMA:
	http://www.cnpma.org.pt/centros_lista.aspx
RO	www.transplant.ro_
SE	http://www.ivo.se/Tillstand-och-register/register/vavnadsinrattningar/Sidor/default.aspx
SI	http://www.slovenija-transplant.si/index.php?id=presajanje-tkiv_
SK	No register. Under preparation.
UK	http://www.hta.gov.uk/ db/ documents/Licensing Reports - HA 201307021659.pdf
	http://guide.hfea.gov.uk/guide/AllClinics.aspx?x=A

Table IV. Publicly accessible national registers of tissue establishments (2011 data)

Under Article 10(3) of Directive 2004/23/EC, Member States and the Commission should establish a network linking the national tissue establishment registers. Until now this network was ensured through Eurocet<sup>7</sup>, which is a registry of national tissue establishments and activity reports managed by the Italian Competent Authority. Twenty-three Member States acknowledged that they also report data to Eurocet on a voluntary basis (AT, BE, BG, CY, CZ, DE, ES, FI, FR, HR, HU, IT, LT, LU, LV, MT, PL, PT, RO, SE, SI, SK UK). Three Member States (Denmark, Ireland, and Netherlands) and EEA countries do not usually report their data to Eurocet. In this respect, the Danish competent authority specified that data request for clinical information on tissues/cells is not part of their activities. Ireland informed that their competent authority (the Irish Medicines Board at the time) is not legally required to submit data regarding tissues and cells activity to the Eurocet registry and Netherlands declared that no raw data is readily accessible to the competent authority.

#### Comments

Overall, the Member States and the EEA countries comply with the requirements in Article 10 of Directive 2004/23/EC. National registers of tissues establishments are made available through the competent authorities' web pages and also via the Eurocet page. However, the tissue establishments' reports are not publicly available in all the reporting countries, mainly due to an insufficient transposition of this provision into the national legislation which resulted in several pre-infringement procedures through the EU Pilot platform. If the issue of making the annual reports provided by the tissue establishments public can be dealt with only at national level, the new legal provisions for the application of the Single European Code shall also satisfy the requirement in Art 10(3), by establishing the EU Tissue Establishment Compendium including all the tissues establishments with their contact details and the status of their accreditation/designation/authorised or licence. By updating the data in this Compendium, the tissues and cells competent authorities demonstrate full transparency and provide support to healthcare professionals searching for a tissue or cell provider within the Union. Moreover, the inclusion in the EU Tissue Establishment Compendium will reinforce the credentials of the EU tissue establishments in front of their partners and customers around the world.

#### 2.2.7. Notification of serious adverse events and reactions

Under Article 11(1) of Directive 2004/23/EC, Member States must ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events<sup>11</sup> and reactions<sup>12</sup> which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells. Serious adverse reactions observed during or after clinical application which

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According to Article 3(m) of Directive 2004/23/EC, 'Serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.

According to Article 3(n) of Directive 2004/23/EC, 'Serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

may be linked to the quality and safety of tissues and cells should be also reported. The procedures for notifying serious adverse events and reactions were adopted in Commission Directive 2006/86/EC.

AT	Austrian Medicines and Medical Devices Agency (AGES)
BE	Federal Agency for Medicines and Health Products (FAMHP)
BG	Executive Agency for Transplantation (IAT)
CY	Ministry of Health
CZ	State Institute for Drug Control (Pharmacovigilance Department)
DE	Paul Ehrlich Institute (PEI)
DK	Danish Health and Medicines Authority
EE	State Agency of Medicines
ES	National Transplant Organisation (ONT), the competent authorities of the autonomous regions and the National Group of Biovigilance.
FI	Finnish Medicines Agency (Fimea)
FR	Agence de la Biomedicine (ABM)
HR	Ministry of Health
HU	National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)
IE	Irish Medicines Board (IMB) - Tissue & Cell Vigilance
IT	National Transplant Centre (CNT)
LI	Amt für Gesundheit
LT	National Transplant Bureau under the Ministry of Health
LU	Direction de la Santé
LV	State Agency of Medicines - Senior expert of Pharmaceutical Activities Compliance Evaluation Department
MT	The Directorate for Health Care Standards of the Superintendence of Public Health
NL	Health Care Inspectorate (IGZ)
NO	Norwegian Directorate of Health
PL	National Centre for Tissue and Cell Banking (for tissue establishments), Poltransplant and National Centre for Tissue and Cell Banking (for procurement and transplantation).
PT	Instituto Português do Sangue e da Transplantação (for non-reproductive tissues and cells) and Conselho Nacional de Procriação Medicamente Assistida (CNPMA - for the ART sector)
RO	Ministry of Health – the State Sanitary Inspectorate
SE	Health and Social Care Inspectorate
SI	Agency of Medicinal Products and Medical Devices of the Republic of Slovenia
UK	HTA (for non-reproductive tissues and cells) and HFEA (for the ART sector)

*Table V. Organisations responsible for tissue and cell vigilance (2011 data)* 

All reporting Member States except for Slovakia have a national vigilance system in place. In most Member States vigilance falls under the responsibility of the main national competent authority, but in several Member States this is either delegated to the regional competent

authorities (DE, ES) or specific bodies (NL - Health Care Inspectorate). An overview of the organisations responsible for tissue and cell vigilance in the reporting EU and EEA countries is included in Table V.

Only in 15 Member States (AT, BE, CZ, DE, DK, ES, FI, FR, HU, IE, LT, MT, NL, PT, SI) and Liechtenstein and Norway, were dedicated vigilance officers appointed. In the other countries, this role is assigned to the tissues and cells inspectors. Additionally in the United Kingdom, for the ART sector the HFEA appointed a dedicated vigilance officer, whereas HTA reported having a dedicated team of Regulation Managers in place who assess SAREs from establishments. A Regulation Officer acts as the administrator and data manager for the team and the reporting system is monitored by the team on a 24-hour basis, and any reports received are responded to within 24 hours.

Regarding the compliance of tissue establishments in reporting SAR and SAE to the national competent authorities, the percentage of the tissue establishments complying with this requirement (expressed as % from the total number of authorised tissue establishments at national level) is shown in Figure 30. The relatively large group of establishments that do not report SARE data is a point that requires further attention.

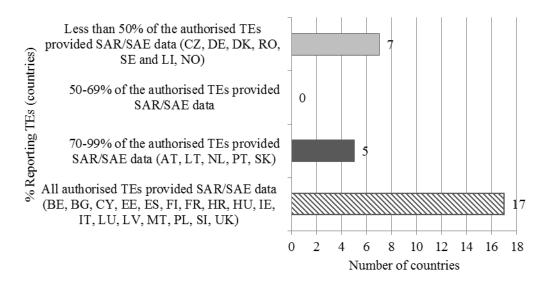


Fig. 30. SAR/SAE reporting to the national competent authorities (2011 data)

In addition, Italy informed that tissue establishments are required to report SAR/SAE as they occur and the competent authority compiles the annual report. However the tissue establishments must provide detailed information to transplant centres on how and when to report SAR/SAE and this is reviewed during routine inspection. A similar approach was reported by the United Kingdom competent authorities (HTA and HFEA), where tissue establishments have to report SAR/SAEs within 24 hours of their discovery, and not via an annual report.

Most of the Member States (AT, BE, BG, CY, CZ, DE, DK, ES, FR, HR, HU, IE, LT, LV, MT, PL, PT, RO, SE, SI, UK-ART sector) and Liechtenstein and Norway confirmed having in place a mandatory procedure for SAR/SAE reporting by the transplantation centres to the

distributing tissue establishments, this also being a requirement in their national legislation. Members States not having such a procedure in place have different approaches:

- In Estonia and Slovakia, reporting of SAR/SAE by the transplantation centres is obligatory by law;
- In Finland, Italy and Netherlands, when distributing tissues and/or cells, the tissue establishments are responsible for providing full instructions for reporting to the transplantation centres;
- In the United Kingdom, for non-reproductive tissues and cells and reproductive tissues, the SAREs reporting requirement is outlined in HTA standards. Establishments licensed by the HTA are required to have end-user agreements in place with transplantation centres, which include the requirement to report SAREs, and incident reporting is promoted and also monitored on inspection.

Regarding recalls, all countries require their tissue establishments to have a recall procedure. Only four Member States (DK, EE, FR and UK) reported that recalls were issued by tissue establishments in their country for 2011.

In accordance with Article 7(1) of Directive 2006/86/EC, Member States must submit to the Commission an annual report on the serious adverse reactions and events notified to the competent authority. Most of the Member States acknowledged using at national level the template (based on the Annexes of Directive 2006/86/EC). In seven Member States (BE, DE, FR, NL, PT, SI, UK) and Norway, a template and guidelines developed at national level are used.

Twenty-two Member States (AT, BE, BG, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK) and Norway confirmed giving feedback to the tissue establishments regarding SAR/SAE recorded at national level.

Nineteen Member States (BE, BG, EE, ES, FI, FR, HR, HU, IE, LT, LU, MT, PL, PT, RO, SE, SI, SK, UK) and Norway reported giving feedback to the tissue establishments regarding SAR/SAE recorded at EU level.

As regards communication of rapid alerts, 22 Member States (AT, BE, CY, DE, EE, ES, FI, FR, HR, HU, IE, LT, LU, LV, MT, NL, PL, PT, SE, SI, SK, UK) and Liechtenstein and Norway reported that a system/procedure is in place at national level for notifying tissue establishments and procurement sites in case of a national rapid alert or of a rapid alert issued via the EU RATC platform. Five Member States reported not having such a system/formal procedure:

- Bulgaria informed that the system is under construction and communication is done by email;
- The Czech Republic reported using the already established system for pharmaceuticals or medical devices;
- Denmark reported that the national system is effective in notifying the tissue establishments which thereafter are responsible for contacting the POs;
- Italy declared that no written procedure was formalised and rapid alerts are communicated by email on a case-by-case basis;

• Romania informed that a national procedure was under development, but the Ministry of Health is responsible for communicating the alerts issued via the EU RATC platform to the National Transplant Agency and the sanitary inspectors.

Moreover, 21 Member States (AT, BE, CY, CZ, DE, DK, ES, FI, FR, HR, HU, IE, LT, MT, NL, PL, PT, RO, SE, SI, UK) circulate the alerts received via the tissues and cells national vigilance system, when relevant, to other national vigilance/alert systems (haemovigilance, pharmacovigilance, medical devices).

Concerning training courses for the personnel in charge of vigilance at national/local level, 22 Member States (AT, BG, CY, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SI, UK) and Norway welcomed the organisation of specific courses at EU level. The training course organised by the SoHO V&S project was ranked as good (one Member State), very good (11 Member States) and excellent (ten Member States). Only five Member States (BE, CZ, LU, SE, SK) and Liechtenstein did not send their staff to these courses, mostly because of lack of time or turnover of personnel.

#### Comments

The importance of SARE reporting is confirmed by the interest of the Member States in collaborating with the Commission to improve the current reporting system (e.g. refine the SARE reporting templates for improving collection of data in the ART sector) and to expand communication with other countries and other sectors (e.g. foster cooperation with relevant third countries with regard to SAR/SAE reporting, establishment of an interface for SARE reporting to other product areas, such as medical devices used throughout the donationclinical application chain. Nevertheless, the aim of the annual reporting to the Commission is to identify the most frequent causes of SAR/SAE allowing for the development of appropriate corrective measures, which will ultimately make the medical application of human tissues and cells safer. In this context, because many errors are not always reported voluntarily or are discovered at a later stage and not reported in a timely manner, the corrective measures may not be made in a timely manner. Additionally, the "root causes" of these SARE/SAE should be correctly identified, analysed and reported with enough level of detail in order to allow for a complete description of the practices/factors which may lead to systematic errors. Moreover, underreporting and accurate data collection remain two objectives which need to be addressed at all levels, from clinical practitioners and tissue establishment staff to competent authorities.

Something that has to be emphasised is the support of the Member States' authorities in the development of the Rapid Alerts for Tissues and Cells (RATC) launched by the Commission in February 2013<sup>13</sup>, which allows national health authorities to exchange, in a timely manner, urgent information in case of alerts (including SAR/SAE) relating to human tissues or cells transferred between Member States. The first annual summary report of the RATC platform<sup>14</sup> published in August 2014 showed an increase in the number of the alerts initiated by the national vigilance contact points, the platform providing wider possibilities of communication and information dissemination with the choice of contacting single or groups of national competent authorities.

13 http://ec.europa.eu/dgs/health\_consumer/dyna/enews/enews.cfm?al\_id=1340

http://ec.europa.eu/health/blood tissues organs/docs/ratc report 2013 en.pdf

## 2.3 Donor selection and evaluation

Directives 2004/23/EC and 2006/17/EC contain a number of requirements regarding donor selection and evaluation. They relate to (1) principles governing tissue and cell donation, (2) consent, data protection and confidentiality the authorisation of tissue establishments, (3) donor selection and evaluation and procurement of tissues/cells, (4) testing of tissue and cell donors.

## 2.3.1. Principles governing tissue and cell donation (Art. 12)

Under Article 12(1) of Directive 2004/23/EC, Member States must endeavour to ensure voluntary unpaid donations of tissues and cells. Donors may receive compensation strictly limited to making good the related inconveniences. In such cases, Member States must define the conditions under which compensation may be granted. Member States must regularly submit reports on these measures to the Commission. On the basis of these reports the Commission will inform the European Parliament and the Council of any necessary measures it intends to take.

The results of the 2014 survey performed by the Commission on the implementation of the principle of VUD for tissues and cells in the Union are included in the Commission Staff Working Document on the implementation of the principle of voluntary and unpaid donation for human tissues and cells, accompanying the Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells.

In a nutshell, the latest survey shows that, overall, Member States comply with Article 12, with most responding countries reporting that the principle of VUD is mandatory at national level. However, its concrete application varies across the Union, with considerable heterogeneity as regards practices vis-à-vis tissue and cell donors.

## 2.3.2. Consent, data protection and confidentiality

Under Article 13(1) of Directive 2004/23/EC, the procurement of human tissues and cells shall be authorised only after all mandatory national consent or authorisation requirements have been met.

Regarding the consent system for living donation of tissues and cells, with the exception of Liechtenstein, all the other reporting countries have an opt-in system (explicit consent) (Figure 31).

Concerning the consent system for deceased donation of tissues and cells, an overview of the replies is shown in Figure 32.

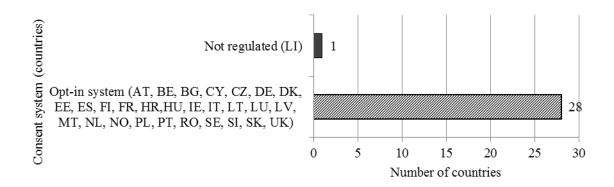


Fig. 31. The consent systems for living donation of tissues and cells

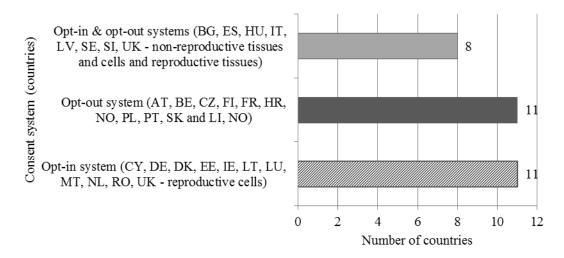


Fig. 32. The consent systems for deceased donation of tissues and cells

Whereas, the consent system for living and deceased donation is different in 17 countries (AT, BE, BG, CZ, FI, FR, HR, HU, IT, LV, PL, PT, SE, SI, SK, UK and Norway), only three Member States (Denmark, Luxembourg and Spain) have different consent systems for deceased tissue and organ donation.

Irrespective of the consent system, in case of deceased donations, there are various options for who is allowed to authorise tissue donation (Figure 33).

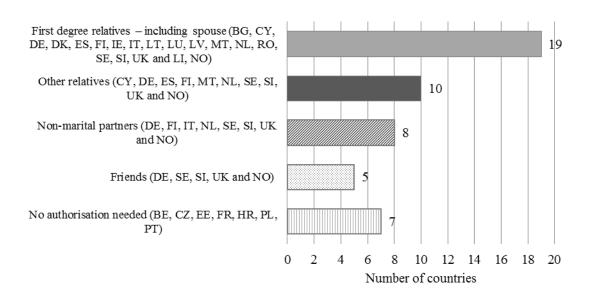


Fig. 33. Persons allowed authorising deceased donation of tissues and cells

Several Member States provided additional clarifications. In Netherlands, in case of a donor child aged 12 or below the consent is given by the legal guardian. The United Kingdom specified that in England, Wales and Northern Ireland a person in life or a person's "nominated representative" can give consent, but there is no mention of "nominated representatives" under the Human Tissue Act in Scotland.

In all reporting Member States and EEA countries, the consent is verified during inspections by various means, from analysis of documentation and interviews with personnel to interviews with living donors or relatives of deceased donors (Figure 34).

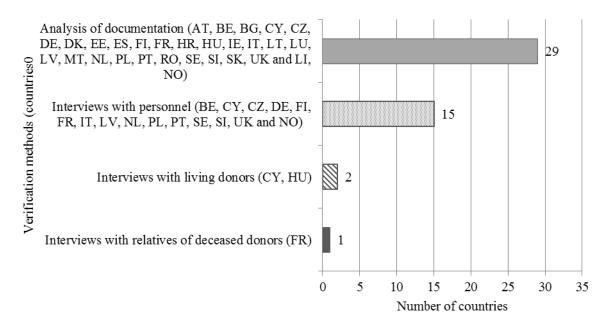


Fig. 34. Verification of donors consent during inspections (2011 data)

Article 13(2) of Directive 2004/23/EC requests the Member States take all the necessary measures to ensure that donors and their relatives, as well as any persons granting authorisation on behalf of the donors are provided with the appropriate information. All reporting countries, except Ireland and Slovakia, stated that only trained personnel are allowed to provide such information. In Ireland, the requirement of Art 13(2), the information provided to donors and their families is also verified during inspections together with the donor files. Additionally, in some Member States (BG, DE, ES, LT, PL, SE, SK, UK), the information for donors is standardised at national or regional level. Germany specified that general information for donors is available due to national public awareness activities and is also provided by medical associations. For ART donors, in Spain the information is controlled at regional level and in the United Kingdom it is assessed during the initial application for tissue establishment licence.

Concerning national measures taken to ensure that both donors and recipients remain unidentifiable as required by Art.14(1) of Directive 2004/23/EC, several approaches were reported. Many Member States (CZ, DE, EE, ES, FI, FR, HR, HU, IE, LT, LV, RO) and Norway stated that anonymity is ensured by the application of the data protection national legislation. In addition, anonymity is ensured by implementing the unique donor identification number (coding system) for both donor and recipient (AT, BE, BG, CY, IT, LU, MT, PL, SE, SI, UK-HTA and LI). Additional methods were: control measures decided by tissue establishments (Denmark); verification by the competent authority of the access to information and of the procedures put in place by the tissue establishment to ensure the confidentiality (Portugal); providing third parties only with the tissue code (Slovakia).

Member States and EEA countries also reported on the measures taken to ensure that the identity of the recipient is not disclosed to the donor and vice versa required under Article 14(3) of Directive 2004/23/EC. Besides applying the national requirements on data protection (CY, DE, EE, ES, FR, HU, IE, LT, LV, NL, RO, SI), introducing the unique donor identification number (AT, FI, HR, IT, LU, MT, PL, SE, SK and LI, NO) is another method widely used for ensuring data confidentiality. Other approaches were reported: restricted access to the donor data (Bulgaria); requirements included in the tissue establishments' SOP and inspected by the competent authority before granting a licence (Czech Republic); appropriate procedures put in place by both tissue establishments and organisations responsible for human application (Denmark); validation by the competent authority of the procedures; validation by the competent authority of the procedures established at tissue establishment level (Portugal); with the exception of directed donations, information regarding the donor identity is not included in the recipient file and vice-versa (United Kingdom).

With regard to disclosure of donor data in case of gamete donation, the approaches taken by the reporting Member States and EEA countries are summarised in Figure 35. The special circumstances in which some countries (generally prohibiting the disclosure of gamete donor data) would allow disclosure include:

- Children reaching 14 years old (Austria);
- When the egg donor is a relative of the woman who wishes to undergo artificial insemination (Estonia);
- In case of a child born with a congenital disease (Spain);

- Children conceived through IVF procedures (Norway);
- When donors express consent to disclose his/her data and only when the children born following ART procedures with donated gametes turn 18; other cases following a court decision (Portugal);
- At the request of authorities (e.g. police, coroner office)(Romania);
- Only to the child at adult age, but not to his/her parents)(Sweden);
- To the medical staff only for medical reasons (Slovenia).

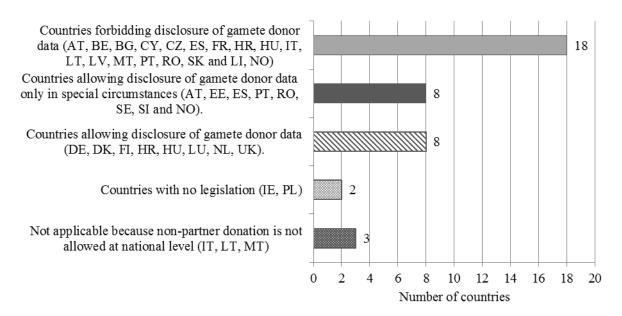


Fig. 35. Disclosure of gamete donor data (2011 data)

#### Comments

Overall, the survey showed that regardless of the consent system, all responding countries put measures in place for verifying donors' consent. On the other hand, only in a few Member States is this checked by interviewing the living donors or the relatives of the deceased donors. In addition only trained personnel are allowed to provide appropriate information to donors, but only in a few countries has this information been standardised at national level. Concerning donor anonymity, most countries rely on the EU and national data protection legislation, but also on coding. In this context, the new requirements on the application of the Single European Code for tissues and cells may be considered an additional tool for ensuring that donor data are not disclosed to the recipient.

#### 2.3.3. Donor selection and evaluation. Procurement of tissues and cells

Under Article 15 of Directive 2004/23/EC, donor evaluation and selection by the tissue establishments should be carried out in accordance with the provisions laid down in Annex I (donors of non-reproductive tissues and cells) and III (donors of reproductive tissues and cells) of Directive 2006/17/EC.

Compliance with these requirements is verified by inspections of tissue establishments, procurement sites, and ART establishments by audit documentation, standardised questionnaires at national levels and/or regular evaluation of medical personnel (Figure 36 and 37).

Furthermore, three Member States (Belgium, Germany, Italy) reported having more stringent criteria for donor selection:

- Belgium reported having one additional selection criterion "persons that have undergone documented or undocumented neurosurgery";
- Germany informed that the exclusion criteria are adapted to the donor of a specific tissue;
- Italy reported that additional tests are required NAT testing for HIV, HBV and HCV of HSC donors; toxoplasma IgM for amniotic membrane donors is mandatory; CMV IgM for heart valve, vessels and amniotic membrane; CMV for skin; CMV, toxoplasma and EBV testing for HPC unrelated donors; serum archive for all donors.

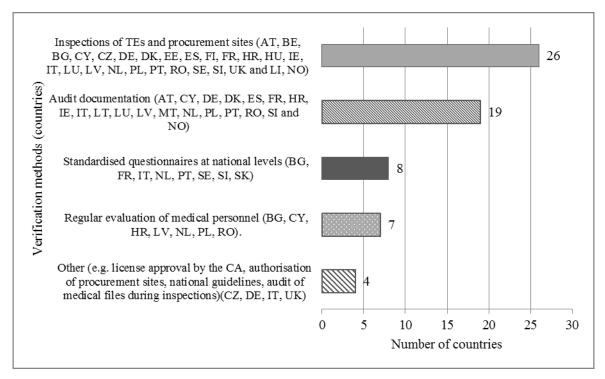


Fig. 36. Verifying the compliance of tissue establishments and procurement sites with the requirements of Annexes I and III of the Directive 2006/17/EC (2011 data)

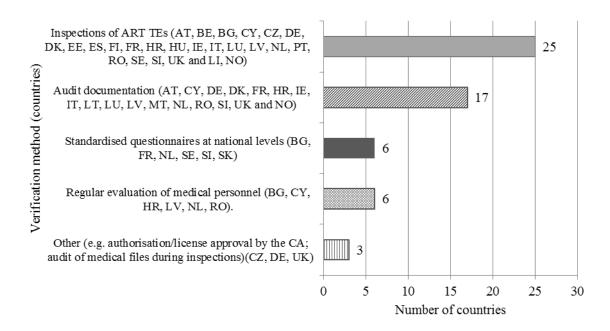


Fig. 37. Verifying the compliance of ART establishments with the requirements of Annex II of the Directive 2006/17/EC (2011 data)

A general concern that is expressed regularly by the competent authorities is the absence of regulation focused on the protection of the living donor.

In most Member States, the evaluation of deceased donors of tissues and cells relies on the medical records of the donor, the interview with the donor's family or a person who knew the donor well and the autopsy report. In approximately half of the reporting countries an interview with the treating physician or with the general practitioner is also required (Figure 38). One country (Liechtenstein) reported having only living donors.

Moreover, other practices were also reported:

- Belgium reported that a physical examination of the body is also required;
- In Germany, a post mortem physical examination as well as the results of the laboratory tests required according to Annex II of Directive 2004/23/EC;
- Liechtenstein reported that there are only living donors, for cord blood cells;
- Slovakia informed that other examinations might be done in case they are needed;
- The United Kingdom reported that there are no mandatory sources and tissue establishments may use several sources to evaluate a donor.

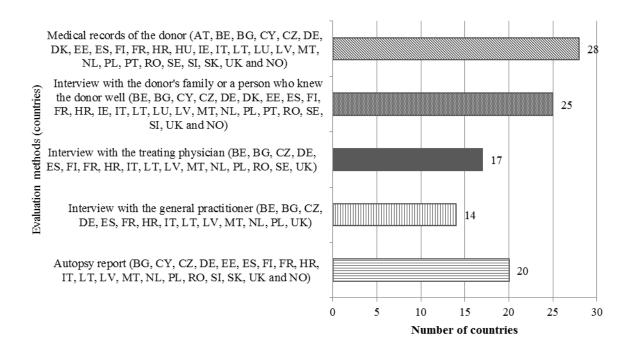


Fig. 38 Evaluation of deceased donors of human tissues and cells (2011 data)

Concerning the selection of donors of reproductive cells, four Member States indicated having more stringent criteria than those listed in Annex III to Directive 2006/17/EC:

- Belgium Testing for Treponema pallidum;
- Czech Republic HIV p 24 laboratory testing (NAT testing is not acceptable);
- Portugal age of the donor (maximum age for oocyte donors is 35 and for sperm is 45. For ovocyte donation only three ovocyte pick-ups cycles per donor are allowed. For sperm donation, a donor can be used for the birth of eight living children);
- United Kingdom age of donors. HFEA also specified that posthumous use of gametes or embryos created using gametes from a donor who has since deceased may only be used if the gamete provider has been screened in accordance with the requirements set out in the EU Directives.

No Member State declared having more stringent criteria for autologous donation than those listed in Annex I to Directive 2006/17/EC. Furthermore, no Member States request more information on the donation of tissues/cells than the mandatory one as laid down in the Annex to Directive 2004/23/EC.

In most of the Member States compliance with the requirements for tissues and cells procurement, packaging and transport is verified by the competent authorities when performing inspections. Auditing of tissue establishments and centres of human application, as well as inspections of the centres of human application have been reported by several countries as additional measures for verifying compliance with the EU procurement, packaging and transport requirements (Figure 39). Other Member States also reported requesting written SOPs and approval licence (Czech Republic), authorisation of procurement

establishments pursuant to sec. 20b of the German Medicinal Products Act (Germany), more requirements for specific tissues and cells (Italy), related information in the Tissue Establishment Dossier that is requested prior to inspections (Malta), correct procedures in place at the initial application assessment stage, and follow up during two-yearly inspections (United Kingdom).

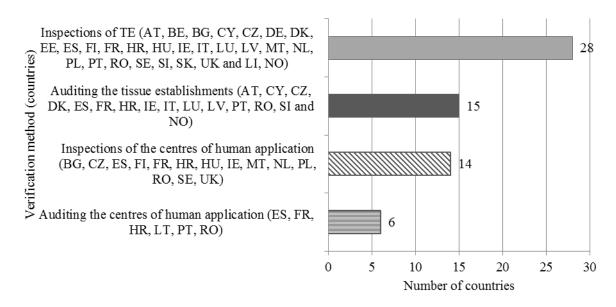


Fig. 39. Verification of compliance with the EU requirements for procurement, packaging in Directive 2006/17/EC (2011 data)

#### Comments

In summary, the survey showed that inspections are the most important verification method used by the Member States' competent authorities when verifying the compliance of tissue establishments with the EU donor evaluation and selection requirements. Nevertheless it has to be underlined that a few countries rely only on the medical records of the donor and/or the autopsy report without interviewing the donor's family or his/her treating physician/general practitioner, which may raise concerns. In relation to the selection of gamete donors, only two Member States (Portugal, United Kingdom) reported that the donor's age was included among the selection criteria for oocyte donors. The use of selection criteria should be transparent and subject to continuous evaluation in order to minimise safety risks.

Several Member States have called for an enhanced harmonisation of the criteria for donor selection and evaluation, stressing the importance of using a standardised donor evaluation procedure (e.g. consultation of all relevant sources for the medical and behavioural history of deceased donors).

## 2.3.4 Donor testing

Under Article 4 of Directive 2006/17/EC, the national competent authorities must ensure that donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Annex II. Also, Article 4(2) of Directive 2006/17/EC requires the

competent authorities to ensure that donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Annex III.

An overview of the donor testing in all the reporting countries is shown in Figure 40 (for donors of non-reproductive tissues and cells) and Figure 41 (for donors of reproductive tissues and cells).

Tests for donors of NON-reproductive tissues and cells/country	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IT	LI	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
Anti-HIV 1 Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Anti-HIV 2 Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
HIV Ag					Y				Y	Y	Y						Y								Y	Y	Y		
NAT HIV 1	Y	Y					Y	Y	Y	Y	Y	Y												Y					
HBs Ag	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Anti HBc Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
NAT HBV	Y	Y							Y	Y	Y	Y					Y							Y					
Anti HCV-Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	у	Y
NAT HCV	Y	Y					Y	Y	Y	Y	Y	Y					Y							Y					
Treponema	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Pallidum																													
HTLV-1									Y		Y						Y					Y		Y	Y				Y
NAT HTLV-1									Y		Y																		

Fig. 40. Testing of donors non-reproductive tissues and cells (2011 data)

m . e . l . e	4 m	DE	D.C.	CT.	07	D.E.	DIZ	TTT.	TC.	TY	r.p.	TTD		m	TOTAL	T	r m	* * * *	T X 7	) (T	N 77	210	DY	DТ	D.O.	or	O.T.	OYZ	x 177.7
Tests for donors of	ΑI	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	ΙE	IT	LI	LT	LU	LV	MI	NL	NO	PL	PT	RO	SE	SI	SK	UK
reproductive																													
tissues and																													
cells/country																													
Anti-HIV 1 Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Anti-HIV 2 Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
HIVAg					Y				Y	Y	Y	Y													Y	Y	Y		
NAT HIV 1	Y	Y						Y	Y	Y																			
HBs Ag	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Anti HBc Ab	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
NAT HBV	Y	Y							Y	Y																			
Anti HCV Ab		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y
NAT HCV	Y	Y						Y	Y	Y																			
NAT Chlamydia	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y							Y		Y	Y		Y					
Treponema	Y	Y	Y	у	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Pallidum																													
HTLV-1									Y									Y				Y		Y	Y	Y			Y
NAT HTLV1									Y																Y				

Fig. 41. Testing of donors of reproductive tissues and cells (2011 data)

The survey confirms that all reporting countries comply with the mandatory testing requirements laid down in Annex I to Directive 2006/17/EC. The other testing requirements such as testing of HTLV-1 antibody for donors living in or originating in high-prevalence areas or with sexual partners origination from those areas, as well as additional testing depending on the donors' travel and exposure history and the characteristics of the tissue and cell donated (e.g. CMV, EBV, Toxoplasma gondii, malaria, West Nile virus, Dengue fever, Chikungunya, Trypanosoma cruzi) are also performed.

One practical concern for the implementation of such requirements is however the lack of a common view on high-prevalence areas for these diseases. The Commission has therefore asked ECDC to elaborate assessments and maps for use by the Member States' competent authorities and tissue establishments across the Union.

Compared to the 2008 data, many countries introduced more stringent testing requirements of donors of non-reproductive tissues and cells (Fig 38), as following:

- NAT HIV: AT, BE, DK, ES, FI, FR, HR, PT;
- NAT HBV: AT, BE, ES, FI, FR, HR, LT;
- NAT HCV: AT, BE, DK, ES, FI, FR, HR, LT, PT.

Regarding testing donors of reproductive cells, most of the reporting countries comply with the requirements in Annex III to Directive 2006/17/EC, with some exceptions. Two Member States (Lithuania, Poland<sup>15</sup>) did not comply entirely because of inappropriate transposition of the Directives for the ART sector. Additionally, nine Member States (HU, IE, IT, LU, MT, RO, SE, SI, SK) and Liechtenstein do not perform NAT for Chlamydia as requested in Annex III to Directive 2006/17/EC.

Three Member States (Austria, Belgium and Finland) declared that more stringent requirements were introduced for donors of reproductive cells (e.g. mandatory NAT testing for HIV, HBV and HCV).

Concerning NAT testing, several countries specified that this type of testing is mandatory only in specific circumstances:

- Austria: only for deceased donations and living autologous donations;
- Croatia: only for non-reproductive tissues and cells;
- Denmark: for deceased donors;
- Estonia: for donors of reproductive and non-reproductive tissues and cells NAT HIV 1 and NAT HCV tests are required only if Anti-HIV 1 and Anti HCV-Ab are not performed;
- Finland: for donors of non-reproductive tissues and cells;
- France: for non-reproductive tissues and cells, and only NAT HIV for egg donation (immediately before the collection of the eggs as a second determination of the viral status of the donor);
- Germany: for deceased donors (exceptions for cornea and skin), in addition to serological testing;
- Lithuania: only for HBV and HCV;
- Portugal: only for non-reproductive tissues and cells.

Countries in which NAT testing is not obligatory by law, have different approaches toward introducing this type of testing:

- Denmark intends to make NAT testing for HIV, HBV and HCV mandatory for egg donors;
- Estonia, Ireland and Romania encourage the use of NAT testing, but the cost-benefit has to be taken into account;
- In Hungary the NAT technique is performed, but it is not compulsory by law;
- In Latvia NAT is performed routinely for HIV, HBV and HCV, but is not mandatory by law;
- In Cyprus the technique is performed for donors of reproductive cells, if cells are issued without retesting of donors after 180 days;
- In Poland NAT testing is used only for verification of questionable serological results;

<sup>&</sup>lt;sup>15</sup> In 2015 Poland has adopted new legislation for the ART sector and is in process of implementing it.

- Four Member States (IE, MT, NL, SE) and Norway declared having no plans to make NAT testing mandatory (mainly because epidemiological data and the cost-benefit analysis do not motivate such a decision);
- Slovenia reported that no discussion/decision was taken at national level regarding this issue:
- In the United Kingdom the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has recommended NAT testing, in particular product testing rather than donor serum testing. Mandatory NAT testing is supported by HTA particularly in case of a treatment involving donation from multiple donors and where the donations are not stored and therefore cannot be retested at 180 days.

Seven Member States (AT, DE, FI, HR, IE, IT, SI) and Norway expressed concerns regarding the accuracy of tests for cadaveric donors, mainly because of the limited number of manufacturers and the absence of validated CE-marked kits. Therefore, in some countries (e.g. Germany) the competent authorities recommend validating the assay systems before use on cadaveric samples.

Nine Member States (CY, ES, HR, HU, IE, IT, LV, PT, SE) reported requesting international accreditation for testing laboratories (e.g. ISO, EFI). In Romania the accreditation is not mandatory, but nevertheless it is frequently used.

#### Comments

The data reported show that most of the EU and EEA countries comply with the testing requirements stipulated in Directives 2004/23/EC and 2006/17/EC. Several countries have introduced more stringent testing requirements such as NAT testing for HBV, HCV and HIV for either or both donors of non-reproductive and reproductive tissue and cells, whereas in most Member States and EEA countries the use of this type of testing is not motivated by the cost-benefit analysis and/or the epidemiological context.

Additional tests required by Member States are usually justified for local reasons, like e.g. the increased prevalence of a certain infectious disease. These criteria may however also create barriers for exchanging tissues and cells between Member States. Members States should therefore have at least mutual transparent view on the tests implemented in each of the Member States.

Several of the testing requirements have been subject to discussion in the bi-annual competent authorities meetings and their relevance/value and use/feasibility should be continuously assessed in order to keep the tests aligned with the changes in the underlying risks that they need to help address.

An agreement at EU level on the compulsory use of NAT screening in certain circumstances based on new scientific data on its efficacy and cost-effectiveness may decrease even further the viral transmission risk.

It should also be kept in mind that the application of (some) tests can have a major impact on the local availability of tissues and cells.

It was noted in the discussions of the competent authority meetings that while the theoretical value of testing can be high, the effective value depends largely on the implementation and validation of these tests. Testing can therefore not be considered as the single pillar for safety of tissues and cells but is to be combined with deferral criteria and, where applicable,

inactivation techniques. It is only the combined implementation of all pillars that can minimise safety risks.

## 2.4 Quality and safety of tissues and cells

Directives 2004/23/EC and 2006/86/EC contain a number of provisions concerning quality and safety of tissues and cells intended for human application. They refer to (1) quality management, responsible person and personnel, (2) tissue and cell reception, processing, storage, labelling and packaging, (3) distribution of tissues and cells for human application, (4) relations between tissue establishments and third parties and (5) penalties applicable to in case of infringement of the national tissues and cells legislation.

## 2.4.1 Quality management, responsible person, personnel

Under Article 16 of Directive 2004/23/EC, Member States must take all the necessary measures to ensure that all tissue establishments put in place and keep up to date a **quality system**, including a minimum of documentation, which must also be available for inspection by the competent authorities.

The compliance of tissue establishments with the requirements of this Article is verified by the national competent authorities when authorising and inspecting the tissue establishments and by performing internal or external audits (Figure 42).

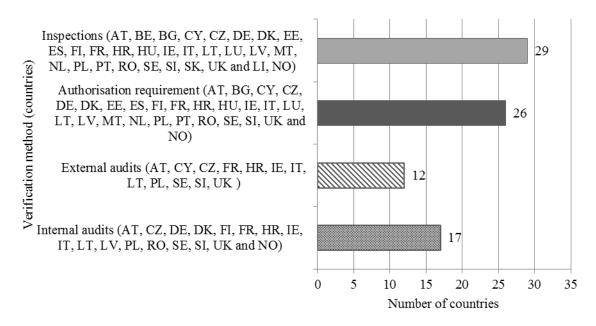


Fig. 42. Verification of compliance with the requirements of Art 16 (quality management) of Directive 2004/23/EC (2011 data)

Article 17 of Directive 2004/23/EC requires every tissue establishment to designate a responsible person with appropriate qualifications, who should fulfil the tasks laid down in this Article. The verification methods employed by the competent authorities for ensuring the fulfilment of this legal obligation are presented in Figure 43.

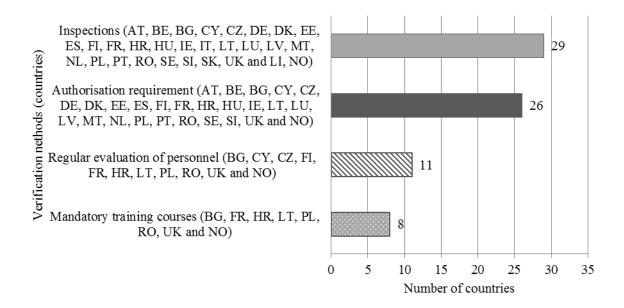


Fig. 43. Verification of compliance with the requirements of Art 17 (responsible person) of Directive 2004/23/EC (2011 data)

Besides the abovementioned methods, Sweden reported that in case of a change of the responsible person, an application together with the CV of the new responsible person must be approved by the competent authority.

Likewise, Article 18 of Directive 2004/23/EC entails that tissue establishment personnel directly involved in all the activities, from procurement to distribution of human tissues and cells, should be properly qualified and should be provided with suitable training. A summary of the verification methods used by the competent authorities for ensuring appropriate training of the tissue establishments' personnel is shown in Figure 44.

Some Member States reported additional procedures:

- Italy specified providing a non-mandatory training for the personnel directly involved in the activity of tissue establishments;
- Malta informed that during inspections, the team of inspectors asks for the documentation concerning the training of the personnel directly involved in the activities of tissue establishments;
- Sweden reported that during the inspections interviews with the personnel directly involved in the activities of tissue establishments are conducted and that the possibility of participation to additional/advanced training courses is discussed.

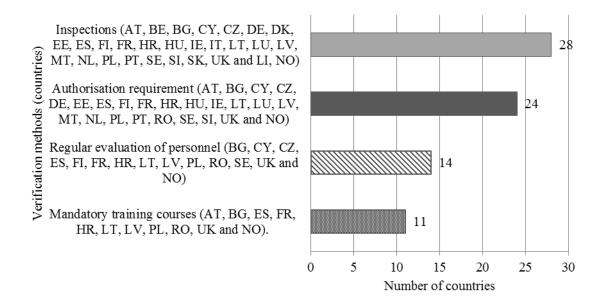


Fig. 44. Verification of compliance with the requirements of Art 18 (personnel) of Directive 2004/23/EC (2011 data)

Twenty Member States (BE, BG, CY, DE, DK, EE, ES, FR, HR, HU, IE, IT, LV, MT, PL, PT, SE, SI, SK, UK) and Norway reported that they have national/regional/local training programmes for the personnel of tissue establishments. Other Member States reported that their personnel is trained in other EU countries (AT, CZ, FI, LT, LV, NL, RO and Liechtenstein) or in non-EU countries (Czech Republic, Netherlands, Romania). In addition, Poland mentioned that each tissue establishment designates a quality manager.

### Comments

As all steps from tissue and cell donation until their distribution for medical application relies on staff professionalism, all personnel should be appropriately qualified and should benefit from appropriate training. The present survey confirmed that Member States are trying to ensure an appropriate level of training for the tissue establishments' personnel, and the compliance with the EU training requirements is systematically checked during inspections and also before granting an authorisation/accreditation/licence to the tissue establishments. It has to be underscored that additional support on training of tissue establishments' personnel was given through EU-funded projects such as European Quality System for Tissue Banking (EQSTB)<sup>16</sup> and European Good Tissue Practices (EuroGTPs)<sup>17</sup>. The good practices on quality management, responsible persons and personnel developed by the EU-funded initiatives were also included by the Council of Europe in a dedicated Guide to the quality and safety of tissues and cells.

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http://ec.europa.eu/chafea/projects/database.html?prjno=2003209
 http://eurogtps.com/HOME/tabid/38/Default.aspx

## 2.4.2. Tissue and cell reception, processing, storage, labelling and packaging

The measures taken by the Member States and EEA countries for ensuring that tissue establishments fulfil the requirements in Article 19 (Tissue and cell reception) of Directive 2004/23/EC and in Annex IV to Directive 2006/17/EC, are presented in Figure 45.

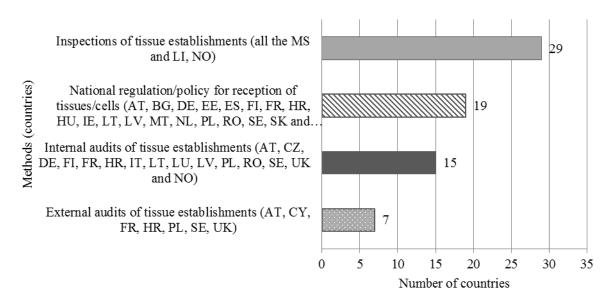


Fig. 45. Verification of compliance with the requirements of Art 19 (tissue and cell reception) of Directive 2004/23/EC (2011 data)

Article 20 of Directive 2004/23/EC obliges tissue establishments to include in their standard operating procedures all processes that affect quality and safety thus ensuring that they are carried out under controlled conditions. Detailed requirements concerning tissue and cell processing are laid down in Annex II to Directive 2006/86/EC. An overview of the verification methods used by the competent authorities for ensuring that these requirements are met is shown in Figure 46.

Article 21 of Directive 2004/23/EC, as well as Annex II to Directive 2006/86/EC lay down the obligations of tissue establishments related to the tissues and cell storage conditions. An outline of the control measures used by the competent authorities for ensuring that these requirements are fulfilled is presented in Figure 47.

Article 22 of Directive 2004/23/EC together with Annex II to Directive 2006/86/EC stipulate the tissue establishments' obligations related to labelling, documentation and packaging of human tissues and cells. A synopsis of the control measures applied by the competent authorities for ensuring that these requirements are fulfilled is presented in Figure 48.

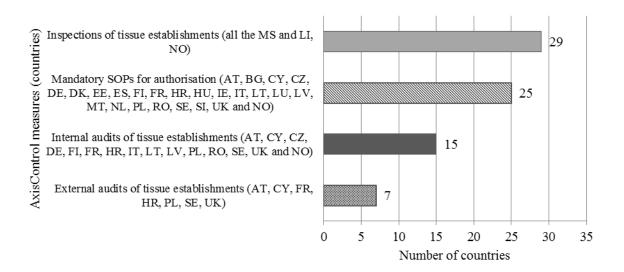


Fig. 46. Verification of compliance with the requirements of Art 20 (tissue and cell processing) of Directive 2004/23/EC (2011 data)

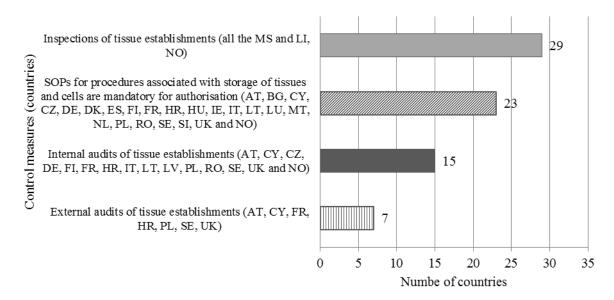


Fig. 47. Verification of compliance with the requirements of Art 21 (storage of tissues and cells) of Directive 2004/23/EC (2011 data)

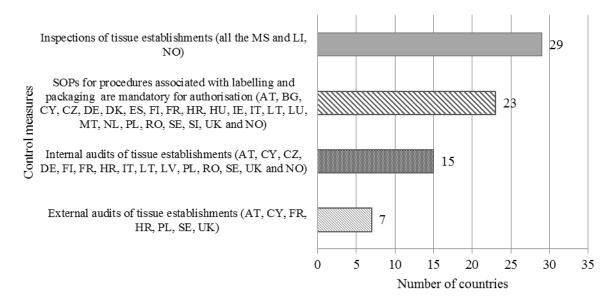


Fig. 48. Verification of compliance with the requirements of Art 22 (labelling, documentation and packaging) of Directive 2004/23/EC (2011 data)

Due to their importance, Germany suggested that requirements for microbiological testing of the source materials as well as of the final tissue product should be included in case of a potential revision of the legislation. It was underlined that microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible.

Additionally, Poland added that external audits are not obligatory, but some of the tissue establishments applied for and received ISO accreditation. The JACIE accreditation programme of procurement and transplantation centres as well as tissue establishments in the field of HSC started in 2013.

## Comments

The importance of inspections is highlighted again in the context of compliance with the reception, processing, storage, labelling and packaging requirements. It is the most frequent approach to control their implementation. Mandatory SOPs are also required during the authorisation/accreditation/designation or licensing process in most of the responding countries.

## 2.4.3. Distribution of tissues and cells for human application (Intra-community exchange)

Most of the Member States and EEA countries reported having cross-border exchanges of human tissues and cells distributed (either distributing or receiving to/from another Member State/EEA country or both).

Eleven Member States (AT, BE, DE, DK, FR, HR, IT, LT, NL, PT, SE) and Norway declared having more stringent safety and quality requirements than the minimum ones required by the EU tissues and cells Directives. Of these, some (BE, DK, SE and Norway) expect that the responsible person of the tissue establishment located in the other Member State/EEA will ensure the compliance with the more stringent requirements before releasing the products. If

needed, the competent authority from the receiving country is informing about the more stringent requirements the tissue establishment intending to distribute tissues and/or cells on their territory.

Different or additional requirements by Member States might be well justified for local reasons, e.g. to address the increased prevalence of a certain disease. Members States should however have a mutually transparent view and understanding on the requirements implemented in each of the Member States.

Article 23 of Directive 2004/23/EC requires tissue establishments to ensure the quality of tissues and cells during distribution. For most of the Member States, national competent authorities ensure that tissue establishments fulfil the requirements of this Article when granting authorisations, by inspections, audit or control of documentation (Figure 49).

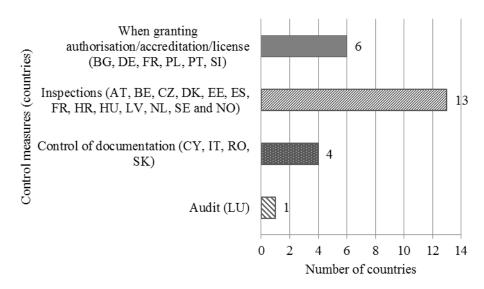


Fig. 49. Verification of compliance with the requirements of Art 23 (distribution) of the Directive 2004/23/EC (2011 data)

In most of the reporting countries direct distribution of tissues and cells from another EU Member State/EEA country to organisations responsible for human application (e.g. hospitals/clinics) on their territory is allowed. Four Member States (CZ, HR, PT and UK but only for gametes) and Liechtenstein reported that direct distribution is not allowed. An outline of the answers provide to this question is shown in Figure 50.

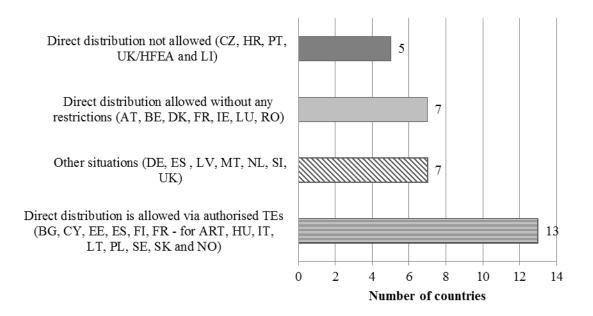


Fig. 50. Direct distribution of tissues and cells (2011 data)

The other situations reported are detailed below:

- Germany specified that before the first placing on the market, a certificate issued by the Paul-Ehrlich Institute is required (section 21a sub-section 9 AMG); the certificate shows that the products to be distributed in Germany have equivalent quality standards with the ones already on the market. In the case of non-equivalence, a "full marketing authorisation" (authorisation for tissue preparations regarding Section 21a AMG) must be obtained;
- Latvia informed that there are no legal provisions regarding distribution to Latvian hospitals from tissue establishments in another Member State;
- Malta indicated that direct distribution to hospitals/clinics through brokers is possible only after notification of the competent authority who authorises the entry if the relevant documentation shows equivalence of standards;
- In the Netherlands, restrictions apply only for unprocessed tissues, which is done only via an authorised tissue establishment;
- In Slovenia distribution to hospitals/clinics is allowed, but with special authorisation issued for each case;
- Spain indicated that only the distribution of products derived of human tissues such as demineralised bone matrix (DBM) and lyophilized products may be distributed directly to hospitals/clinics;
- In the United Kingdom, direct distribution is allowed to end users, without requiring a licence, provided tissues and cells will not be stored for longer than 48 hours.

Concerning direct distribution of specific tissues and cells to a recipient (Article 6 of Directive 2006/17/EC), five Member States (FR, LT, MT, SI, SK) reported having authorised such procedures in 2011 for haematopoietic stem cells (France, Lithuania), musculoskeletal tissues (Lithuania, Malta) as well as gametes and embryos (FR).

Only 18 Member States (BE, BG, DE, EE, ES, FI, FR, HR, IE, IT, LT, NL, PT, RO, SE, SI, SK, UK) reported that data related to the cross-border exchange between their country and another Member State/EEA country are collected at national level. However, the data collected varies from one country to another, with some Member States providing data on the number and type of tissues distributed as well the country of destination/origin (BE, BG, DE, EE, FI, HR, IE, IT, LT, PL, PT), other only data on the number and type of tissues distributed (Netherlands, Spain, Sweden) or just the total number distributed within the EU (United Kingdom). Additionally, Germany collects data on tissues and cells entering and leaving their territory with no distinction between import/export from/to third countries and distribution within the EU.

Overall, for 2011, 18 countries reported that 59,375 units of human tissues and cells were distributed to other EU and EEA countries:

- 41,271 units were distributed by United Kingdom. Data per tissue type were not reported;
- 16,461 units were distributed by 13 Member States (BE, BG, EE, ES, FI, IE, IT, LT, NL, PL, PT, SE, UK/HFEA) (Figure 51);
- 1,643 units of replacement tissues (musculoskeletal, ocular tissues and cardiovascular tissues) were distributed by France. It was specified that distribution of haematopoietic stem cells units was reported to EBMT. Distribution of cryopreserved sperm to one Member State (Spain) for patients who travel abroad for egg donation was also was reported.

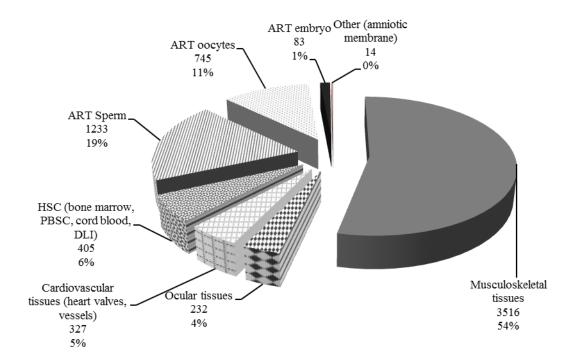


Fig. 51. Volume of tissues and cells distributed for clinical application to another Member State or EEA country (units of tissues or cells – absolute and relative values; 2011 data)

The number above does not include cord blood units, cord blood segments and teeth for autologous use transported for storage in another Member State (e.g. as reported by Slovenia).

One Member State (Romania) collects data on distribution of tissues and cells but reported that no such products were distributed in 2011. Slovakia informed that data collection started only in December 2012, so 2011 data is not available.

Information on tissues and cells received from other EU Member States and EEA countries was also asked. For 2011 it was reported that 255,346 units of human tissues and cells were received from other EU and EEA countries:

- 238, 244 units were received by the United Kingdom;
- 4,480 units of replacement tissues (musculoskeletal, ocular tissues and cardiovascular tissues) were reported by France. Data per tissue type were not reported;
- 12,622 units were reported by 13 Member States (BE, BG, EE, ES, FI, IE, IT, LT, NL, PL, PT, SE, UK/HFEA) (Figure 52).

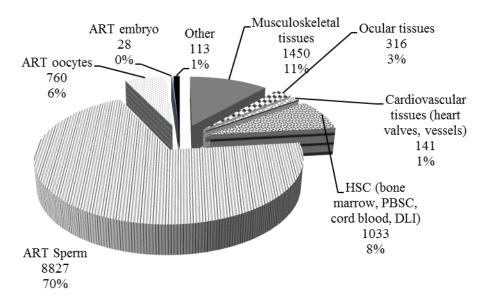


Fig. 52. Volume of tissues and cells received for clinical application from another EU Member State or EEA country (units of tissues or cells – absolute and relative values; 2011 data)

Four Member States (HR, PL, RO, SK) informed that no tissues and cells were received from other EU or EEA countries in 2011.

Slovenia and Slovakia did not provide details on the type of tissues and cells for which the authorisation was granted.

In addition, only nine Member States (AT, DE, DK, ES, IE, IT, MT, NL, UK for non-reproductive tissues and cells) and Liechtenstein and Norway reported allowing **brokerage** companies for either distribution in EU and/or import/export of tissues and cells. The legal framework for the brokerage companies varies, as follows:

- Authorisation by the national competent authority is required (Austria, Malta);
- No specific legal provisions, but the competent authority informs the brokerage company on the principles of tissues and cells legislation and periodically monitors their activities (Denmark);

- National legislation in place for "brokering of medicinal products" (sec. 4 para. 22a German Medicinal Products Act), but no experience in implementing these regulations with regard to "classical tissues" (Germany);
- Possibility to operate under a third party agreement with a public, authorised tissue establishment (e.g. currently occurring for processed bone products) (Italy);
- Legislation in place, according to which a broker is a legal entity allowed to make financial and logistic arrangements between seller and buyer without handling the tissues (handling the tissues is only allowed to authorised tissue establishments) (Netherlands);
- Authorisations for brokerage are provided by the regional authorities (Spain);
- Brokers are considered intermediaries obtaining tissue for end-users, however most of them are licensed as they are engaged in an intermediate storage step. The competent authority's role is to authorise and monitor them through inspection. Currently only one broker is licensed for distribution and import/export, without storage (United Kingdom).

Three Member States (Austria, Germany, Ireland) as well as Liechtenstein and Norway specified that even though brokers are allowed, they are not actively supplying healthcare professionals and other types of establishments.

In the six Member States which indicated that brokers actively supply health professionals in their country (DK, ES, IT, MT, NL, UK), brokers are located either on their territory (DK, ES, IT, MT, UK) or in another country (ES, IE, IT, NL). Spain also specified that the verification of compliance with the safety and quality requirements is performed through analysis of the documentation provided by the broker.

#### Comments

As demonstrated by the Member States' replies, there are important cross-border movements of human tissues and cells within the EU and EEA countries. This may be considered the result of the quality and safety standards laid down in Directive 2004/23/EC and its implementing Directives, which have created the framework for facilitating transnational movements within the Union. However, it has to be underlined that like for import and export, data collected by the Member States probably serve different purposes and use various methodologies, so it is very difficult to draw a clear conclusion on the volume of tissues exchanged and the importance of EU distribution compared to import/export in this sector. Additionally the more stringent requirements introduced by some Member States, as well as the different legal framework under which the EU tissues and cells legislation was transposed (e.g. transplantation vs. medicinal products) may hamper to some extent the flow of tissues and cells within the Union.

#### 2.4.4 Relations between tissue establishments and third parties

Article 24 of Directive 2004/23/EC lays down the requirements between tissue establishments and third parties, which include the situations when a written third party agreement is mandatory and the obligations of the tissue establishments when selecting the third parties, as well as their obligation to keep a complete lists of these agreements and to provide copies of the agreements upon request from competent authorities.

Only two Member States (Hungary, Luxembourg) reported that third party agreements are not included in their national legislation. From the countries allowing third parties agreements, only four Member States (CY, FI, RO, SK) and Liechtenstein reported that no third party agreements were notified to the national competent authorities.

Concerning the responsibilities entrusted to third parties, Member States reported that written agreements with third parties have been concluded for several activities within the donation-distribution chain (Figure 53).

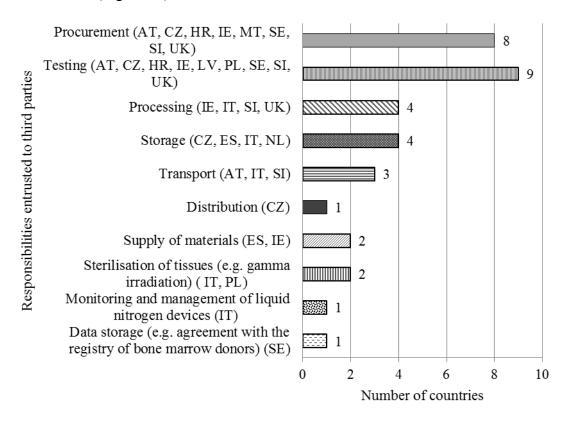


Fig. 53. Tissue establishments' written agreements with third parties (2011 data)

Seven Member States (BE, BG, DE, EE, FR, LT, PT) and Norway reported only the circumstances and did not provide detailed data on activities for which third parties agreements can be concluded.

Member States and EEA countries reported that third party agreements are checked (Art 6.2) by the competent authority(ies) mainly by inspection (AT, BE, BG, CZ, DE, DK, EE, ES, FR, HR, IE, IT, LV, NL, PL, PT, SE, UK and NO), by evaluating the contractual agreements (Denmark, Latvia, Malta), but also when granting authorisations/accreditations /designations or licences (BG, CZ, DE, EE, ES, FR, IE, NL, PL, PT, SE, SI, UK and NO).

The competent authority for non-reproductive tissues and cells in United Kingdom (HTA) specified having powers to enter and inspect third party premises, powers to direct a licensed establishment to put in place a third party agreement with a supplier of goods or services where it considers this necessary. The HTA equally has powers to direct an individual licensed establishment not to use a named supplier of either goods or services. Under extreme

circumstances the HTA may give details of suppliers from whom no licensed establishment may receive goods or services.

In Italy, third parties that carry our critical steps such as processing or storage of tissues or cells on behalf of tissue establishments must have direct authorisations from the Ministry of Health, which are issued by the national competent authority (*Centro Nazionale Trapianti*) on the basis of inspections. In Sweden, a new third party agreement is considered a major change in the authorisation of a tissue establishment and it requires the approval of the competent authority (by document review).

#### **Comments**

The fact that third parties may be involved in all the steps of the chain from donation and procurement until distribution shows the importance that needs to be given to the written agreements established by the tissue establishments and their verification by the national competent authorities. In this respect, it should be highlighted that Directive (EU) 2015/566 as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells provides for the harmonisation of the minimum requirements in terms of contents of written agreements between importing tissue establishments and their third country suppliers.

#### 2.4.5. Penalties

Under Article 6(4) of Directive 2004/23/EC, the competent authority or authorities may revoke or suspend the accreditation/designation/authorisation/licence of a tissue establishment if it is found to no longer comply with the requirements of the Directives.

Twenty-two Member States (AT, BE, BG, CY, CZ, DE, EE, ES, FI, FR, IE, IT, LU, LV, MT, NL, PL, PT, RO, SE, SI, UK) and Liechtenstein and Norway indicated that penalties for infringements of the national provisions pursuant to Directive 2004/23/EC were defined. Five Member States (AT, CZ, DE, NL, UK) indicated that such penalties were already imposed, but only two Member States reported imposing penalties in 2011 (Germany – one fine; United Kingdom/HTA – 11 penalties). The United Kingdom reported that the majority of penalties were imposed following inspections where shortfalls against regulatory requirements had been identified; penalties imposed included conditions or directions on seven licences, suspensions of specific licensable activities on three licences and one revocation, but none were followed by criminal sanctions.

## Comments

The penalties foreseen in national legislation, their criteria for implementation and their effective implementation can differ significantly between Member States. In order to ensure mutual trust between Member States, in particular for cross-border movements, some Member States suggested further collaboration and coordination, potentially in a dedicated EU initiative related to inspections and authorisations.

Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells Text with EEA relevance. OJ L 93, 9.4.2015, p. 56–68

# Annex 1: Individual country responses to the survey on the implementation of the EU Tissues and Cells Directives conducted in 2012 and based on 2011 information

Note: In a number of cases clarification requests were sent to Member States to verify the information included in their submission. It is important to note that while the original replies of Member States are shown below, the text, tables and figures reflect the updated information provided by Member States during a verification process. Where there are discrepancies, the text, tables and figures in the document itself contain the correct information.

## A.1.1. Survey response Austria

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Federal Office for Safety in Health Care (BASG) / AGES Austrian
	Agency for Health and Food Safety
1.1.2. Address of NCA 1:	Traisengasse 5 A-1200 Vienna Austria
1.1.3. Telephone (central access point):	+43505550
1.1.4. E-mail (central access point):	inspektionen@ages.at
1.1.5. Website:	www.basg.gv.at
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Pharmaceuticals
	Medical devices
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	Federal Office for Safety in Health Care (BASG) and AGES The
organisation of the National Competent Authority(ies) (e.g.	Federal Office for the Safetyin Health Care (BASG) / AGES was set
departments, staffing, number of senior and junior inspectors, staff	up in January 2006 and is responsible for marketing authorisation of
working on EU affairs and legal matters, vigilance officers, budget,	medicinal products in Austria and assessment of medicinal products
independence from government etc.).	and medical devices which are already on the market regarding
	efficacy, adverse reactions, production, shipment and storage. Fully
	owned by the Republic of Austria, BASG / AGES acts on behalf of
	the Republic as represented by the Federal Ministry of Health
	(BMG). The Federal Office for Safety in Health Care (BASG) is
	responsible for carrying out public services undertakings. BASG is
	directly subordinate to the Federal Ministry of Health (BMG). It
	consists of three members, which are appointed by the Federal
	Minister of Health. One of these members was delegated by the
	BMG, another by AGES; the third member is the head of BASG /
	AGES. AGES is thus connected closely to the BASG; it is
	represented by two members in the Federal Office and provides it
	with services, staff and facilities. The employees of BASG / AGES
	are responsible for carrying out public services undertakings and act
	on behalf of the Federal Office. The written decisions issued by the
	BASG are not subject to reversal change by the administration, thus
	making it the first and final authority. The instituts of the Austrian
	Medicines and Medical Devices Agency: Institute
	Pharmakovigilance (Head: Dr. Bettina Schade) Institute OMCL
	(Head: Dr. Gerhard Beck) Institut Marketing Authorisation &
	Lifecycle Management (Head: Dr. Christa Wirthumer-Hoche)
	Institute Inspections, Medical Devices & Haemovigilance (Head:
	DDr. Alexander Hönel) Head of the Austrian Medicines and
	Medical Devices Agency: Ao. UnivProf. Dr. Marcus Muellner

	The tasks concerning tissues and cells are mainly located at the Instituts Inspections, Medical Decives & Haemovigilance at the department Pharma and there at the group Blood & Tissues Inspections & Vigilance. The group Blood & Tissues Inspections & Vigilance consists of a team of inspetors (4), a vigilace team (3), and the head of the group.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
-	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	Not applicable
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	By inspecting some procurement centres By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	35
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	32
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	15
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	36
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	9
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)	Inspections of the site/centre
2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	No
2.4.2. Which National Authority is in charge of this activity?	missing implementation in national law
2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible)	Analysis of the mandatory documentation requested from the tissue establishment
2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.).	missing implementation in national law
2.7. Do you have any additional comments on procurement?	-
3. Testing (Art 4 Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab

	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	NAT HIV 1
,	HBs AG
	Anti HBc
	NAT HBV
	NAT HCV
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	only for autologous donations NAT testing is not mandatory
please indicate whether you intend to make it mandatory or to	reproductive autologous: NAT testing not mandatory reproductive
encourage its use? Please specify why or why not (e.g. number of	allogeneic: NAT testing mandatory deceased: NAT testing
additional cases detected, cost-benefit etc.).	mandatory living autologous: NAT testing not mandatory living
	allogeneic: NAT testing mandatory
3.4. Do you have concerns on accuracy of the available tests and test	Yes
procedures for deceased donors?	
3.4.1. Please specify why:	because there are no CE-marked kits for the testing of blood of dec
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	No
3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	No
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	INO INO
3.8. Do you have any additional comments on testing?	-
<b>4.</b> Accreditation, designation, authorisation or licensing of tissue es 4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	Yes
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	165
4.2.1. How many inspections were performed in 2011 for	57
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During inspections organised for this purpose
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	2
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC.	A
4.7. Tissue establishments with authorisation pending approval at	Musculo-skeletal tissue establishments
01/01/2011 (more than 1 answer possible):	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.7.2. How many musculo-skeletal tissue establishments?	1
4.7.6. How many cord blood tissue establishments?	1
4.7.7. How many ART tissue establishments?	7
4.7.8. How many multi-tissue establishments?	1
4.8. Tissue establishments with authorisations pending approval by	Skin tissue establishments
31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.8.1. How many skin tissue establishments?	1 1

4.8.2. How many musculo-skeletal tissue establishments?	16
4.8.4. How many cardiovascular tissue establishments?	1
4.8.5. How many HSC tissue establishments?	3
4.8.6. How many cord blood tissue establishments?	2
4.8.7. How many ART tissue establishments?	4
4.8.8. How many multi-tissue establishments?	2
4.9. Tissue establishments first time authorised between 01/01/2011	Musculo-skeletal tissue establishments
and 31/12/2011 (more than 1 answer possible):	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.9.2. How many musculo-skeletal tissue establishments?	9
4.9.5. How many HSC tissue establishments?	1
4.9.6. How many cord blood tissue establishments?	2
4.9.7. How many ART tissue establishments?	22
4.9.8 How many multi-tissue establishments?	5
4.10. All tissue establishments authorised by 31/12/2011 (more than	Musculo-skeletal tissue establishments
1 answer possible):	Ocular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?	10
4.10.2.2. How many private musculo-skeletal tissue establishments?	6
4.10.3.1. How many public ocular tissue establishments?	1
4.10.3.2. How many private ocular tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	6
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	0
4.10.6.2. How many private cord blood tissue establishments?	3
4.10.7.1. How many public ART tissue establishments?	14
4.10.7.2. How many private ART tissue establishments?	18
4.10.8.1. How many public multi-tissue establishments?	14
4.10.8.2. How many private multi-tissue establishments?	3
4.10.9.1. Please specify the type of 'other' public tissues/cells	none
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	Tumor tissue (Glioblastoma multiforme) 1TE Subcutaneous adipose
establishements and how many.	tissue 1TE
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	1 11
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	V
4.16.1. Have penalties already been imposed?	Yes
4.16.1.1. How many penalties have been imposed in 2011 (from	0
01/01/2011-31/12/2011)?	
4.16.1.2. What were the reasons for imposing the penalties? Please describe.	-
4.16.1.3. What kind of penalties were imposed? Please describe (e.g.	-
suspension of authorisation, criminal penalty etc.)	-
	A legally necessary certificate for tissue establishments, issued after
4.17. Do you have any additional comments on accreditation,	
authorisation, designation and licensing?	each inspection, would be desireable in order to display the current
	each inspection, would be desireable in order to display the current status of authorization (comparable to a GMP-Certificate in the
authorisation, designation and licensing?	each inspection, would be desireable in order to display the current
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)	each inspection, would be desireable in order to display the current status of authorization (comparable to a GMP-Certificate in the pharmaceutical area).
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control	each inspection, would be desireable in order to display the current status of authorization (comparable to a GMP-Certificate in the
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)	each inspection, would be desireable in order to display the current status of authorization (comparable to a GMP-Certificate in the pharmaceutical area).

of inspections.	Inspections, Medical Devices & Haemovigilance
5.1.2. If yes, please specify staffing (how many inspectors).	4
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
5.2.1. 11 yes, please specify. (more than 1 answer possible)	Pharmaceuticals
	Advanced therapies
5.3. How many routine inspections of tissue establishments for non-	40
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	40
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
<u> </u>	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	2 (enforcement inspections)
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4 Outcome of inspections of TEs for non-reproductive	11
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	29
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	2
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	2, Due to major changes in the TE additional inspections were
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	performerd.
was the number of other inspections carried out? Please specify.	<b>^</b>
5.4. How many routine inspections were conducted in ART	18
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	V
inspections carried out where no shortcomings were observed?	
	1
5.4.4. What was the number of inspections carried out in ART	1
establishments where minor shortcomings were noted?	16
5.4.5. What was the number of inspections carried out in ART	16
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0

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6.4. Please specify which procedures you have in place for verifying	Inspections at the importing establishments take place, the product is
the equivalent standards of quality and safety for importation of skin	released by the Austrian establishment, SOPs and contracts are
from third countries.	inspected to ensure the equivalent standards, the Austrian company
	has to perform audits at the site they are importing from
6.5. Please specify which procedures you have in place for verifying	Inspections at the importing establishments take place, the product is
the equivalent standards of quality and safety for importation of	released by the Austrian establishment, SOPs and contracts are
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	inspected to ensure the equivalent standards, the Austrian company
countries.	has to perform audits at the site they are importing from
6.6. Please specify which procedures you have in place for verifying	Inspections at the importing establishments take place, the product is
the equivalent standards of quality and safety for importation of	released by the Austrian establishment, SOPs and contracts are
ophtalmic (cornea, sclera, etc ) tissues from third countries.	inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from
6.7. Please specify which procedures you have in place for verifying	Inspections at the importing establishments take place, the product is
the equivalent standards of quality and safety for importation of	released by the Austrian establishment, SOPs and contracts are
cardio vascular tissues from third countries.	inspected to ensure the equivalent standards, the Austrian company
	has to perform audits at the site they are importing from
6.8. Please specify which procedures you have in place for verifying	Inspections at the importing establishments take place, the product is
the equivalent standards of quality and safety for importation of	released by the Austrian establishment, SOPs and contracts are
haematopoietic stem cells (HSC) (other than cord blood) from third	inspected to ensure the equivalent standards, the Austrian company
countries.	has to perform audits at the site they are importing from
6.9. Please specify which procedures you have in place for verifying	Inspections at the importing establishments take place, the product is
the equivalent standards of quality and safety for importation of cord	released by the Austrian establishment, SOPs and contracts are
blood from third countries.	inspected to ensure the equivalent standards, the Austrian company
blood from time countries.	has to perform audits at the site they are importing from
6.10. Please specify which procedures you have in place for	
	Inspections at the importing establishments take place, the product is
verifying the equivalent standards of quality and safety for	released by the Austrian establishment, SOPs and contracts are
importation of reproductive cells (sperm, egg cells) from third	inspected to ensure the equivalent standards, the Austrian company
countries.	has to perform audits at the site they are importing from
6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
6.11.1. If yes, please provide the data concerning the	no data available, notification not required by national law
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	F. Other
and self-sufficiency? (more than 1 answer possible)	
Please specify 'other':	only import is authorised - no estimations are performed
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	-
7. Distribution/intra community exchanges (Article 23 Directive 20	
7.1. Do you have intra-community exchanges of tissues and cells?	
	Yes
7.1.1. If yes, how do you address the possible more stringent quality	The different, more stringent national laws of all member states can
and safety measures established by other Member States? Please	not be known. Product which are brought to other member states
specify.	must fulfill the Austrian Cell and Tissue Safety Act.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	Yes
7.1.2.1. How do you address this difference for tissues and cells	If the tissues or cells have been released by a responsible person in
coming from a MS with minimum quality requirements? Please specify.	the EU, the products can be used in Austria.
7.2. How do you ensure that tissues establishments fulfil the	During inequations records SODs are reviewed
· · · · · · · · · · · · · · · · · · ·	During inspections records, SOPs are reviewed.
requirements of Art. 23 of Directive 2004/23/EC regarding quality	
of tissues and cells during distribution? Please specify.	Voc no restrictions anniv
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, no restrictions apply
form TE- in an all on MC9 (and a 1 )	
from TEs in another MS? (only 1 answer possible).	N.
from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No

7.5. Do you collect data regarding the cross-border exchange of	No
tissue/cells between your country and other EU MS?	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	Yes
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.7.1. Please describe the legal requirements and your role (if any) as	For import/export of tissue and cells an authorisation by the CA is
a Competent Authority, in their authorisation/monitoring or	required. For the arrangement of transactions within the EU no
inspection.	authorisation is required.
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	-
8. Register of tissue establishments and reporting obligations (Arti	icle 10. Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	60-99%
their activities during 2011. Please provide an estimation. (1 answer	00 7770
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	NO
8.4.2. If no, why not?	Data for 2009 were published, due to no national legislations there
8.4.2. If no, why not:	was no further publishing since then. Legislation was changed
	recently. The data of 2012 will be published.
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	res
8.5.1. If yes, please provide us with the link to the register's web site.	http://www.basg.gv.at/arzneimittel/gewebe/register-29-gsg/
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	to do to amplicate the state of the property
8.6.1. If yes, what data are provided to EUROCET? Please specify.	update of register of TEs and their tasks was provided to EUROCET
0.7.75	in July 2013
8.7. Do you have any additional comments on reporting?	-
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	No
your country?	
9.1.1. If no, why not?	The Federal Ministry of Health deferred the implementation of
	ISBT128 on 16.12.2008 due to difficuties in the practical
	implementation in the area of tissues and cells.
9.2. Who assigns the unique code for each donation? (only 1 answer	Other
possible)	
Please specify 'other'.	TE or procurement center
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
5.5. Trowns are data storage for a decading purposes organised in	1
your tissue establishements (Art 8(4))? (only 1 answer possible)	
	Needs to be specified in SOPs. Checking examples during routine
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is	Needs to be specified in SOPs. Checking examples during routine inspections.
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?	inspections.
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11)	inspections.  - Directive 2004/23, Article 6 Directive 2006/76)
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the	inspections.
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	inspections.  - Directive 2004/23, Article 6 Directive 2006/76)  Yes
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	inspections.  - Directive 2004/23, Article 6 Directive 2006/76)  Yes  AGES (our CA)
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.	inspections.  - Directive 2004/23, Article 6 Directive 2006/76)  Yes  AGES (our CA) see 1.5
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	inspections.  - Directive 2004/23, Article 6 Directive 2006/76)  Yes  AGES (our CA)
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.	inspections.  - Directive 2004/23, Article 6 Directive 2006/76)  Yes  AGES (our CA) see 1.5

10.3. Do you use the Common Approach Document developed for	V
	Yes
the Annual reporting to the EC also at national level?	V
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	70.000/
10.5. How many tissue establishments provided in 2011 the	70-99%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	it is regulated by national law
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at national level?	
10.7.1. Please specify.	each TE receives a confirmation of the notification after submitting
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at EU level?	
10.8.2. Please specify why not.	currently there is no summary report of the Commission available
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	there were no recalls in 2011
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	all involved TE and procurement sites will be informed by email
system/procedure.	
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	all involved TE and procurement sites will be informed by email
system/procedure.	
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
1 105.00.j (non manamor) reporting):	
10.13.2. If no, please specify why not.	leck of capacity, not mandatory
10.13.2. If no, please specify why not.	leck of capacity, not mandatory Yes
10.13.2. If no, please specify why not. 10.14. Do you notify alerts communicated via these tissues and cells	
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	Yes
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are	
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	Yes Haemovigilance
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are	Yes  Haemovigilance Pharmacovilance
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	Yes  Haemovigilance Pharmacovilance Medical devices
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes  Haemovigilance Pharmacovilance Medical devices
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of	Yes  Haemovigilance Pharmacovilance Medical devices Yes
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	Yes  Haemovigilance Pharmacovilance Medical devices Yes
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	Yes  Haemovigilance Pharmacovilance Medical devices Yes
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?	Yes  Haemovigilance Pharmacovilance Medical devices Yes  5
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direction)	Yes  Haemovigilance Pharmacovilance Medical devices Yes  5  - tive 2004/23/EC)
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direction 11.1. What consent system for living tissue/cell donation do you	Yes  Haemovigilance Pharmacovilance Medical devices Yes  5
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direction 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Yes  Haemovigilance Pharmacovilance Medical devices Yes  5  - tive 2004/23/EC)  Explicit consent (opt-in)
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Yes  Haemovigilance Pharmacovilance Medical devices Yes  5  - tive 2004/23/EC)  Explicit consent (opt-in)  Before procurement of tissues or cells the donor has to be informed
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direction 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Haemovigilance Pharmacovilance Medical devices Yes  5
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Haemovigilance Pharmacovilance Medical devices Yes  5
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Haemovigilance Pharmacovilance Medical devices Yes  5  tive 2004/23/EC)  Explicit consent (opt-in)  Before procurement of tissues or cells the donor has to be informed about the procedure, any risks, testings etc. and has to give his
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1. Please specify your choice of consent system for living tissue/cell donation.	Haemovigilance Pharmacovilance Medical devices Yes  5  Explicit consent (opt-in)  Before procurement of tissues or cells the donor has to be informed about the procedure, any risks, testings etc. and has to give his consent with his signature.  Presumed consent (opt-out)
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Haemovigilance Pharmacovilance Medical devices Yes  5
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the	Haemovigilance Pharmacovilance Medical devices Yes  5  Explicit consent (opt-in)  Before procurement of tissues or cells the donor has to be informed about the procedure, any risks, testings etc. and has to give his consent with his signature.  Presumed consent (opt-out)
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	Haemovigilance Pharmacovilance Medical devices Yes  5
10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the	Haemovigilance Pharmacovilance Medical devices Yes  5  Explicit consent (opt-in)  Before procurement of tissues or cells the donor has to be informed about the procedure, any risks, testings etc. and has to give his consent with his signature.  Presumed consent (opt-out)

	before any procurement of tissues or organs of deceased donors can
	take place.
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	Usually donors are traceable by a unique donor identification
recipients remain unidentifiable when access is given to third parties	number.
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	Usually donors are traceable by a unique donor identification
identity of the receipient is not disclosed to the donor and vice	number.
versa.	
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures in	Parents will just get any necessary medical information or
place.	information regarding physical appearance of the sperm donor.
·	However to the child the personal data of the sperm donor will be
	disclosed when he or she is 14 year old.
11.10. Do you have any additional comments on consent and data	-
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23: Anneyes LIV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive	radit of documentation
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	Truck documentation
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Medical records of the donor
deceased donor of tissues/cells? (more than 1 answer possible)	Thousan records of the donor
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	-
and procurement?	
13. Quality management, responsible person, personnel (Article 10	5. 17. 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
F-ace a quanty system respecting the provisions of the	

Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	No
the personnel of tissue establishments?	110
13.4.2. If no, in which country(ies) is your personnel trained?	EU countries
13.4.2.1. Please specify EU-countries.	EATB training, a.s.o.
13.5. Any additional comments on quality management, responsible	-
person, personnel?	
14 Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	External audits of tissue establishments (e.g. ISO)
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
Brook ve 200 (/25/20. (more than 1 district possions)	Internal audits of tissue establishments
	External audits of tissue establishments (e.g. ISO)
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
	External audits of tissue establishments (e.g. ISO)
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
	External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception, processing, storage,	-
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	transport agreements, agreements with laboratories for laboratory
2 Shaer which enganisances and for which responsibilities:	testing, agreements with clinical teams (procurement)
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	during routine inspections
Competent Auhtority(ies) in your MS? Please specify.	daring routine inspections
15.2. Any additional comments on third party agreements?	-
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	Yes
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.1.1. Please specify.	The donation fo egg cells or embryos is not allowed. Deceased
	donors have to be tested by NAT for HIV, HBV and HCV. Of all
	the blood samples of donors samples have to be stored at the TE for
	30 years so that all laboratory tests can be repeated twice.
1	1

16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	difficulties regarding the requirements on the premisis (air grade,
short description.	monitoring of air grade)
16.3. In your opinion, in which of following Directives are there	Directive 2006/17/EC
shortcomings (if any)? (more than 1 answer possible)	Directive 2006/86/EC
16.3.2. How would you suggest to solve these issues in Directive	In the case of donations of autologous living donors or partner
2006/17/EC?	donations where test results are positive (HIV 1, 2, Hepatitis B, C
	etc.) the tissues or cells should not only be stored separately (Annex
	I 2.1.1, Annex III 2.3) but there should also be facilities in place to
	ensure separate processing to eliminate the risk of cross-
	contamination and mix up. For deceased donors blood samples
	should be tested for HIV, Hepatits B and C genome by NAT.
16.3.3. How would you suggest to solve these issues in Directive	The paragraph "Annex I, D Facilities/Premises 4 (c)" should be
2006/86/EC?	explained and it should be clarified under which circumstances it
	applies. It should be defined which air quality for the environment is
	required if this paragraph is applicable.

## A.1.2. Survey response Belgium

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	FAMHP: Federal Agency for Medicines and Health Products
1.1.2. Address of NCA 1:	Eurostation building, place Victor Horta, 40/40 B – 1060 Brussels
1.1.3. Telephone (central access point):	00.32.2.524.80.00
1.1.4. E-mail (central access point):	welcome@afmps-fagg.be
1.1.5. Website:	www.fagg-afmps.be
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
(more than 1 and wer possible)	Reproductive tissues and cells
	Blood and blood components
	Pharmaceuticals
	Medical devices
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
possione	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	The Federal Agency for Medicines and Health Products (FAMHP)
organisation of the National Competent Authority(ies) (e.g.	(Law of 20/07/2006), a federal agency of public interest, is the
departments, staffing, number of senior and junior inspectors, staff	competent authority in terms of quality, safety and efficacy of drugs
working on EU affairs and legal matters, vigilance officers, budget,	and health Products. Our activities are divided into three branches
independence from government etc.).	(DG) also called "pillars" PILLAR 1 "DG PRE authorization"
independence from government etc.).	manages all activities before the first authorization to market a drug
	or a health product . PILLAR 2 "DG POST authorization" manages
	all activities after the first authorization to market a drug or a health
	product . PILLAR 3 "DG inspection" ensures all inspection and
	control activities
1.6. In case of MS with federal or decentralised systems, please	Not applicable
_ · · · · · · · · · · · · · · · · · · ·	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	/
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
Procurement (Article 5 Directive 2004/23/EC)     1. Do you authorise the "conditions of procurement"?	Yes
-	
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting the documentation associated with procurement that is
than 1 answer possible)	available in the tissue establishment working with procurement
212 11 21 22 22 22 22 22 22 22 22 22 22	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	27 TE's
31/12/2011)?	27 TE
2.2.1 Please provide the number of procurement centres in which	37 TE's
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	22 TEL-
2.2.2 Please provide the number of procurement centers in which	23 TE's
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	(A TEL
2.2.3 Please provide the number of procurement centers in which	62 TE's
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	15 777
2.2.4. Please provide the number of procurement centers in which	15 TE's
procurement of tissues/cells for ATMP manufacturing were carried	
4: 2011 (01/01 21/12/2011)	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Analysis of the mandatory documentation
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel,	Analysis of the mandatory documentation
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than	Analysis of the mandatory documentation
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)	
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than	Analysis of the mandatory documentation  No

2.4.2 WILLIAM 1.4. 4. 4. 4. 4. 4. 4. 4. 4. 4. 4. 4. 4.	Direction of the Control of the Management
2.4.2. Which National Authority is in charge of this activity?	Belgium: Scientific Institute for Public Health (WIV-ISP)
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	The following data are available for each laboratory: Agreement
authorised or licensed in your country (e.g. number, year of	number, Issue Date, Validity Date, Name Director, Type of service
accreditation/authorisation/license, which donor tests are performed	for which the agreement is valid, Agreement valid for 5 year
etc.).	maximum.
2.7. Do you have any additional comments on procurement?	In Belgium, procurement is the responsibility of the TEs. There are
	no "procurement centers" in Belgium. "Procurement" is mentioned
	in the EU directive, but "procurement centers" are not mentioned
	nor defined in the EU Directive. Therefore, the term "procurement
	center" should not be used in this questionnaire.
3. Testing (Art 4 Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	NAT HIV 1
anoner possible)	HBs AG
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
22 Pl (6.11 4 4 4 1 1 6 1 6	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	NAT HIV 1
	HBs AG
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT testing is mandatory.
please indicate whether you intend to make it mandatory or to	
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	HTLV-1 and NAT HTLV-1 should be asked in the questionnaire,
2 y 2 2 2 y 2 2 2 2 2 2 2 2 2 2	not HTLV-2. In Belgium, for living donors, NAT tests may be
	replaced by serology 6 months after collection/procurement of
	tissues or cells.
A Appredication designation outh-vi-ti-v-v-li-v-iv-	
4. Accreditation, designation, authorisation or licensing of tissue e 4.1. Do you have a system of designation, authorisation,	
	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	**
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	5 inspections as a prerequisite for the authorization of TEs
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections

	During inspections organised for this purpose
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	By review of a submitted application with supporting documentation
how many authorisations/accreditation/licenses were suspended in	U
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC	A
4.7. Tissue establishments with authorisation pending approval at	Musculo-skeletal tissue establishments
01/01/2011 (more than 1 answer possible):	HSC tissue establishments
	ART tissue establishments
	Other tissue establishments
4.7.2. How many musculo-skeletal tissue establishments?	1
4.7.5. How many HSC tissue establishments?	1
4.7.7. How many ART tissue establishments?	23
4.7.9. Please specify the type of tissues/cells and how many.	Cell Therapy 1
4.8. Tissue establishments with authorisations pending approval by	ART tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.7. How many ART tissue establishments?	3
4.9. Tissue establishments first time authorised between 01/01/2011	Musculo-skeletal tissue establishments
and 31/12/2011 (more than 1 answer possible):	HSC tissue establishments
100 1	ART tissue establishments
4.9.2. How many musculo-skeletal tissue establishments?	1
4.9.5. How many HSC tissue establishments?	
4.9.7. How many ART tissue establishments?	20
4.10. All tissue establishments authorised by 31/12/2011 (more than	Skin tissue establishments Musculo-skeletal tissue establishments
1 answer possible):	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Other tissue establishments
4.10.1.1. How many public skin tissue establishments?	3
4.10.1.2. How many private skin tissue establishments?	0
4.10.2.1. How many public musculo-skeletal tissue establishments?	15
4.10.2.2. How many private musculo-skeletal tissue establishments?	0
4.10.3.1. How many public ocular tissue establishments?	4
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue establishments?	6
4.10.4.2. How many private cardiovascular tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	16
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	7
4.10.6.2. How many private cord blood tissue establishments?	1
4.10.7.1. How many public ART tissue establishments?	62
4.10.7.2. How many private ART tissue establishments?	0
4.10.9.1. Please specify the type of 'other' public tissues/cells	Cell Therapy: 15 Keratinocytes: 3 Tympano-ossicular: 4 Amniotic
establishements and how many.	membrane: 4
4.10.9.2. Please specify the type of 'other' private tissues/cells	Cell Therapy: 3
establishements and how many.	
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	

4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	In 2011: three new applications for an authorisation have not
authorisation, designation and licensing?	resulted in the granting of an authorization
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Directorate General Inspection of FAMHP
of inspections.	5 inspectors Tissues & Cells, Blood
5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	1 es
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
5.3. How many routine inspections of tissue establishments for non-	40
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from	0
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	40
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	24
5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	24
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?  5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	Ŭ
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	29
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011). What was the number of	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	29
2.1.1. A flat was the number of hispections carried but in ART	-/

establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	15
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	O .
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	O Company
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	O .
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
5.6. How do you decide which type of routine inspection to conduct?	Every 2 years: a general system-oriented inspection or a thematic
3.6. How do you decide which type of foutthe hispection to conduct?	inspection. Every 4 years: a general system-oriented inspection for a
	extension of the agreement.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	ies
5.8. How many TEs were inspected at least twice between 2008-	65
*	65
2011 (01/01/2008-31/12/2011)?	N/
5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?	Yes
	1
5.9.1. If yes, how many?	1
5.10. Did you carry out inspections of third parties?	Yes
5.10.1. If yes, how many?	1
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	3
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	69
import tissues and cells from third countries (recorded by	
31/12/2011).	
31/12/2011).	l ·
6.3. Please specify the number of tissue establishments authorised to	69
	69
6.3. Please specify the number of tissue establishments authorised to	69

6.4. Please specify which procedures you have in place for verifying	The import of skin is restricted to the TEs authorized for skin
the equivalent standards of quality and safety for importation of skin	tissues. The importing TEs are responsible for verifying the
from third countries.	equivalent standards of quality and safety.
6.5. Please specify which procedures you have in place for verifying	The import of musculoskeletal tissues is restricted to the TEs
the equivalent standards of quality and safety for importation of	authorized for musculoskeletal tissues. The importing TEs are
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	responsible for verifying the equivalent standards of quality and
countries.	safety.
6.6. Please specify which procedures you have in place for verifying	The import of ophtalmic tissues is restricted to the TEs authorized
the equivalent standards of quality and safety for importation of	for ophtalmic tissues. The importing TEs are responsible for
ophtalmic (cornea, sclera, etc) tissues from third countries.	verifying the equivalent standards of quality and safety
6.7. Please specify which procedures you have in place for verifying	The import of cardiovascular tissues is restricted to the TEs
the equivalent standards of quality and safety for importation of	authorized for cardiovascular tissues. The importing TEs are
cardio vascular tissues from third countries.	responsible for verifying the equivalent standards of quality and
	safety
6.8. Please specify which procedures you have in place for verifying	The import of HSC is restricted to the TEs authorized for HSC. The
the equivalent standards of quality and safety for importation of	importing TEs are responsible for verifying the equivalent standards
haematopoietic stem cells (HSC) (other than cord blood) from third	of quality and safety
countries.	
6.9. Please specify which procedures you have in place for verifying	The import of cord blood is restricted to the TEs authorized for cord
the equivalent standards of quality and safety for importation of cord	blood or HSC. The importing TEs are responsible for verifying the
blood from third countries.	equivalent standards of quality and safety.
6.10. Please specify which procedures you have in place for	The import of reproductive cells is restricted to a& limited number
verifying the equivalent standards of quality and safety for	of TEs authorized for reproductive cells. The importing TEs are
importation of reproductive cells (sperm, egg cells) from third	responsible for verifying the equivalent standards of quality and
countries.	safety.
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	I to Dillion
6.11.1. If yes, please provide the data concerning the	Import to Belgium Type Units Country
number/volume of imported tissues and cells by country of origin.	Hematopoietic stem cells 23 USA - Australia Musculo-skeletal tissue 159 USA
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes 139 USA
(01/01/2011-31/12/2011)?	165
6.12.1. If yes, please provide the data concerning the	Export from Belgium: Hematopoietic stem cells: 41 USA; Cardiac
number/volume of exported tissues and cells by country of	valve: 1 New Zealand; Cord blodd: 9 USA, Canada, Australia;
destination.	Sperm: 9 Koweit
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
your country and other time countries.	
	C Export of tissues/cells is authorised irrespective of national needs
6.14. What is the relation between import/export of tissues and cells	C. Export of tissues/cells is authorised irrespective of national needs
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)	
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to	C. Export of tissues/cells is authorised irrespective of national needs
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?	No
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20)	No No 104/23/EC)
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20 7.1. Do you have intra-community exchanges of tissues and cells?	No  104/23/EC)  Yes
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality	No  104/23/EC)  Yes  The country that imports verifies that the criteria of quality and
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please	No  104/23/EC)  Yes
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 11. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify.	No  No  No  No  No  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 11. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures	No  104/23/EC)  Yes  The country that imports verifies that the criteria of quality and
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 11. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	No  No  No  1004/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20 7.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells	No  No  No  No  1004/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please	No  No  No  1004/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.	No  No  No  No  O04/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line with the Belgium law
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. 7.2. How do you ensure that tissues establishments fulfil the	No  No  No  No  1004/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality	No  No  No  No  O04/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line with the Belgium law
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	No  No  No  No  O04/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line with the Belgium law  By inspection
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20, 1.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. 7.3. Do you allow direct distribution to hospitals/clinics in your MS	No  No  No  No  O04/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line with the Belgium law
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20 7.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	No  No  No  No  No  O04/23/EC)  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line with the Belgium law  By inspection
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export? 7. Distribution/intra community exchanges (Article 23 Directive 20 7.1. Do you have intra-community exchanges of tissues and cells? 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. 7.3. Do you allow direct distribution to hospitals/clinics in your MS	No  No  Yes  The country that imports verifies that the criteria of quality and safety are in line with national legislation.  Yes  All tissues and cells coming from another MS needs to be in line with the Belgium law  By inspection  Yes, no restrictions apply

Tagas and the second se	Lw.
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination, type of	Hematopoietic stem cells: 11 units , Ireland, Germany Sperm: 46
tissue/cell and number of units distributed) concerning distribution	(straw), The Netherlands, France, Spain, Danemark, Germany
to other MS in 2011 (01/01/2011-31/12/2011).	Embryo: 43, Spain, United Kingdom Cardiac valve: 170, France,
(01/01/2011 51/12/2011).	germany, Luxembourg, Austria, The Netherlands, Lettonia,
	Slovenia, Switzerland Ocular tissue: 33, ? Cord Blood: 35, The
	Netherlands, Spain, France, United Kingdom, Sweden, Denmark,
	Germany, Italy, Hungary
7.5.2. Please provide us with data (country of origin, type of	Hematopoietic stem cells: 91, Germany, United kingdom, Spain, The
tissue/cell and number of units distributed) concerning distribution	Nederlands, Germany, Italy, Portugal, France Sperm: 7824 (straw),
to other MS in 2011 (01/01/2011-31/12/2011)	Denmark, Italy, Germany, France, Spain, The Nederlands Oocyte:
	760, The Nederlands Embryo: 28, Spain, United Kingdom Male
	gonad: 89, The Nederlands Cardiac valve: 128, Luxembourg, france,
	Germany, Switzerland Ocular tissue: 129, france, The Nederlands
7.6 4	Cord blood: 2, Spain, Italy
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Arti	icle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
* 11 1	1000/ ( 11)
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	
possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	www.fagg-afmps.be
8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	
8.4.1. Please insert the link to the published national annual report.	www.fagg-afmps.be
8.5. Is there a publicly accessible register of authorised tissue	Yes
1 2	165
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	www.fagg-afmps.be
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please specify.	The data requested by Eurocet and that are reported in the annual
, ,	report from each TE
8.7. Do you have any additional comments on reporting?	
	(INCIDED)
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Tissue establishment
possible)	
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	F-F 3. 1000100 mild electronic forms
	In the law and during increasing
9.4. How do you ensure that the 30 years data storage requirement is	In the law and during inspection.
respected (Directive 2006/89/EC, Art. 9)? Please specify.	
9.5. Do you have any additional comments on traceability?	
10. Notification of serious adverse events and reactions (Article 11	Directive 2004/22 Anticle 6 Directive 2006/76)
	Directive 2004/25, Article o Directive 2000/70)
10.1. Do you have a national vigilance system in place (for the	Yes

reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	FAMHP
10.1.2. If yes, please provide a short description of its organisation.	Establishments responsible for the application of tissues and cells have to report to the biovigilance cell of the FAMHP and to the supplying tissue establishment serious adverse reactions and serious adverse events concerning to human tissues and cells. Tissue establishments have also to report the SARs and SAEs including SARs in living donors and SAEs that may influence the quality and safety of thee tissues and cells. Furthermore, standard notification forms, definitions and instructions for use were elaborated and distributed by the FAMHP.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	No
10.2.1. If no, what template do you use? You are welcome to upload the template if you wish.	The template used in point 8.1
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	Yes
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes
10.6.1. If yes, please provide a brief description.	see point 10.2.1
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	When necessary specific information notes are distributed to all or the concerned part of the tissue establishments
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	When necessary specific information notes are distributed to all or the concerned part of the tissue establishments
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	No recalls in 2011.
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes
10.11.1. If yes, please give a short description of the system/procedure.	When necessary specific information notes are distributed to all or to the concerned part of the tissue establishments
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes
10.12.1. If yes, please give a short description of the system/procedure.	When necessary specific information notes are distributed to all or to the concerned part of the tissue establishments
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	Yes
10.13.1. If yes, please specify what data.	N.A.
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	Yes
10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	No

10.15.0.16	T W
10.15.2. If no, please specify why not.	We are convinced of the value of this training. We would have liked to send a new vigilance officer, but the selection procedure for this one still running. And for the current biovigilance officer the training was not useful
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	The presumed consent is the basis, the explicit consent allows – in addition to the presumed consent - to express ones consent explicitly.
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed (opt-out) and explicit (opt-in) consent
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.	The presumed consent is the basis, the explicit consent allows – in addition to the presumed consent - to express ones consent explicitly.
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	No further authorisation is needed
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	A unique donor identification system is implemented, assigning
recipients remain unidentifiable when access is given to third parties	after procurement or (at the latest) at reception in the tissue
(Art. 14(1)). Please specify.	establishment a unique code to each donation and to each human body material collected in order to guarantee donor identification and traceability of all human body materiel. The identity of the donor may not be disclosed to third parties. Assigning of the identification code is the responsibility of the responsible person. The inspector controls the information over the code during the inspection.
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	The necessary steps are taken to ensure that in allogenic donation, data on the (s) recipient (s), including genetic data, which could identify the recipient cannot be accessed by third parties. The necessary steps are taken to ensure that in allogenic donation, the identity of the recipient is not disclosed to the donor or his family and vice versa. The inspector controls the different steps taken to respond to these obligation during the inspection
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?  11.9.1. If no, please specify the circumstances and measures in place.	If yes instead of no.
11.10. Do you have any additional comments on consent and data protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23: Annexes LIV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive	The state of the s
2006/17/EC)? (more than 1 answer possible)	L CAPT
12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible)	Inspections of ART centres
12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC?	Yes
12.3.1. If yes, please specify.	One extra selection criterium: "persons that have undergone

	documented or undocumented neurosurgery
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
·	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
	Other
Please specify 'other'.	A physical examination of the body
12.5. Do you have more stringent criteria for selection of donors of	Yes
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.5.1. Please specify.	Test for Treponema Pallidum
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	•
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
13. Quality management, responsible person, personnel (Article 16	6, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Inspections
have in place a quality system respecting the provisions of the	
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of	
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).	
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a	Authorisation requirement
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more	Authorisation requirement Inspections
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)	Inspections
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel	·
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to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.	Inspections  Inspections  Yes
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?	Inspections  Inspections  Yes  The TE has a training for his personnel. It is checked during the
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.	Inspections  Inspections  Yes  The TE has a training for his personnel. It is checked during the
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to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19, 14.1. How do you ensure that tissue establishments in your country	Inspections  Yes  The TE has a training for his personnel. It is checked during the inspection.
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19).	Inspections  Yes  The TE has a training for his personnel. It is checked during the inspection.
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) (A	Inspections  Yes  The TE has a training for his personnel. It is checked during the inspection.
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) (A	Inspections  Yes  The TE has a training for his personnel. It is checked during the inspection.  -22 Directive 2004/23/EC)  Inspections of tissue establishments
to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) (Art. 19) (Ar	Inspections  Inspections  Yes  The TE has a training for his personnel. It is checked during the inspection.
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14.3. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	
of Directive 2004/23/EC? (more than 1 answer possible)	
14.4. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 22 (labelling, documentation and	
packaging) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	Agreements between institutions and third parties must comply with
15.1.1.1. Chack which cheambanees and for which responsionates.	the Belgian legislation. Agreements with third parties must specify
	the terms of cooperation and responsibility, as well as the protocols
	to be followed to meet the performance requirements.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	1 1
	The agreement between the TE and the third party are seen during
Competent Auhtority(ies) in your MS? Please specify.	the inspections of tissue establishments and if needed, an inspection
	takes place of the third party. Copies of the agreements have also to
	be sent to the FAMHP.
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	Yes
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.1.1. Please specify.	NAT Tests for HIV1, HBV and HCV.
16.2. Has your Member State encountered any difficulties in	Import-export
implementing the requirements in the EU Tissues and Cells	1 1
implementing the requirements in the EU rissues and Cens	
· · ·	
Directives? Please choose from the options below.	How to force a TE in an other EU member state to meet the extra
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a	
Directives? Please choose from the options below.	Belgian law requirements if that TE distributes tissues or cells
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there	Belgian law requirements if that TE distributes tissues or cells
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium  Directive 2006/17/EC
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)  16.3.2. How would you suggest to solve these issues in Directive	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium  Directive 2006/17/EC  Annexes II and III: the requirement "HTLV-I antibody testing must
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium  Directive 2006/17/EC  Annexes II and III: the requirement "HTLV-I antibody testing must be performed for donors living in or originating from high-incidence
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)  16.3.2. How would you suggest to solve these issues in Directive	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium  Directive 2006/17/EC  Annexes II and III: the requirement "HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)  16.3.2. How would you suggest to solve these issues in Directive	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium  Directive 2006/17/EC  Annexes II and III: the requirement "HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;" For some tissues
Directives? Please choose from the options below.  16.2.1. For all selected options in question 16.2., please provide a short description.  16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)  16.3.2. How would you suggest to solve these issues in Directive	Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium  Directive 2006/17/EC  Annexes II and III: the requirement "HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where

## A.1.3. Survey response Bulgaria

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Bulgarian Executive Agency for Tansplantation
1.1.2. Address of NCA 1:	1202 Sofia, Bulgaria, 112 Bratia Miladinovi Str.
1.1.3. Telephone (central access point):	tel.: +359 2 813 50 10, fax: +359 2 931 61 51
1.1.4. E-mail (central access point):	iat@bgtransplant.bg
1.1.5. Website:	www.bgtransplant.bg
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.).	The Executive Agency for Transplantation is a public body, second rank budget operator. The overall budget: 312000 Euro Number of staff of the Executive Agency for Transplantation - 30 positions Executive Director - 1 Deputy Executive Director-1 General Secretary -1 Security Officer of information -1 General Administration: Department "Financial,-economic and administrative activity "- 6 positions Specialized Administration: Department "Registers, information, control and development of transplant"-20 positions Staff working on EU affairs and legal matters: 5 persons but not fully engaged in the EU activity Number of fully engaged inspectors-2 Number of Senior experts - 3. Their responsibilities also include inspection activities. Vigilance officers - We have not such a position. This activities is also included in the responsibilities of all experts and inspectors.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	There are no Regional CAs. It is a centralized system by Executive
Regional Competent Authority(ies) and their relation with the	Agency for Transplantation.
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	By inspecting all procurement centres By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres Other
Please specify 'other':	The authorisation is given by Ministry of Health for hospitals and by
	Regional Health Inspections for outpatient health establishments.
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	5
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which	13
procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	26
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	We couldnt provide the data. ATMP is out of our competence. It is within the scope of Drug Agency.

Γ	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed)? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	No
authorisation or licensing of laboratories performing donor testing?	
2.4.2. Which National Authority is in charge of this activity?	This accreditation is done by Bulgarian Service for Accreditation.
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	We could not provide such data because we do not maintain such
authorised or licensed in your country (e.g. number, year of	registry but every TE is obliged to have a contract agreement only
accreditation/authorisation/license, which donor tests are performed	with qualified accredited laboratories. We inspect the relevant
etc.).	documentation at site
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
r	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT testing is mandatory for Chlamydia in case of reproductive
please indicate whether you intend to make it mandatory or to	tissues and cells. It is recommended that HIV1/2, HBV and HCV are
encourage its use? Please specify why or why not (e.g. number of	tested via NAT.
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	CMV antibody, EBV antibodies and Toxoplasma antibodies are
5.5.1.1 lease specify.	required in immunosuppressed patients. Testing for antibodies to
	HTLV-I is performed for donors who were born or lived in areas
	with high risk or have sexual partners originating from those
	regions, as well as the donor's parents are from such regions. When
	Anti HBc is positive and HBsAg is negative, TEs are obliged to
	conduct additional studies to assess the risk and to establish
	conduct additional studies to assess the risk and to establish
	aligibility for clinical use Scientifically validated algorithm for
	eligibility for clinical use. Scientifically validated algorithm for
	testing is applied for the exclusion of active infection with
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the characteristics of the donations (E.g. RhD, HLA, malaria, CMV,
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the characteristics of the donations (E.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi.
3.6. Are any other laboratory tests required for donors of	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the characteristics of the donations (E.g. RhD, HLA, malaria, CMV,
reproductive tissues and cells in your Member State?	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the characteristics of the donations (E.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi.
	testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the characteristics of the donations (E.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi.

	originating from those regions, as well as the donor's parents are
	from such regions. Further testing for malaria, CMV, RhD,
	Tripanosoma cruzi are required if a history of foreign travel or the
	presence of other risk factors for these diseases. The anonymous
	donor is performed genetic screening for common autosomal
	recessive genetic disease in ethnicity, which requires it, or ancestry
	with genetic problems. Genetic screening is performed after written
	informed consent of the donor. Recipients are fully informed about
	the risks of transmission of genetic diseases and the measures to
	reduce the risk of them.
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing of tissue e	
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	14
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	There were no licenses suspended.
how many authorisations/accreditation/licenses were suspended in	·
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	There were no licenses revoked.
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by the NC	<u> </u>
4bis. Overview of tissue/cells establishments authorised by the NC	A Cord blood tissue establishments
4bis. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at	
<b>4bis. Overview of tissue/cells establishments authorised by the NC</b> 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):	Cord blood tissue establishments
4bis. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments?	Cord blood tissue establishments
4bis. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by	Cord blood tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):	Cord blood tissue establishments  1  Multi-tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments?	Cord blood tissue establishments  1  Multi-tissue establishments  1
4.7. Tissue establishments with authorisation pending approval by 31/12/2011 (more than 1 answer possible): 4.8. How many cord blood tissue establishments? 4.8. How many multi-tissue establishments? 4.8. How many multi-tissue establishments?	Cord blood tissue establishments  1  Multi-tissue establishments  1  Cord blood tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments?	Cord blood tissue establishments  1  Multi-tissue establishments  1  Cord blood tissue establishments  ART tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	Cord blood tissue establishments  1  Multi-tissue establishments  1  Cord blood tissue establishments  ART tissue establishments  Multi-tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments  Multi-tissue establishments 2
4bis. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments? 4.9.8. How many multi-tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1
4.5. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments? 4.9.8. How many multi-tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments? 4.9.8. How many multi-tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments
4.5. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments? 4.9.8. How many multi-tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments? 4.9.8. How many multi-tissue establishments? 4.10. All tissue establishments authorised by 31/12/2011 (more than	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.6. How many cord blood tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): 4.9.6. How many cord blood tissue establishments? 4.9.7. How many ART tissue establishments? 4.9.8. How many multi-tissue establishments? 4.10. All tissue establishments authorised by 31/12/2011 (more than	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments
4bis. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.6. How many cord blood tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.6. How many cord blood tissue establishments?  4.9.7. How many ART tissue establishments?  4.9.8. How many multi-tissue establishments?  4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible):	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments Multi-tissue establishments
4.10.2.1. How many private musculo-skeletal tissue establishments?  4.10.2.1. How many private musculo-skeletal tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments Multi-tissue establishments 0 1
4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments 0 1 0
4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public cocular tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments Multi-tissue establishments 0 1
4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments 2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments 0 1 0
4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments  2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments 0 1 0 1
4-10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public dusculor-skeletal tissue establishments?  4.10.3.1. How many public dusculor tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments  2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments 0 1 0 1
4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?  4.10.2.1. How many public musculo-skeletal tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments  2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments 0 1 0 1 2 5
4.10.2.1. How many public musculo-skeletal tissue establishments? 4.10.2.1. How many public musculo-skeletal tissue establishments? 4.10.3.1. How many public dusculor-skeletal tissue establishments? 4.10.3.2. How many public dusculor tissue establishments?	Cord blood tissue establishments  1 Multi-tissue establishments  1 Cord blood tissue establishments ART tissue establishments Multi-tissue establishments  2 11 1 Musculo-skeletal tissue establishments Ocular tissue establishments HSC tissue establishments Cord blood tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments 0 1 0 1 2 5 1

5.1	24
,	1
J 1	2
,	None
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	In the Department "Registers, information, control and development
	of transplant" there is a unit of two fully engaged inspectors. In
	addition there are 3 senior and 2 junior experts whose
	responsibilities include inspections.
	7
	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
	Organs
	Hospitals
5.3. How many routine inspections of tissue establishments for non-	10
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	2
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	1
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	9
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
· · · · · · · · · · · · · · · · · · ·	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
· · · · · · · · · · · · · · · · · · ·	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
· · · · · · · · · · · · · · · · · · ·	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	

5.4. How many routine inspections were conducted in ART	18
establishments (from 1/1/2011 to 31/12/2011)?	3
5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof	3
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	2
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	3
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	12
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	3
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	Consent anatom painted in the
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)  5.6. How do you decide which type of routine inspection to conduct?	Thematic inspections  It depends on the risk assessment of the TE activities.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	165
5.8. How many TEs were inspected at least twice between 2008-	9
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	4
2.2.1. 11 yes, new many:	T
	Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?	
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for	Yes
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many?	Yes 2
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission	Yes 2
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	Yes 2 Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses	Yes 2
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO	Yes 2 Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	Yes  2 Yes  Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of	Yes 2 Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 =	Yes  2 Yes  Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	Yes  2 Yes  Yes  5
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue	Yes  2 Yes  Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that	Yes  2 Yes  Yes  5
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  No
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that	Yes  2 Yes  Yes  5
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue	Yes  Yes  Yes  No
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in	Yes  Yes  Yes  No
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  Yes  Yes
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14.1. Could you please explain why?	Yes  Yes  Yes  The Bulgarian TE for this period was subsidiary of French TE.
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14.1. Could you please explain why?	Yes  Yes  Yes  The Bulgarian TE for this period was subsidiary of French TE. French competent authorities asked Bulgarian competent authorities
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establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries.  5.18. Do you have any additional comments on inspections?  6.1 Import/export (Article 9 Directive 2004/23/EC)  6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries?  6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).
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6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by
31/12/2011).
6.4. Please specify which procedures you have in place for verifying  We don't have specific procedure for skin but the import of skin
the equivalent standards of quality and safety for importation of skin from third countries.  should meet the general requirements for diceased donors according to our Law of the Transplatation of Organs, Tissues and Cells and
two ordinances: Ordinance 6 on establishing medical standards for
organ transplants, tissues and cells and Ordinance 13 on the terms
be met by the quality of tissues and cells under international
exchanges for the needs of the Republic of Bulgaria.
6.5. Please specify which procedures you have in place for verifying We don't have specific procedure for musculo-skeletal tissues but
the equivalent standards of quality and safety for importation of the import of bone, tendons, fascia should meet the general
musculo-skeletal (bone, tendons, fascia etc.) tissues from third  requirements for diceased donors according to our Law of the
countries. Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplan
tissues and cells and Ordinance 13 on the terms to be met by the
quality of tissues and cells under international exchanges for the
needs of the Republic of Bulgaria.
6.6. Please specify which procedures you have in place for verifying We don't have specific procedure for ophtalmic tissues but their
the equivalent standards of quality and safety for importation of import should meet the general requirements for diceased donors
ophtalmic (cornea, sclera, etc) tissues from third countries.  according to our Law of the Transplatation of Organs, Tissues and
Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 1
on the terms to be met by the quality of tissues and cells under
international exchanges for the needs of the Republic of Bulgaria.
6.7. Please specify which procedures you have in place for verifying We don't have specific procedure for cardio vascular tissues but the
the equivalent standards of quality and safety for importation of import should meet the general requirements for diceased donors
cardio vascular tissues from third countries.  according to our Law of the Transplatation of Organs, Tissues and
Cells and two ordinances: Ordinance 6 on establishing medical
standards for organ transplants, tissues and cells and Ordinance 1 on the terms to be met by the quality of tissues and cells under
international exchanges for the needs of the Republic of Bulgaria.
6.8. Please specify which procedures you have in place for verifying We don't have specific procedure for haematopoietic stem cells
the equivalent standards of quality and safety for importation of (HSC) but their import should meet the general requirements for
haematopoietic stem cells (HSC) (other than cord blood) from third living donors according to our Law of the Transplatation of Organ
countries.  Tissues and Cells and two ordinances: Ordinance 6 on establishin
medical standards for organ transplants, tissues and cells and
Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of the Rep
Bulgaria.
6.9. Please specify which procedures you have in place for verifying We don't have specific procedure for cord blood but their import
the equivalent standards of quality and safety for importation of cord should meet the general requirements for living donors according
blood from third countries. our Law of the Transplatation of Organs, Tissues and Cells and tw
ordinances: Ordinance 6 on establishing medical standards for
organ transplants, tissues and cells and Ordinance 13 on the terms
$1 \cdot 1 \cdot$
be met by the quality of tissues and cells under international
exchanges for the needs of the Republic of Bulgaria.
exchanges for the needs of the Republic of Bulgaria.  6.10. Please specify which procedures you have in place for We don't have specific procedure for cord blood but their import
exchanges for the needs of the Republic of Bulgaria.

T	
	Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of
	Bulgaria.
6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	No
6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	No
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	A. Export of tissues/cells is authorised only after checking that
and self-sufficiency? (more than 1 answer possible)	local/national needs are fulfilled.
	B. Export of tissues/cells is authorised based on estimations
	performed on an annual basis
	D. Import of tissues/cells is authorised only after checking that
	local/national needs are not fulfilled
	E. Import of tissues/cells is authorised based on estimations showing
	that there is chronic deficiency of those tissues/cells
6.14.1. If A or D were selected, please explain how you quantify	After the assessment and the written conclusions made by the head
local/national needs.	of the public multi-tissue bank we release or not tissues and cells for
	import or export
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 2)	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	We try immediately to fulfil the stringent quality and safety
and safety measures established by other Member States? Please	measures established by other MS
specify.	
7.1.2. If yes, do you have more stringent quality and safety measures	No
than in other Member States?	
7.2. How do you ensure that tissues establishments fulfil the	We demand licensing, authorisation or accreditation of the local CA;
requirements of Art. 23 of Directive 2004/23/EC regarding quality	contract agreements between TEs; relevant SOPs for the activities
of tissues and cells during distribution? Please specify.	the TE apply for; documentations verifying the qualification of the
	staff donation, procurement, testing, processing, preservation,
	storage and distribution of human tissues and cells, etc.
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Yes, but only via an authorised TE in my MS
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	Court Dutain Coulding 1 214 Fe Tay 1 1 12 D 1 1 1 C
7.5.1. Please provide us with data (country of destination, type of	Great Britain, Cord blood, 314 distributed units Belgium, Cord
tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).	blood, 520 distributed units Greece, Cord blood, 61 distr. units Germany, CB, 13 distributed units Great Britain, fragment from
to other MS in 2011 (01/01/2011-31/12/2011).	umbilical cord, 175 distributed units Belgium, fragment from
	umbilical cord, 336 distributed units Greece, fragment from
	umbilical cord, 536 distributed units Greece, Teeth, 6 teeth Germany,
	Bones, 843 units Germany, Tendons, 407 Germany, Skin, 6
	Germany, Fascia, 12 Netherlands, Skin, 93 Italy, Bones, 15 Italy,
	Tendons, 12 Italy, Fascia, 4
7.5.2. Please provide us with data (country of origin, type of	No
tissue/cell and number of units distributed) concerning distribution	
to other MS in 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	1
(tissue establishment/company selling tissues or cells) and a buyer (a	

tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Artic	cle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.  8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	100% (all)
possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	http://www.bgtransplant.bg/iat/registers%20and%20statistics.php?target_f=statistics.htm
8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?	Yes
8.4.1. Please insert the link to the published national annual report.	http://www.bgtransplant.bg/iat/registers%20and%20statistics.php?ta rget_f=%D0%A2%D1%8A%D0%BA%D0%B0%D0%BD%D0%B 8%20%D0%B8%20%D0%BA%D0%BB%D0%B5%D1%82%D0% BA%D0%B8.html; http://www.bgtransplant.bg/iat/registers%20and%20statistics.php?ta rget_f=%D0%90%D1%81%D0%B8%D1%81%D1%82%D0%B8%D1%80%D0%B0%D0%B0%D0%B0%20%D1%80%D0%B5%D0%BF%D1%80%D0%BE%D0%B4%D1%83%D0%BA%D1%86%D0%B8%D1%8F.html
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	http://www.bgtransplant.bg/iat/transplantation.php?target_f=%D0%9B%D0%B5%D1%87%D0%B5%D0%B1%D0%BD%D0%B8%20%D0%B7%D0%B0%D0%B8%20%D0%B5%D0%B4%D0%B5%D0%BD%D0%B8%D1%8F%20%D0%B8%D0%B7%D0%B2%D1%8A%D1%80%D1%88%D0%B2%D0%B0%D1%89%D0%B8%20%D0%B4%D0%B5%D0%B9%D0%BD%D0%BE%D1%81%D1%82%D0%B8%20%D0%BF%D0%BE%20%D1%82%D1%80%D0%B0%D0%BB%D0%BD%D0%BD%D0%BD%D0%BD%D0%BD%D0%BD%D0%BD%D1%82%D1%86%D0%B5%D1%86%D0%B8%D0%B0%D0%BD%D0%B0%D0%B0%D0%B8%20%D1%82%D1%8A%D0%BA%D0%B0%D0%BD%D0%B8%20%D0%B8%20%D0%BA%D0%B8%D0%B5%D1%82%D0%BA%D0%B8.html
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	D : 4 1 1 2 1 11 1 0 1 1 1 1 1
8.6.1. If yes, what data are provided to EUROCET? Please specify.	During the years we have submited all kind of data which they required from us.
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Tissue establishment
possible)	Doth manor records and alcotronic forms
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement is	This requirement is laid down in our law for transplatation and we
respected (Directive 2006/89/EC, Art. 9)? Please specify.	check this obligation during every inspection.
9.5. Do you have any additional comments on traceability?	O O y
10. Notification of serious adverse events and reactions (Article 11	Directive 2004/23, Article 6 Directive 2006/86)
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	Executive Agency for Transplantation.
10.1.2. If yes, please provide a short description of its organisation.	We have special Ordinance 10 on the conditions and procedure for

10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the	reporting, recording and transmission of information on SAR/E and barring, withdrawal and destroying tissues and cells. (1) Medical specialist who observed or suspected SAE/SAR is required to fill immediately report according to Annex No 1 and submit it to the responsible person assigned to a hospital. (2) The responsible person immediately label all the tissues and cells taken from the donor with "quarantine" and notifies the head of the TE and the Executive Agency for Transplantation, providing them with all the information regarding the case. (3) The head of the TE is required to report immediately to all relevant health establishments. (4) All the notified health establishments shall promptly labeled "quarantine" all tissues and cells derived from the same donor, and place them in a designated container marked "quarantine". (5) The responsible person of the TE notified the already established committee of the TE investigating the case. (6) The committee shall hold a hearing within three days where it analyzes the causes, circumstances and the outcome related to suspected serious adverse reaction and produces a report. (7) In case of occurred serious adverse reaction commission is obliged to propose measures in order to solve and prevent the issue and write them down in the report which is then submitted to the responsible person, the head of the TE and the person under Art. 10, para. 5 from the Ordinance mentioned above. (8) The responsible person notifies within 7 days the Executive Agency for Transplantation about the results actions from the investigation of the committee and the undertaken by sending a copy of the notice under par. 1 and report under par. 6 from above mentioned ordinance. (9) The head of the TE shall immediately notify all concerned health establishments for confirming results of SAE/R. (10) When the committeefinds out that a SAE/R can affect the quality and safety of the retrieved tissues and cells, the responsible person and the Executive Agency for Transplantation take immediate acti
Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	No
collecting SAR/E from all TEs? 10.4.1. Why not?	It is a matter of our budget.
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes
10.6.1. If yes, please provide a brief description.  10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	The procedure follows the items described in p. 10.1.2. Yes
at national level?  10.7.1. Please specify.	We inform only the concerned TE regarding relevant SAR/SAE.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	We inform only TEs which provide the activities as the recorded SAR/SAE.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality	0

defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid	No
alert?  10.11.2. If no, please specify why not.	It is still under construction. For now we are using only email correspondence.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	No
10.12.2. If no, please specify why not.	For now we are using email correspondence with short description in case of relevant activities of the TEs. Because part of the information is confidential.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	Yes
10.13.1. If yes, please specify what data.	We fulfil all data which can be extracted from our registries and transfer it to the EUROCET nomenclature.
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	No
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	5
10.16. Do you have any additional comments on SARE reporting?	The vigilance officers are engaged in other activities as experts.
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Explicit written consent system
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed (opt-out) and explicit (opt-in) consent
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased	Presumed consent: According to the Bulgarian Law of the Transplantation of Organs, Tissues and Cells: (1) Shall not be admitted retrieving organs, tissues and cells for implantation if the person has expressed dissent in writing thereof during his/her lifetime. (2) Not admitted shall be taking of organs, tissues and cells from a corpse of a person under 18 years of age or of a person under judicial disability, except by the written consent of his/her parents, guardian or trustee. (3) Not admitted shall be taking of organs, tissues and cells for implanting from a corpse of a person with unknown identity. (4) If the corpse is subject to a forensic expertise the taking of organs, tissues and cells from him/her shall be performed upon a permit in writing by a forensic expert, who shall not participate in transplantation activities. Explicit consent: Taking of organs, tissues and cells from the person, who passed away, may be performed if the following requirements are met: 1. in the health insurance book of the person, in the cases where there is such, there is not a registered dissent of the person for taking organs, tissues and cells after his/her death; 2. the name of the person has not been entered in the official register of the Executive Agency for Transplantations under Art. 39, para 1, item 2; 3. the forthcoming taking of organs, tissues or cells obligatorily is announced and there is no dissent in writing presented within reasonably short term from his/her: a) spouse or parent; b) child; c) brother or sister. (2) The manner of ascertainment and certification of the Circumstances under para 1 shall be determined by an ordinance of the Minister if Health.
donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	
11.4. Is the consent system for deceased tissue donation the same as	Yes

for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	Information for donors are standardised at national/regional level
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	According to the Bulgarian Law of the Transplantation of Organs,
recipients remain unidentifiable when access is given to third parties	Tissues and Cells: Prohibited is the spreading of data allowing the
(Art. 14(1)). Please specify.	identification of the donor or of the recipient.
11.8. Please specify what measures are in place to ensure that the	The information is official secret. Only restricted access is allowed.
identity of the receipient is not disclosed to the donor and vice versa.	
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures in	The information is official secret. Only restricted access is allowed.
place.	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	
12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of reproductive	Inspections of TEs and procurement sites
cells) are respected in your country (Art. 15(1), Annex I Directive	Regular evaluation of medical personnel
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Standardised questionnaires at national level
evaluation and selection of donors of reproductive cells are	Inspections of ART centres
respected in your country (Art 15 (1), Annex III of Directive	Regular evaluation of medical personnel
2006/17/EC)? (more than 1 answer possible)	No
12.3. Do you have more stringent criteria for donor selection than	N0
those listed in Annex I of the Directive 2006/17/EC?  12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
deceased donor or dissues/cens? (more than 1 answer possible)	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Inspection of the centre of human application (e.g. transplantation
tissue establishments in your country (Art 15(1), Annex IV of	centre, ART centre)
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
13. Quality management, responsible person, personnel (Article 10	6, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	
this question "audit" means a documented review of procedures,	
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records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	According to Bulgarian Law for Transplantation of Organs, Tissues
July Francisco	and Cells: Art. 4 (7) the personnel shall be trained within every two
	years; Art. 11 (5) p. 17 BEAT organizes training on quality and
	safety in carrying out transplantation activities for responsible
	persons and personnel engaged in procurement, testing, processing,
	labeling, storage, transportation and distribution of organs, tissues
	and cells.
13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
	Inspections of tissue establishments
packaging) of Directive 2004/23/EC and Annex IV of Directive	inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	According to our Law of Transplantation of Organs, Tissues and
	Cells: Art. 15a. (new - SG 71/06, in force from 01.01.2007) (1) The
1	
	tissue establishments shall conclude written contracts between them,
	tissue establishments shall conclude written contracts between them,
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment,
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells.
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells.  (2) The tissue establishments shall conclude written contracts with
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells.  (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the contracts concluded under para 1 and 2. (4) The tissue
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the contracts concluded under para 1 and 2. (4) The tissue establishments shall send copies of the contracts under para 1 and 2
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the contracts concluded under para 1 and 2. (4) The tissue establishments shall send copies of the contracts under para 1 and 2 to the Executive Agency for Transplantation in 7-days term from
	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the contracts concluded under para 1 and 2. (4) The tissue establishments shall send copies of the contracts under para 1 and 2 to the Executive Agency for Transplantation in 7-days term from their conclusion.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify.	tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the contracts concluded under para 1 and 2. (4) The tissue establishments shall send copies of the contracts under para 1 and 2 to the Executive Agency for Transplantation in 7-days term from

	and stored in official registries of CA (BEAT), TEs shall maintain registries themselves.
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)?	No
16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below.	Import-export
16.2.1. For all selected options in question 16.2., please provide a short description.	Import-export: Directive 2004/23/EC Art. 9 p. 3 (c) "The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive." What kind of "necessary measures" should be fulfiled to ensure that imports from third countries met the requirements of EU T&C Directives?
16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)	Directive 2004/23/EC
16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC?	We suggest the following: Directive 2004/23/EC Art. 9 p. 3 (c) "The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive." In Art. 9 p.3 it should be included the following text: shall take all necessary measures: Inspection at site by CA of MS or written declaration by CA of the third country which ensures that they fulfil all requirements for safety and quality of all the three EU T&C Directives

## A.1.4. Survey response Croatia

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health
1.1.2. Address of NCA 1:	Ksaver 200a, 10000 Zagreb, Croatia
1.1.3. Telephone (central access point):	+385 1 460 7671
1.1.4. E-mail (central access point):	vanja.nikolac@miz.hr
1.1.5. Website:	, <u>.</u>
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
(	Reproductive tissues and cells
	Blood and blood components
	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
	Other
Please specify 'other':	1.Regulation (proposing laws and strategic documents, enacting sub-
	laws) 2. Monitoring of activities 3. Managemet of capital
	investitions in the field
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	Ministry of Health is a central state administration body. Activities
organisation of the National Competent Authority(ies) (e.g.	are financed from the state budget. Additionaly, for the costs of
departments, staffing, number of senior and junior inspectors, staff	authorization TE are paying fee. Two units share responsibility for
working on EU affairs and legal matters, vigilance officers, budget,	T&C. 1. Health Protection Directorate 1.1. Service for Blood,
independence from government etc.).	Tissues and Cells Inspection (1 head od Service and 2 inspectors) 2.
	Institute for transplantation and biomedicine (head of Institute –
	assistant of Minister) 2.1. Service for transplantation (3 employees)
	2.2. Service for biomedicine (3 employees)
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	no regional CA
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	By inspecting the documentation associated with procurement that is
	available in the tissue establishment working with procurement
	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	10
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	4
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	4
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	107.0
2.2.3 Please provide the number of procurement centers in which	non-partner ART: 0, partner ART: 13
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	0
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its	Inspections of the site/centre Analysis of the mandatory documentation
out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel,	
out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its	

2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	163
2.4.1. Please provide the number of the laboratories performing	1
donor testing.	
2.5. How do you ensure, as CA for T&C, that tests required for	Inspections of the laboratories
donors are carried out only by qualified laboratories accredited,	Analysis of the mandatory documentation requested from the tissue
designated, authorised or licensed Art. 5(2))? (more than 1 answer	establishment
possible)	Other
Please specify 'other':	Inspections of the TEs
2.6. Please provide data on qualified laboratories accredited,	Laboratory is authorised for blood donors' testing from 2005.
authorised or licensed in your country (e.g. number, year of	Testing cca 100 000 blood donors per year. In process for the
accreditation/authorisation/license, which donor tests are performed	authorisation for T&C donors' testing, according to the new
etc.).	legislation (enacted in June 2013.) Tests: Minimum testing
	requirements - HIV 1 i 2 – Anti-HIV-1,2 – Hepatitis B – HBsAg
	iAnti-HBc – Hepatitis C – Anti-HCV – Syphilis - NAT HIV 1,
	HBV i HCV. Additional tests - HTLV-I - ABO - RhD - HLA
	antigens and antibodies
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	A C TIME!
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	NAT HIV 1 HBs AG
	Anti HBc NAT HBV
	Anti HCV-Ab
	NAT HCV
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
1 /	HBs AG
	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT is mandatory for non-reproductive tissues and cells but not for
please indicate whether you intend to make it mandatory or to	reproductive tissues and cells. NAT for reproductive T&C is not
encourage its use? Please specify why or why not (e.g. number of	foreseen since only partner donation occurs. For non-partner
additional cases detected, cost-benefit etc.).	donation CA will propose NAT testing to scientific bodies for
	consideration.
3.4. Do you have concerns on accuracy of the available tests and test	Yes
procedures for deceased donors?  3.4.1. Please specify why:	Limited number of manufacturers and tests which are validated for
J.T.1. I lease specify wify.	deceased donors, short period of validation, relatively small number
	of examinees.
3.5. Are any other laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	HTLV 1, Anti HBs, Malaria, CMV, Toxoplasma, EBV,
	Tripanosoma cruzi
3.6. Are any other laboratory tests required for donors of	Yes
reproductive tissues and cells in your Member State?	
3.6.1. Please specify.	HTLV 1, Anti HBs, Malaria, Toxoplasma, Tripanosoma cruzi
	Dengue fever, CMV, WEB
3.7. Do you request/use international accreditation systems for	Yes
testing laboratories?	100 15 100 0
3.7.1. Please specify.	ISO 15 189 for each method performing
3.8. Do you have any additional comments on testing?	El (Acid CPi di 2004/22/72)
4. Accreditation, designation, authorisation or licensing of tissue estab	
4.1. Do you have a system of designation, authorisation,	Yes

accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?	Yes
4.2.1. How many inspections were performed in 2011 for	1 TE; 8 ART centers
authorising/accrediting/licensing/designating TEs?	1 1E, WART CERCIS
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
(	During inspections organised for this purpose
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in	0
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?	0
4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?	Yes
4.6.1. What is the relation between the indpendent certification(s)	Mandatory for authorisation
(e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	
4bis. Overview of tissue/cells establishments authorised by the NCA	
4.7. Tissue establishments with authorisation pending approval at	Skin tissue establishments
01/01/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
01/01/2011 (more than 1 answer possible).	ART tissue establishments
4.7.1. How many skin tissue establishments?	1
4.7.2. How many musculo-skeletal tissue establishments?	3
4.7.7. How many ART tissue establishments?	3
4.8. Tissue establishments with authorisations pending approval by	Skin tissue establishments
31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
4.8.1. How many skin tissue establishments?	1
4.8.2. How many musculo-skeletal tissue establishments?	3
4.9. Tissue establishments first time authorised between 01/01/2011	Cardiovascular tissue establishments
and 31/12/2011 (more than 1 answer possible):	HSC tissue establishments
	ART tissue establishments
4.9.4. How many cardiovascular tissue establishments?	1
4.9.5. How many HSC tissue establishments?	1
4.9.7. How many ART tissue establishments?	3
4.10. All tissue establishments authorised by 31/12/2011 (more than	Cardiovascular tissue establishments
1 answer possible):	HSC tissue establishments
	ART tissue establishments
4.10.4.1. How many public cardiovascular tissue establishments?	1
4.10.4.2. How many private cardiovascular tissue establishments?	1
4.10.5.1. How many public HSC tissue establishments?	1
4.10.5.2. How many private HSC tissue establishments?	0
4.10.7.1. How many public ART tissue establishments?	1
4.10.7.2. How many private ART tissue establishments?	2
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	No
pursuant to the Directive been defined (Article 27)?	
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?	
<u></u>	
5. Inspections (Article 7, Directive 2004/23/EC)	
Inspections (Article 7, Directive 2004/23/EC)     In a system in place for organising inspections and control	Yes
5. Inspections (Article 7, Directive 2004/23/EC)     5.1. Is a system in place for organising inspections and control measures of tissue establishments?	Yes
5.1. Is a system in place for organising inspections and control	Yes Service for Blood, Tissues and Cells Inspection

5.1.2. If yes, please specify staffing (how many inspectors).	1 head of Service and 2 inspectors
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Organs
	Pharmaceuticals
	Advanced therapies
	Hospitals
5.3. How many routine inspections of tissue establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	1
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	licensing inspections (4)
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	0
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	3
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	1
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	-
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	1
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	4
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	licancing ingrestions (9)
5.4.2. How many other type of inspections were conducted on ART	licensing inspections (8)
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	8
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
J 1	ı

5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	8
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	Report(s) of previous inspection(s): number and qualification of
	non-conformities Report(s) of SAREs Report(s) of activities
	Complexity of activity Various data collected due to everyday close
55 77 (100)	communication
5.7. Until 2011, did you implement the requirement concerning the	No
time interval between two inspections (Art. 7.3.)?	TY STATE OF THE COLUMN AS A STATE OF THE COLUM
5.7.1. Why not?	Unit dedicated to T&C' inspection was established in the end of
5.70 W	2009. Licensing inspections have started in second half of 2010.
5.7.2. How do you prioritise tissue establishments to be inspected?	Decision based on: Number of tissue types processing Number of
	tissues of each type processing/distributing Method of processing
	Report(s) of previous inspection(s): number and qualification of
	non-conformities Report(s) of SAREs Various data collected due to
5.0 Harmonia TE-mana in market 1.1	everyday close communication
5.8. How many TEs were inspected at least twice between 2008-	0
2011 (01/01/2008-31/12/2011)? 5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	INU
5.9.2. If no, why not?	Procurement rarely takes a place outside TEs since TEs are
3.9.2. If no, why not:	established only in the main (biggest) hospitals which are
	concurrently main procurement sources. Program for countrywide
	tissue procurement, foreseeing larger number of procurement-only
	hospitals is under development.
5.10. Did you carry out inspections of third parties?	Yes
5.10.1. If yes, how many?	1
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	163
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	5
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	Yes

are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	0
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	Importation from a third countries is prohibited except for
the equivalent standards of quality and safety for importation of skin	emergency.
from third countries.	omergency.
6.5. Please specify which procedures you have in place for verifying	Importation from a third countries is prohibited except for
the equivalent standards of quality and safety for importation of	emergency.
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	Importation from a third countries is prohibited except for
the equivalent standards of quality and safety for importation of	emergency.
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	Importation from a third countries is prohibited except for
the equivalent standards of quality and safety for importation of	emergency.
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	Importation from a third countries is prohibited except for
the equivalent standards of quality and safety for importation of	emergency. Whenever is possible JACIE accreditation is required.
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	Importation from a third countries is prohibited except for
the equivalent standards of quality and safety for importation of cord	emergency. Whenever is possible FACT-NetCord accreditation is
blood from third countries.	required.
6.10. Please specify which procedures you have in place for	There are no procedures for importation of reproductive cells.
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	57 corneas from USA
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	N.
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	A F
6.14. What is the relation between import/export of tissues and cells	A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.
and self-sufficiency? (more than 1 answer possible)	D. Import of tissues/cells is authorised only after checking that
	local/national needs are not fulfilled
	F. Other
Please specify 'other':	Import is authorised, additional to point D, only in emergency
Trease specify office.	situations.
6.14.1. If A or D were selected, please explain how you quantify	1. waiting lists for: a) transplantation (corneas, heart valve) b)
local/national needs.	procedures including use of tissues (e.g. hip prostheses revision) 2.
	donor registers for matching tissues
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	
6.15.1. If yes, please specify the number of cases and for which type	57 corneas
of tissues/cells.	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 2004)	23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	Authorised TE is responsiible for compliance check
and safety measures established by other Member States? Please	
	•

amonify.	T
specify.	N.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	Yes
7.1.2.1. How do you address this difference for tissues and cells	NA
coming from a MS with minimum quality requirements? Please	
specify.	
7.2. How do you ensure that tissues establishments fulfil the	By inspection
requirements of Art. 23 of Directive 2004/23/EC regarding quality	By hispection
of tissues and cells during distribution? Please specify.	
7.3. Do you allow direct distribution to hospitals/clinics in your MS	No
	NO
from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	**
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination, type of	No T/C distributed to other MS
tissue/cell and number of units distributed) concerning distribution	
to other MS in 2011 (01/01/2011-31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	No T/C distributed to other MS
tissue/cell and number of units distributed) concerning distribution	
to other MS in 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Article	10. Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	165
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	60-99%
	00-99%
their activities during 2011. Please provide an estimation. (1 answer	
possible)	N.
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	Insuficient administrative capacity of CA
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	ART:
	http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republ
	ici_hrvatskoj/ustanove_s_odobrenjem_za_obavljanje_djelatnosti_me
	dicinski_pomognute_oplodnje T&C:
	http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republ
	ici_hrvatskoj/ustanove_s_odobrenjem_za_obavljanje_djelatnosti_uzi
	manja_pohranjivanja_i_presadivanja_tkiva_i_stanica
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please specify.	HSC, ART, TISSUES
8.7. Do you have any additional comments on reporting?	· · ·
Q Traceability (Article & Directive 2004/22/EC; and Directive 2006/9	6/EC)
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/8	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/8 9.1. Was the donor identification system (Art. 8(2)) implemented in your country?	Yes

9.2. Who assigns the unique code for each donation? (only 1 answer possible)	Tissue establishment
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	TE are responsible for ensurance of data storage
9.5. Do you have any additional comments on traceability?	
10. Notification of serious adverse events and reactions (Article 11 Dir	rective 2004/23, Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
10.1.1. If yes, which CA/institution is responsible?	Ministry of Health
10.1.2. If yes, please provide a short description of its organisation.	Responsible person from TE or procurement/application center informs CA . CA is responsible for monitoring of investigation process, data distribution and corrective actions implementation.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	Yes
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	No
10.4.1. Why not?	Insuficient administrative capacity of CA
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes
10.6.1. If yes, please provide a brief description.	Responsible person from transplantation center reports to the responsible person of TE and to CA in written or electronic form or by phone, without delay.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	SAREs are presented and discussed at Ministry's Expert Committee (regular and ad hoc)
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	SAREs are presented and discussed via e-mail communication or at regular Ministry's Expert Committee meetings in the case not affecting national users. In cases affecting national users ad hoc meetings can be convened
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	0
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes
10.11.1. If yes, please give a short description of the system/procedure.	CA notifies responsible persons in TE, in written and electronic/phone form. Ministry's Expert Committee proposes measures, which Ministry imposes.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes
10.12.1. If yes, please give a short description of the system/procedure.	CA notifies responsible persons in TE, in written and electronic/phone form. Ministry's Expert Committee proposes measures, which Ministry imposes.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	Yes

10.12.1.16	HGC ART TIGGLIEG
10.13.1. If yes, please specify what data.	HSC, ART, TISSUES
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert	Yes
systems?  10.14.1. If yes, please specify which of the following systems are	Pharmacovilance
usually contacted. (more than 1 answer possible)	Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings	
	Yes
organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of	4
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	4
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Directive	2004/22/EC\
11.1. What consent system for living tissue/cell donation do you	
have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living	Evaluate consent (ent in)
tissue/cell donation.	Explicit consent (opt-in)
11.2. What consent system for deceased tissue/cell donation do you	Presumed consent (opt-out)
have in place within your Member State?	Tresumed consent (opt-out)
11.3. According to your national legislation, in case of deceased	No further authorisation is needed
donations, please specify who is giving the authorisation for the	110 Interest diamonisation is needed
tissue donation? (more than 1 answer possible)	
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Other
answer possible)	
Please specify 'other'.	Deceased donors: Presumed consent system is in place, no need for
	verification Living donors: Analysis of documentation
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	All stakeholders are obliged to protect personal data according to the
recipients remain unidentifiable when access is given to third parties	special legislation.
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	Establishment of coding system according to which only TE can
identity of the receipient is not disclosed to the donor and vice versa.	connect data of recipient with donor data.
11.9. Does your national legislation allows disclosure of donor data	Yes
in case of gametes donation?	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 2004/2	·
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive	Regular evaluation of medical personnel
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	Regular evaluation of medical personnel
2006/17/EC)? (more than 1 answer possible)	No
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	Interview with the departs family on a person with the departs of a
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
	Other
Please specify 'other'.	family and close friends

10.5 72	L v
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
	110
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	Inspection of the centre of human application (e.g. transplantation
Directive 2006/17/EC? (more than 1 answer possible)(For this	centre, ART centre)
question "audit" means a documented review of procedures, records,	Audit of the centre of human application
	Addit of the centre of numan application
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
1	10 75'
13. Quality management, responsible person, personnel (Article 16, 17	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
	-
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	Professional society meetings Pre-accession instruments (TAIEX,
13.11.11 yes, premse speerly.	IPA)
12.5 A 1127 1 4 174	IIA)
13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19-22	Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	External audits of tissue establishments (e.g. ISO)
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
	External audits of tissue establishments (e.g. ISO)
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
	-
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	T
, , , , , , , , , , , , , , , , , , ,	Inspections of tissue establishments
, , , , , , , , , , , , , , , , , , , ,	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	Internal audits of tissue establishments
	Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)

packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
, , , , , , , , , , , , , , , , , , ,	External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	For the cessation of activity, procurement of cord blood and testing
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	By inspection
Competent Auhtority(ies) in your MS? Please specify.	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	Yes
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.1.1. Please specify.	• prohibition of third countries tissue importation, • mandatory
	unpaid donation, • requirement for international accreditation for
	HSC banks, CB banks and testing laboratories, • mandatory NAT
	testing for T&C donors
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Import-export
Directives? Please choose from the options below.	Vigilance
	Authorisation-accreditation-licensing of TEs
	Inspections
16.2.1. For all selected options in question 16.2., please provide a	ART provisions –problems in fulfilling requirements for personel,
short description.	quality system and facilities Vigilance – insufficient number of CA
	employees Authorisation-accreditation-licensing of TEs, and
	inspections – insufficient number of inspectors, in 2011 was one
	inpector for blood, tissues and cells and ART Import-export-vague
	EU legislation allowing broad interpretations
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	

## A.1.5. Survey response Cyprus

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health, Cyprus
1.1.2. Address of NCA 1:	1, Prodromou and 17, Chilonos str, Nicosia 1449, Cyprus
1.1.3. Telephone (central access point):	22605600
1.1.4. E-mail (central access point):	cgregoriadou@moh.gov.cy, emakrigiorgi@moh.gov.cy,
	cstylianou@mphs.moh.gov.cy
1.1.5. Website:	www.moh.gov.cy
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	3 inspectors/vigilance officers, no separate budget (Ministry of
organisation of the National Competent Authority(ies) (e.g.	Health)
departments, staffing, number of senior and junior inspectors, staff	
working on EU affairs and legal matters, vigilance officers, budget,	
independence from government etc.).	
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	N/A

Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	V
	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	By inspecting the documentation associated with procurement that is
	available in the tissue establishment working with procurement
212 11 21 (01/01	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	3
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	0
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	3
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	0
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	0
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	Y C Cd iv
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed)? (more than	
answer possible)  2.4. Are you also responsible for the accreditation, designation,	No
authorisation or licensing of laboratories performing donor testing?	NO NO
2.4.2. Which National Authority is in charge of this activity?	Ministry of Health, under different legislation
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	Other
possible)	Other
Please specify 'other':	licensed laboratories only under the Licensing of Clinical
Trease speerly other.	Laboratories Law
2.6. Please provide data on qualified laboratories accredited,	Under a different inspection and licensing system, there are 136
authorised or licensed in your country (e.g. number, year of	licensed clinical laboratories, 2 EFI accredited laboratories
accreditation/authorisation/license, which donor tests are performed	inventor annion modulos, 2 di i notivanon modulos
etc.).	
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
1	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
· ′	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	We require this testing if tissues or cells will be issued without
please indicate whether you intend to make it mandatory or to	retesting of donors after 180 days of collection
encourage its use? Please specify why or why not (e.g. number of	
	I

additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	Yes
testing laboratories?	
3.7.1. Please specify.	ISO, EFI
3.8. Do you have any additional comments on testing?	Licensed Testing Laboratories under the Clinical Laboratories Legis
4. Accreditation, designation, authorisation or licensing of tissue e	stablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	3
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During inspections organised for this purpose
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	2
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	Y.
4.6. Do you require TEs to be certified by an external entity to a	Yes
quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s)	Outional but TE- and annual to act a satisfaction
(e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue	Optional, but TEs are encouraged to get a certification
establishments? (more than 1 answer possible)	
4bis. Overview of tissue/cells establishments authorised by the NC	
4.7. Tissue establishments with authorisation pending approval at	ART tissue establishments
01/01/2011 (more than 1 answer possible):	THE USSUC ESTABILITIES
4.7.7. How many ART tissue establishments?	1
4.8. Tissue establishments with authorisations pending approval by	ART tissue establishments
31/12/2011 (more than 1 answer possible):	THE USSUC ESTABILITIES
4.8.7. How many ART tissue establishments?	1
4.9. Tissue establishments first time authorised between 01/01/2011	Cord blood tissue establishments
and 31/12/2011 (more than 1 answer possible):	
4.9.6. How many cord blood tissue establishments?	1
4.10. All tissue establishments authorised by 31/12/2011 (more than	Ocular tissue establishments
_	
1 answer possible):	HSC tissue establishments
1 answer possible):	HSC tissue establishments Cord blood tissue establishments
1 answer possible):	
1 answer possible): 4.10.3.1. How many public ocular tissue establishments?	Cord blood tissue establishments
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments?	Cord blood tissue establishments ART tissue establishments
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments?	Cord blood tissue establishments ART tissue establishments 0
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments?	Cord blood tissue establishments ART tissue establishments 0 3
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments?	Cord blood tissue establishments ART tissue establishments 0 3 2
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments?	Cord blood tissue establishments ART tissue establishments 0 3 2 0
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments?	Cord blood tissue establishments ART tissue establishments 0 3 2 0 1
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments? 4.10.7.2. How many private ART tissue establishments?	Cord blood tissue establishments ART tissue establishments 0 3 2 0 1 5 0 8
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments? 4.10.7.2. How many private ART tissue establishments? 4.11. How many tissues and cells were distributed under the direct	Cord blood tissue establishments ART tissue establishments  0 3 2 0 1 5 0
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments? 4.10.7.2. How many private ART tissue establishments? 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during	Cord blood tissue establishments ART tissue establishments 0 3 2 0 1 5 0 8
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments? 4.10.7.2. How many private ART tissue establishments? 4.11. How many tissues and cells were distributed under the direct	Cord blood tissue establishments ART tissue establishments 0 3 2 0 1 5 0 8
4.10.3.1. How many public ocular tissue establishments? 4.10.3.2. How many private ocular tissue establishments? 4.10.5.1. How many public HSC tissue establishments? 4.10.5.2. How many private HSC tissue establishments? 4.10.6.1. How many public cord blood tissue establishments? 4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments? 4.10.7.2. How many private ART tissue establishments? 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during	Cord blood tissue establishments ART tissue establishments 0 3 2 0 1 5 0 8

pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
	INO INC.
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Inpectors
of inspections.	
5.1.2. If yes, please specify staffing (how many inspectors).	3
5.2. Does the inspection scheme interact or overlap with the	No
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.3. How many routine inspections of tissue establishments for non-	11
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	2 for new processes not licensed
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	4
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	1 for new process
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	6
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	4

establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	General system for licensing and re issue of license, and every year,
	thematic for new process applications, desk based for import only
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	16
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	
5.9.2. If no, why not?	Procurement for autologous cord blood banks occurs only outside
	licensed tissue establishments. Clinics were cord cord blood is
	procured need to be licensed under the Private Clinic Act
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	Third parties are usually testing laboratories. Clinical laboratories
,	have to be licensed by a different legislation in order for TEs to have
	a third party agreement
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	5
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	No
inspections should be understood as inspections of tissue	110
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
	Lack of resources
5.17.1. Could you please explain why not?  5.18. Do you have any additional comments on inspections?	Lack of resources
6. Import/export (Article 9 Directive 2004/23/EC)	Lv
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	3

import tissues and cells from third countries (recorded by	
31/12/2011).	1
6.3. Please specify the number of tissue establishments authorised to	1
export tissues and cells from third countries (recorded by	
31/12/2011).	1
6.4. Please specify which procedures you have in place for verifying	no skin is imported
the equivalent standards of quality and safety for importation of skin	
from third countries.	
6.5. Please specify which procedures you have in place for verifying	no bone is imported
the equivalent standards of quality and safety for importation of	
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	FDA licence, AATB valid acredidation
the equivalent standards of quality and safety for importation of	
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	no cadio vascular tissues are imported
the equivalent standards of quality and safety for importation of	
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	no haematopoietic cells are imported
the equivalent standards of quality and safety for importation of	
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	cord blood procured in third countries is imporetd for processing and
the equivalent standards of quality and safety for importation of cord	storage.
blood from third countries.	
6.10. Please specify which procedures you have in place for	no gametes are imported
verifying the equivalent standards of quality and safety for	S
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	110
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	165
6.12.1. If yes, please provide the data concerning the	2 Donations of Peripheral stem cells
number/volume of exported tissues and cells by country of	2 Donations of Peripheral stem cens
destination.	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	NO
your country and other third countries?	T OI
6.14. What is the relation between import/export of tissues and cells	F. Other
and self-sufficiency? (more than 1 answer possible)	
Please specify 'other':	only export of highly matched stem cell donations
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	
6.15.1. If yes, please specify the number of cases and for which type	Patient's own gametes or embryos due to relocation
of tissues/cells.	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 20	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.2. How do you ensure that tissues establishments fulfil the	SOPs review and records
requirements of Art. 23 of Directive 2004/23/EC regarding quality	
of tissues and cells during distribution? Please specify.	
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, but only via an authorised TE in my MS
from TEs in another MS? (only 1 answer possible).	,
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	110
7.5. Do you collect data regarding the cross-border exchange of	No
	INU
tissue/cells between your country and other EU MS?	N-
7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells	No
	I .

between your country and other EU MS?	N.
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	No brokers were licensed yet
8. Register of tissue establishments and reporting obligations (Art	· · · · · · · · · · · · · · · · · · ·
8.1. Do you have an annual report model/template on the activities	No
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.1.1. If no, why not?	use the Eurocite templates
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	Interested parties can view these reports at the Ministry of Health
	offices
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	www.moh.gov.cy
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please specify.	Tissues, HPCs, ART
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Tissue establishment
possible)	Tissue establishment
	Tissue establishment  Both paper records and electronic forms
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is	
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	Both paper records and electronic forms
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is	Both paper records and electronic forms
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	Both paper records and electronic forms  Through inpections
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?	Both paper records and electronic forms  Through inpections
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes  Same
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes  Same Inspectors act as vigilance officers
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes  Same Inspectors act as vigilance officers
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possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes  Same Inspectors act as vigilance officers Yes  Yes
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possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).  10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes  Same Inspectors act as vigilance officers  Yes  No Inspectors act as vigilance officers  100%
possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).  10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the	Both paper records and electronic forms  Through inpections  Directive 2004/23, Article 6 Directive 2006/76)  Yes  Same Inspectors act as vigilance officers  Yes  No Inspectors act as vigilance officers  100%

10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at national level?	
10.7.2. Please specify why not.	Only for those concerned
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at EU level?	
10.8.2. Please specify why not.	only if involved
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	163
alert?	
10.11.1. If yes, please give a short description of the	Through the responsible person of TE via email, mail, tel
system/procedure.	
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	As above if affected
system/procedure.	
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	Not required
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Pharmacovilance
10.15. Did you send a vigilance officer/contact point to the trainings	Medical devices
organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of	5
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	Mostly living donation for HPCs and Gametes
tissue/cell donation.	
11.2. What consent system for deceased tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other relatives
tissue donation? (more than 1 answer possible)	
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	Interviews with personnel
11.6 What massaures are in place to account that	Interviews with living donors
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are	Only trained personnel is allowed to provide such information
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	Assignement of unique codes
recipients remain unidentifiable when access is given to third parties	3
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	Penalty if any information regarding donors or recipients is
identity of the receipient is not disclosed to the donor and vice versa.	disclosed in legislation

11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	No
11.9.1. If no, please specify the circumstances and measures in	Financial and imprisonment sentences in legislation
place.	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	·
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible)	Regular evaluation of medical personnel
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well Medical records of the donor
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	110
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	Town and any of discours and a blind on and
12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by	Inspection of tissue establishment Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	Addit of tissue establishment
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
13. Quality management, responsible person, personnel (Article 16	5. 17. 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	External audits
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?  13.4.1. If yes, please specify.	ISO training programmes
13.4.1. 11 yes, piease specify.	150 training programmes

13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Internal audits of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	External audits of tissue establishments (e.g. ISO)
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
	External audits of tissue establishments (e.g. ISO)
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
	External audits of tissue establishments (e.g. ISO)
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
	External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	Y/
15.1. Are third party agreements foreseen/allowed in your national legislation?	Yes
15.1.1. If yes, have tissue establishments in your Member State	No
notified third party agreements?	
15.2. Any additional comments on third party agreements?	Usually with testing laboratories
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	Vigilance
implementing the requirements in the EU Tissues and Cells	Inspections
Directives? Please choose from the options below.	N. J. C.
16.2.1. For all selected options in question 16.2., please provide a	Need ongoing inspectors/vigilance european training programs as
short description.	personel may change sectors
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC
16.2.1. How would you appared to asked these issues in Dir. C	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC?	Please take into account suggestions of the 1st Informal Competent Authorities meeting in 2012
16.3.2. How would you suggest to solve these issues in Directive	Please take into account suggestions of the 1st Informal Competent
2006/17/EC?	Authorities meeting in 2012
16.3.3. How would you suggest to solve these issues in Directive	Please take into account suggestions of the 1st Informal Competent
2006/86/EC?	Authorities meeting in 2012

## A.1.6. Survey response Czech Republic

1.1 Name of National Competent Authority (NCA) 1: 11.2 Address of NCA 1: 11.3 Telephone (central access point): 11.4 E-mail (central access point): 11.4 E-mail (central access point): 11.5 Website: 11.6 The NCA is responsible for? (more than 1 answer possible) 11.6 The NCA is responsible for? (more than 1 answer possible) 11.7 What are the role/tasks of the NCA? (more than 1 answer possible) 11.8 Website: 12.8 National Competent Authority 2? 12.1 Name of National Competent Authority 2: 12.1 Name of National Competent Authority 2: 12.2 Address of NCA 2: 12.3 Telephone (central access point): 12.4 E-mail (central access point): 12.5 Website: 12.6 The NCA is responsible for? (more than 1 answer possible) 12.6 The NCA is responsible for? (more than 1 answer possible) 12.6 The NCA is responsible for? (more than 1 answer possible) 12.7 What are the role/tasks of the NCA? (more than 1 answer possible) 12.8 The mail (central access point): 12.9 Website: 12.1 A E-mail (central access point): 12.1 A E-mail (central access point): 12.2 Website: 12.3 Telephone (central access point): 12.4 E-mail (central access point): 12.5 Website: 12.6 The NCA is responsible for? (more than 1 answer possible) 12.6 The NCA is responsible for? (more than 1 answer possible) 12.7 What are the role/tasks of the NCA? (more than 1 answer possible) 12.8 The mail (mail tasks) and blood components Human organs Pharmaceuticals 12.8 The mail (mail tasks) and blood components Human organs Pharmaceuticals 12.9 Website: 12.1 What are the role/tasks of the NCA? (more than 1 answer possible) 12.1 What are the role/tasks of the NCA? (more than 1 answer possible) 12.1 What are the role/tasks of the NCA? (more than 1 answer possible) 13. National Competent Authority is an adversary of the legal status and organisaments, signal and blood components Human organs Pharmaceuticals 13. National Competent Authority (responsible) 14.1 What are the role/tasks of the NCA? (more than 1 answer possible) 15. Please greetify buther: 16. Responsible for the National Compe	1. Public information	
Stokarowa 48, 100 41 Prague 10 Czoch Republic		State Institute for Drug Control
1.1.3 E-mail (central access point): 1.1.4 E-mail (central access point): 1.1.5 Website: 1.1.6 The NCA is responsible for? (more than 1 answer possible) Please specify other?: 1.1.7 What are the role/tasks of the NCA? (more than 1 answer possible) Please specify other?: 1.2. National Competent Authority 2? 1.2. National Competent Authority 3? 1.2.1 Name of National competent access point): 1.2.2. Address of NCA 2: 1.2.3 Telephone (central access point): 1.2.4.E-mail (central access point): 1.2.5. Website: 1.2.6. The NCA is responsible for? (more than 1 answer possible) Please specify other?: 1.2. What are the role/tasks of the NCA? (more than 1 answer possible) Please specify other?: 1.3. Telephone (central access point): 1.4. E-mail (central access point): 1.5. Website: 1.6. The NCA is responsible for? (more than 1 answer possible) Please specify other?: 1.7. What are the role/tasks of the NCA? (more than 1 answer possible) Please specify other?: 1.8. Regulation of prices and reimbursements of pharmaceuticals (access point): 1.9. Access and cells (access point): 1.10 Access point): 1.11 A complete the Authority of the pharmaceuticals (access point): 1.12 A complete the pharmaceutical (access point): 1.13 National Competent Authority 3? 1.15 Please give a short description of the legal status and organisation of the National Competent Authority(cs) (e.g. departments, staffing, number of section and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government exity.  1.15 In case of MS with federal or decentralised systems, please indicate the roles tasks of the Regional Competent Authority(cs) (e.g. departments, staffing, number of section and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government exity and their relation with the National Competent Authority(cs) (e.g. department) (e.g. department) (e.g. department) (e.g. department) (e.g. department) (e.g. department) (e.g. departme		
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Other		*
Regulation of prices and reimbursements of pharmaceuticals		Medical devices
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Inspection   Inspection   Vigilance	Please specify 'other':	Regulation of prices and reimbursements of pharmaceuticals
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1.2.1. Name of National Competent Authority 2:   Ministar of Health of the Czech Republic		Vigilance
Palackeho namesti 4 128 01 Prague 2 Czech Republic   +420 224971111   12.4 E-mail (central access point):   mzzf@mzcr.cz	1.2. National Competent Authority 2?	Yes
1.2.3. Telephone (central access point): 1.2.4. E-mail (central access point): 1.2.5. Website: 1.2.6. The NCA is responsible for? (more than 1 answer possible) 2.5. Website: 1.2.6. The NCA is responsible for? (more than 1 answer possible)  Please specify 'other': 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)  Please specify 'other': 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)  Please specify 'other': 1.3. National Competent Authority 3? 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies) (cross and cells) (answer possible)  1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) for tissues and cells  2. Procurement (Article 5 Directive 2004/23/EC) 2. 1. Do you authorise the "conditions of procurement"? (more than 1 answer possible)  2. Procurement (Article 5 Directive 2004/23/EC) 2. 1. 1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  1.0. Please specify other: 2. 1. How many such authoristions were granted in 2011 (01/01-31/12/2011)? 2. 2. 1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissue, scan, ocular tissues, skin, ocular tissues, amniotic membrane,		
1.2.4. E-mail (central access point):   mzcr@mzcr.cz   www.mzcr.cz   www.cz   www.mzcr.cz   www.mzcr.cz   www.mzcr.cz   www.mzcr.cz   www.cz   www.mzcr.cz   www.cz   www.mzcr.cz   www.cz   www		
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Non-reproductive tissues and cells Reproductive tissues and cells Blood and blood components Human organs Pharmaceuticals Medical devices Other	1.2.4. E-mail (central access point):	mzcr@mzcr.cz
Reproductive tissues and cells Blood and blood components Human organs Pharmaceuticals Medical devices Other  Please specify 'other': Regulation of prices and reimbursements of pharmaceuticals Other  Please specify 'other': Licencing of import and export ,contacts with EC, preparation of legal matters in national legislation  1.3. National Competent Authority 3? No  1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.).  1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible)  1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) for tissues and cells:  2. Procurement (Article 5 Directive 2004/23/EC)  2.1. Do you authorise the "conditions of procurement"? (more than 1 answer possible)  Please specify 'other': Approval licence issued by State Institute for Drug Control  1.1. Please give a short description of the legal status and organisation of the National Competent Authority(ies) and the relation with the National Competent Authority(ies) and the relation with the National Competent Authority(ies) for tissues and cells:  2. Procurement (Article 5 Directive 2004/23/EC)  2.1. Do you authorise the "conditions of procurement"? (more than 1 answer possible)  Please specify 'other': Approval licence issued by State Institute for Drug Control  102  1102  1102  1102  1112  1102  1112  1103  1104  1104  1104  1104  1104  1104  1105  1105  1106  1107  1107  1108		www.mzcr.cz
Blood and blood components Human organs Please specify 'other': 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) Please specify 'other': 1.3. National Competent Authority 3? 1.5. Please give a short description of the legal status and organisation of the National Competent Authority (ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies) (more than 1 answer possible) 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) for tissues and cells:  2. Procurement (Article 5 Directive 2004/23/EC) 2.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) 1.2. Lewes give a short described and their relation with the National Competent Authority(ies) for tissues and cells:  2. Procurement (Article 5 Directive 2004/23/EC) 2.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) 1.2. Lewes give a short described the competence/mandate in answer possible) 1.3. Autional Competent Authority (ies) and their relation with the National Competent Authority(ies) for tissues and cells:  2. Procurement (Article 5 Directive 2004/23/EC) 2.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) 1.2. How many such authorisations were granted in 2011 (01/01- 31/12/2011)? 2.2. Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amnitoite membrane,	1.2.6. The NCA is responsible for? (more than 1 answer possible)	
Human organs   Pharmaceuticals   Medical devices   Other		
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than 1 answer possible)  Please specify 'other':  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane,  Other  Approval licence issued by State Institute for Drug Control  102  45		By inspecting all procurement centres
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane,		Other
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2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane,		102
procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane,	31/12/2011)?	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,		45
	procurement of "traditional tissues and cells" (skeletal tissues,	
	cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	2011 (01/01-31/12/2011).	

2.2.2 Please provide the number of procurement centers in which	67
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	35
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	4
procurement of tissues/cells for ATMP manufacturing were carried	7
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Other
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed) ? (more than	
1 answer possible)	
Please specify 'other':	Approval licence issued by State Institute for Drug Control
2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	
2.4.1. Please provide the number of the laboratories performing	26
donor testing.	20
$\varepsilon$	Instructions of the leberatories
2.5. How do you ensure, as CA for T&C, that tests required for	Inspections of the laboratories
donors are carried out only by qualified laboratories accredited,	Other
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
Please specify 'other':	Approval licence issued by State Institute for Drug Control
2.6. Please provide data on qualified laboratories accredited,	26
authorised or licensed in your country (e.g. number, year of	
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	No
	1.10
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
0.1.70	4 - 2
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
	Anti-HIV 2 Ag HIV
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab
reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 2 Ag HIV HBs AG Anti HBc
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HBc Anti HCV-Ab
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HBc Anti HCV-Ab NAT Chlamydia
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum  Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HBc Anti HCV-Ab NAT Chlamydia
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum  Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum  Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum  Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum
answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum  Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum
answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum  NAT testing is not allowed by the Czech national legislation
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answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum  NAT testing is not allowed by the Czech national legislation  No  Yes  HTLV for donor living in or originate from high incidence areas
answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.5.1. Please specify.	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum  NAT testing is not allowed by the Czech national legislation  No  Yes  HTLV for donor living in or originate from high incidence areas (sexual partners, parents)
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answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.5.1. Please specify.	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum  NAT testing is not allowed by the Czech national legislation  No  Yes  HTLV for donor living in or originate from high incidence areas (sexual partners, parents)
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum  NAT testing is not allowed by the Czech national legislation  No  Yes  HTLV for donor living in or originate from high incidence areas (sexual partners, parents) Yes
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.5.1. Please specify.  3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?  3.6.1. Please specify.	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum NAT testing is not allowed by the Czech national legislation  No  Yes  HTLV for donor living in or originate from high incidence areas (sexual partners, parents) Yes  HTLV for donor living in or originate from high incidence areas
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum NAT testing is not allowed by the Czech national legislation  No  Yes  HTLV for donor living in or originate from high incidence areas (sexual partners, parents)  Yes  HTLV for donor living in or originate from high incidence areas (sexual partners, parents)

3.8. Do you have any additional comments on testing?	No
4. Accreditation, designation, authorisation or licensing of tissue es	stablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	86
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011? 4.6. Do you require TEs to be certified by an external entity to a	No
	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4 bis. Overview of tissue/cells establishments authorised by the NCA	
4.7. Tissue establishments with authorisation pending approval at	Ocular tissue establishments
01/01/2011 (more than 1 answer possible):	HSC tissue establishments ART tissue establishments
	Multi-tissue establishments  Multi-tissue establishments
4.7.3. How many ocular tissue establishments?	Multi-tissue establishments 2
4.7.5. How many HSC tissue establishments?	1
4.7.7. How many ART tissue establishments?	7
4.7.8. How many multi-tissue establishments?	2
4.8. Tissue establishments with authorisations pending approval by	Multi-tissue establishments
31/12/2011 (more than 1 answer possible):	171did Good Coldonomicito
4.8.8. How many multi-tissue establishments?	2
4.9. Tissue establishments first time authorised between 01/01/2011	Musculo-skeletal tissue establishments
and 31/12/2011 (more than 1 answer possible):	ART tissue establishments
, r,	Multi-tissue establishments
	Other tissue establishments
4.9.2. How many musculo-skeletal tissue establishments?	2
4.9.7. How many ART tissue establishments?	4
4.9.8. How many multi-tissue establishments?	1
4.9.9. Please specify the type of tissues/cells and how many.	Adipose tissues- 2 TE Distribution - 2 TE
4.10. All tissue establishments authorised by 31/12/2011 (more than	Musculo-skeletal tissue establishments
1 answer possible):	Ocular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?	10
4.10.2.2. How many private musculo-skeletal tissue establishments?	0
4.10.3.1. How many public ocular tissue establishments?	1
4.10.3.2. How many private ocular tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	2
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	0
4.10.6.2. How many private cord blood tissue establishments?	1
4.10.7.1. How many public ART tissue establishments?	3
4.10.7.2. How many private ART tissue establishments?	28
4.10.8.1. How many public multi-tissue establishments?	5
4.10.8.2. How many private multi-tissue establishments?	0
4.10.9.1. Please specify the type of 'other' public tissues/cells	0

establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	1 storage of TCs, 2 distribution, 2 adipose tissues
establishements and how many.	2 marpose about 5
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	Yes
4.16.1.1. How many penalties have been imposed in 2011 (from	0
01/01/2011-31/12/2011)?	
4.16.1.2. What were the reasons for imposing the penalties? Please	NA
describe.	
4.16.1.3. What kind of penalties were imposed? Please describe (e.g.	NA
suspension of authorisation, criminal penalty etc.)	
4.17. Do you have any additional comments on accreditation,	No
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	Clinical Development Come 211
5.1.1. If yes, please specify the CA/Department of the CA in charge	Clinical Practice and Survaillance over Biological Materila
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).	Processing (part of Inspection Division) 2
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	Yes
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
(	Pharmaceuticals
	Advanced therapies
5.3. How many routine inspections of tissue establishments for non-	78
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	3 - suspection of illegal activities (procurement, processing and use)
for non-reproductive tissues/cells were conducted in 2011 (from	concerning TC without any licence reguested by the law
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify. 5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	U
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	72
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	6
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation? 5.3.7. Outcome of inspections of TEs for non-reproductive	
1 3 3 / LUITCOME OF INSPECTIONS OF LES FOR NON-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	

was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	9
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	6
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	3
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	·
5.6. How do you decide which type of routine inspection to conduct?	According to the AIDE MEMOIRE of the inspection (standard
	inspection protocol)
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	8
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
outside tissue establishments? 5.9.1. If yes, how many?	92
5.9.1. If yes, how many?	92 Yes
5.9.1. If yes, how many? 5.10. Did you carry out inspections of third parties?	
5.9.1. If yes, how many? 5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many?	Yes 28
5.9.1. If yes, how many? 5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for	Yes
5.9.1. If yes, how many? 5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement	Yes 28
5.9.1. If yes, how many? 5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for	Yes 28
5.9.1. If yes, how many?     5.10. Did you carry out inspections of third parties?     5.10.1. If yes, how many?     5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	Yes 28
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses	Yes 28 Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO	Yes 28 Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	Yes 28 Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of	Yes 28 Yes Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 =	Yes 28 Yes Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	Yes 28 Yes Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue	Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that	Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  28  Yes  Yes  Yes  Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that	Yes  Yes  Yes  Yes  To share experience, to get more information about the regulatory
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.13.1. Could you please explain why?	Yes  Yes  Yes  Yes  To share experience, to get more information about the regulatory approach in another MS
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.13.1. Could you please explain why?	Yes  28  Yes  Yes  Yes  To share experience, to get more information about the regulatory
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.13.1. Could you please explain why?	Yes  Yes  Yes  Yes  To share experience, to get more information about the regulatory approach in another MS
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  To share experience, to get more information about the regulatory approach in another MS  Yes
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14.1. Could you please explain why?	Yes  Yes  Yes  Yes  Yes  At the request of another NCA
5.9.1. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  To share experience, to get more information about the regulatory approach in another MS  Yes

cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	No
6. Import/export (Article 9 Directive 2004/23/EC)	110
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	res
celles from/to third countries?	
	17
6.2. Please specify the number of tissue establishments authorised to	17
import tissues and cells from third countries (recorded by	
31/12/2011).	16
6.3. Please specify the number of tissue establishments authorised to	16
export tissues and cells from third countries (recorded by	
31/12/2011).	The second secon
6.4. Please specify which procedures you have in place for verifying	TE has written SOPs for import including verifying quality and
the equivalent standards of quality and safety for importation of skin	safety requirements according to the Czech law
from third countries.	
6.5. Please specify which procedures you have in place for verifying	TE has written SOPs for import including verifying quality and
the equivalent standards of quality and safety for importation of	safety requirements according to the Czech law
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	TE has written SOPs for import including verifying quality and
the equivalent standards of quality and safety for importation of	safety requirements according to the Czech law
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	TE has written SOPs for import including verifying quality and
the equivalent standards of quality and safety for importation of	safety requirements according to the Czech law
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	TE has written SOPs for import including verifying quality and
the equivalent standards of quality and safety for importation of	safety requirements according to the Czech law
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	TE has written SOPs for import including verifying quality and
the equivalent standards of quality and safety for importation of cord	safety requirements according to the Czech law
blood from third countries.	
6.10. Please specify which procedures you have in place for	TE has written SOPs for import including verifying quality and
verifying the equivalent standards of quality and safety for	safety requirements according to the Czech law
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	PBSC 82, BMSC 2, DLI 6 (SI, DE, USA, UK, CAN)
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	C. Export of tissues/cells is authorised irrespective of national needs
and self-sufficiency? (more than 1 answer possible)	F. Other
Please specify 'other':	Import of TCs is authorised irrespective of national needs, upon the
	request of TE
6.15. Did you authorise direct imports of tissues/cells to	No No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	Rules for import/export of TCs are the same in case of 3rd countries
	and EU MS, the same approval licence

7.2. How do you ensure that tissues establishments falfill the quite and the control of the cont	7 Distribution/intra community evaluates (Auticle 23 Directive 20	7 D' 4 T 4		
7.2. How do you ensure that tissues establishments fulfil the requirements of AT, 23 of Directive 2006/23/EC (2006/23/EC) 2006/23/EC (2006/23/EC) 2006/23/EC (2006/23/EC) 2006/23/EC (2006/23/EC) 2006/23/EC (2006/23/EC) 2006/23/EC) 2006/23/EC (2006/23/EC) 2006/23/EC) 2006	7. Distribution/intra community exchanges (Article 23 Directive 20			
requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitalsclaines in your MS from TEs in another MSC only 1 answer possible).  7.4. How you authorised direct distribution to the recipient of specific issues and cells Art. 6. Directive 2006/17/EC9?  7.5. Do you collect data regarding the cross-border occhange of tissuescells between your country and other EU MS?  7.6. Are you award of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissuescells between your country and other EU MS?  7.7. Do you allow brokenge companies for either distribution in EU and/or importecynot of issuescells If this coincit, a brokenge companies for either distribution in EU and/or importecynot of issuescells If this coincit, a brokenge company means a body that arranges transactions between a supplier (tissue establishment/company selling issues or cells) and a buyer (a tissue establishment/company selling issues or cells) and a buyer (a tissue establishment knopsitul or clinic/an individual) without undertaking activities of processing, preservation or storage.  7.8. Are brokens actively supplying health professional/selablishmenes in your country?  7.9. Do you have an annual report model/template on the activities of insease establishments in your Member State? (Article 10(1)) If yes, please upload the template.  8.1. Dir yes, please upload the template.  8.2. How many tissue establishments submitted annual report of their activities of unit susce establishments in your country?  8.3. How many tissue establishments submitted annual report of the consolidated activities of all dissect establishments in your country?  8.3. How many tissue establishments in your country?  8.4. How have tissue establishments submitted annual report of the consolidated activities of all dissect series in your country?  8.5. If yes, please provide an arrand report in the consolidated activities				
of tissues and cells during distribution? Please specify.  3. Do you allow direct distribution to hospitals/clinics in your MS from Tis in another MS? (only 1 answer possible).  7. Here you authorized direct element to hospitals/clinics in your MS from Tis in another MS? (only 1 answer possible).  7. Here you authorized direct element of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7. Do you allow provide data regarding the cross-border exchange of the statistical between your country and other EU MS?  7. A very our aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of its issues/cells between your country and other EU MS?  7. Do you allow brokerage companies for either distribution in EU and/or import export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment) company selling tissues or cells) and a buyer (a tissue cestablishment) company selling tissues or cells) and a buyer (a tissue cestablishment) company selling tissues or cells) without undertaking activities of processing, preservation or storage.  8. Age between the statistic formed individually without undertaking activities of processing, preservation or storage.  8. Age between the statistic means and reporting obligations (Article 10, Directive 2004/23/EC)  8. Li Jiron, why not?  8. Li Jiron why not?  8. Jiron why not?  8. Are these reports publicly available? (Article 10(1)) 17  9. Sp. plasse upload the template.  8. Li Jiron, why not?  8. Li Jiron, why not?  8. Sp. Li Jiron, why not?  9. Traceability (Article 10(2))  9. Traceability (Article 8, Directive 2004/23/EC) and Directive 2006/86/EC)  9. Traceability (Article 8, Directive 2004/23/EC) and Directive 2006/86/EC)  9. Traceability (Article 8, Directive 2004/23/EC) and Directive 2006/86/EC)  9. Li How she data stor				
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8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)  9.1. Was the donor identification system (Art. 8(2)) implemented in your country?  9.2. Who assigns the unique code for each donation? (only 1 answer possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  Yes  Yes  Tissue establishment  Established in written SOPs of TEs, requested by national legislation No.  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  Yes  State Institute for Drug Control				
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)  9.1. Was the donor identification system (Art. 8(2)) implemented in your country?  9.2. Who assigns the unique code for each donation? (only 1 answer possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. If yes, which CA/institution is responsible?  State Institute for Drug Control		Not requested by national legislation		
8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)  9.1. Was the donor identification system (Art. 8(2)) implemented in your country?  9.2. Who assigns the unique code for each donation? (only 1 answer possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishments (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  Yes  Wow.sukl.cz/Rewievs and Lists/List of subjects from human tissues, cells and blood branch/List of holders of licence according the law on human TC  Yes  Detailed information of TE, upon the request of EUROCET  No.  Tissue establishment  Both paper records and electronic forms  Established in written SOPs of TEs, requested by national legislation respected (Directive 2006/89/EC, Art. 9)? Please specify.  No.  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. If yes, which CA/institution is responsible?  State Institute for Drug Control		Yes		
cells and blood branch/List of holders of licence according the law on human TC  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)  9.1. Was the donor identification system (Art. 8(2)) implemented in your country?  9.2. Who assigns the unique code for each donation? (only 1 answer possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control				
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possible)  9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control		Tisque establishment		
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control		1 ISSUE ESTADIISIIIIEIIL		
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respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  No.  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control		EALL I WOOD CTP		
9.5. Do you have any additional comments on traceability?  No.  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control		Established in written SOPs of TEs, requested by national legislation		
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reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control	10. Notification of serious adverse events and reactions (Article 11	Directive 2004/23, Article 6 Directive 2006/76)		
10.1.1. If yes, which CA/institution is responsible?  State Institute for Drug Control	10.1. Do you have a national vigilance system in place (for the	Yes		
	reporting of serious adverse events and reactions (Article 11(1))?			
10.1.2. If yes, please provide a short description of its organisation. See above - Pharmacovigilance Department	10.1.1. If yes, which CA/institution is responsible?	State Institute for Drug Control		
	10.1.2. If yes, please provide a short description of its organisation.	See above - Pharmacovigilance Department		

10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	V
1 0 1	Yes
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in 2011 the	<50%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	SAR - TE - State Institute for Drug Control, requested by national
10.0.1. If yes, piease provide a orier description.	legislation
10.7 D	No
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	NO
at national level?	
10.7.2. Please specify why not.	System has not been established yet, no reports.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at EU level?	
10.8.2. Please specify why not.	System has not been established yet, no reports.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	No
Establishments and procurement sites in case of a national rapid	110
alert?	
	System has not been established yet, no RA yet. in case of RA is
10.11.2. If no, please specify why not.	
	possible to use established RA system for pharmaceuticals or
	medical devices
10.12. Do you have in place a system/procedure to notify Tissue	
Establishments and procurement sites when a rapid alert is issued via	medical devices
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	medical devices No
Establishments and procurement sites when a rapid alert is issued via	medical devices
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	medical devices No
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	nedical devices  No  System has not been established yet, no RA yet, in case of RA is
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.	Mo  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.  10.16. Do you have any additional comments on SARE reporting?	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs No.
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direction)	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs No.  tive 2004/23/EC)
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.  10.16. Do you have any additional comments on SARE reporting?	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs No.
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Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direction of the place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs No.  tive 2004/23/EC)  Explicit consent (opt-in)  Written informed consent for each donation, requested by national legislation.
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs No.  tive 2004/23/EC)  Explicit consent (opt-in)  Written informed consent for each donation, requested by national
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Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?  10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.1. If yes, please specify what data.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?  10.15.2. If no, please specify why not.  10.16. Do you have any additional comments on SARE reporting?  11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you	medical devices  No  System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices  Yes  Requested data (no SAR/SAE reported)  Yes  Haemovigilance Pharmacovilance Medical devices  No  No specialised vigilance officer for TCs No.  tive 2004/23/EC)  Explicit consent (opt-in)  Written informed consent for each donation, requested by national legislation.

tissue donation? (more than 1 answer possible)	
Please specify 'other'.	National Register for Persons Withagreeing with Post-mortem Removal of Organs and Tissues, responsible person verifies information from this register before procurement
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	TALLED IN CORP. CERT. AND ALL CERT
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties	Established in written SOPs of TEs, inspected by NCA berofe TE licencing, requested by national legislation
(Art. 14(1)). Please specify.	incenting, requested by flational registation
11.8. Please specify what measures are in place to ensure that the	Established in written SOPs of TEs, inspected by NCA berofe TE
identity of the receipient is not disclosed to the donor and vice versa.	licencing, requested by national legislation
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures in	Established in written SOPs of TEs, inspected by NCA berofe TE
place.	licencing, requested by national legislation
11.10. Do you have any additional comments on consent and data	No
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive	Other
2006/17/EC)? (more than 1 answer possible)	
Please specify 'other'.	Approval licence from NCA for procurement centers
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Other
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
Please specify 'other'.	Approval licence from NCA
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?  12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
deceased donor of dissues/cens. (more than I answer possible)	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	Yes
reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	
2006/17/EC? 12.5.1. Please specify.	HIV p 24 laboratory testing, NAT is not acceptable
12.5.1. Please specify.  12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this	Inspection of the centre of human application (e.g. transplantation centre, ART centre)
question "audit" means a documented review of procedures, records,	Other
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	

Tissues and Cells, 2011))	
12.8.1. Please specify.	Written SOPs, approval licence
12.9. Do you have any additional comments on selection, evaluation	No.
and procurement?	
13. Quality management, responsible person, personnel (Article 16	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a	Authorization requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Authorisation requirement Inspections
than 1 answer possible)	Regular evaluation of personnel
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
13.4. Do you have national/regional/local training programmes for	No
the personnel of tissue establishments?	
13.4.2. If no, in which country(ies) is your personnel trained?	EU countries
• • • •	Non-EU countries
13.4.2.1. Please specify EU-countries.	No
13.4.2.2. Please specify non EU-countries.	No
13.5. Any additional comments on quality management, responsible	No request for personnel training in EU, Non-EU countries
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Internal audits of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	Internal audits of tissue establishments  SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
of Directive 2004/23/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	No
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1 Under which circumstances and for which responsibilities?	Laboratory testing, storage, distribution, procurement Written agreements Issued in the approval licence of TE
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	Approval licence, inspected before approval, inspected every 2 years
Competent Auhtority(ies) in your MS? Please specify.	
15.2. Any additional comments on third party agreements?	No.
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field	No
	1

(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Import-export
Directives? Please choose from the options below.	Vigilance
16.2.1. For all selected options in question 16.2., please provide a	Some ART refuse regulation Special approval licence for
short description.	distributors Access into the DB
16.3. In your opinion, in which of the following Directives are there	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	

## A.1.7. Survey response Denmark

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Danish Health & Medicines Authority
1.1.2. Address of NCA 1:	Axel Heides Gade 1 2300 Copenhagen S Denmark
1.1.3. Telephone (central access point):	+45 7222 7400
1.1.4. E-mail (central access point):	sst@sst.dk
1.1.5. Website:	www.@sst.dk
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals Medical devices
1 1 7 What are the real-throller of the NCA2 (many than 1 arrows	
1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection
possible)	Vigilance
	Other
Please specify 'other':	Development and implementation of national legislation,
	formulation of national health policies, etc.
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	In Denmark, the Danish Health and Medicines Authority is the
organisation of the National Competent Authority(ies) (e.g.	supreme authority in healthcare and regulatory control of medicines.
departments, staffing, number of senior and junior inspectors, staff	We assist and advise the Ministry of Health as well as other
working on EU affairs and legal matters, vigilance officers, budget,	authorities with the administration of healthcare services and inform
independence from government etc.).	Danish citizens on health issues. It is also our responsibility to
	ensure the availability of effective and safe medicines, medical
	devices and new therapies and to promote their proper use. We are
	here to create the best possible framework for the healthcare system
	to prevent and treat illness, suffering and functional limitations for the individual. We give advice on the Danish regions healthcare
	plans. We follow health conditions through monitoring and
	evaluation and endeavour to be at the cutting edge of professional
	knowledge within the healthcare area. We have the responsibility for
	education, authorisation, registration and supervision of Healthcare
	professionals. There are approximately 700 employees devided
	between 10 departments and with resides at 4 addresses.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	The National Competent Authority has primary responsibility for all
Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	aspects of TE Directives. Regional Competent Authorities are not present in Denmark.
* * * * * * * * * * * * * * * * * * * *	present in Denmark.
2. Procurement (Article 5 Directive 2004/23/EC) 2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1 Bo you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting some procurement centres
than 1 answer possible)	By inspecting some procurement centres  By inspecting the documentation associated with procurement that is
	available in the tissue establishment working with procurement
	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	Seven.
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	Forty-seven
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	military of
2.2.2 Please provide the number of procurement centers in which	Thirty-five
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	Easter
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues	Forty
procurement of gametes, emoryos and other reproductive dissues	

. 1 4. 2011 (01/01 21/12/2011)	T
were carried out in 2011 (01/01-31/12/2011).	Ton
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried	Ten
•	
out in 2011 (01/01-31/12/2011).	A1
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
*	
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed)? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	
2.4.1. Please provide the number of the laboratories performing	Nine testing laboratories in Denmark.
donor testing.	
2.5. How do you ensure, as CA for T&C, that tests required for	Inspections of the laboratories
donors are carried out only by qualified laboratories accredited,	
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	There are nine within Denmark. These were first authorised in 2007.
authorised or licensed in your country (e.g. number, year of	HIV Ag/Ab NPU19649; Anti-HCV NPU12033, HBsAg
accreditation/authorisation/license, which donor tests are performed	NPU02349; Anti-HBc NPU02346; Ultrio Plus NAT NPU26888;
etc.).	Syfilis NPU12993; HCV RNA NPU14475; HIV RNA NPU26884;
	HBV DNA NPU12183
2.7. Do you have any additional comments on procurement?	Testing of donors is regulated as a tissue establishment in Denmark.
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	See 3.5 below as well. NAT testing is mandated nationally for
please indicate whether you intend to make it mandatory or to	deceased donors. Established by national scientifi committee several
encourage its use? Please specify why or why not (e.g. number of	years to be beneficia in minimizing infection transmission. We
additional cases detected, cost-benefit etc.).	intend to make NAT testing for HIV, HBV og HCV mandatory for
	egg donors
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	NAT testing is mandated nationally for deceased donors.
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	Testing laboratories should be included in Eurocet registry with
z.s. = 5 , 5a mare any additional commonts on costing.	authorised analyses listed with IUPAC numbers.
4. Accreditation, designation, authorisation or licensing of tissue es	
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
_	Thirteen
1 4 2 1 How many inspections were performed in 2011 for	
4.2.1. How many inspections were performed in 2011 for	Thirteen
4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?  4.3. Are preparation processes authorised?	No

4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC	A
4.7. Tissue establishments with authorisation pending approval at	Other tissue establishments
01/01/2011 (more than 1 answer possible):	
4.7.9. Please specify the type of tissues/cells and how many.	It is only possible to continue if accepting one pending in 4.7
4.8. Tissue establishments with authorisations pending approval by	Other tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.9. Please specify the type of tissues/cells and how many.	To accept Other tissue establishment in 4.8 is the only way to be
	able to continue this questionaire
4.9. Tissue establishments first time authorised between 01/01/2011	Musculo-skeletal tissue establishments
and 31/12/2011 (more than 1 answer possible):	
4.9.2. How many musculo-skeletal tissue establishments?	1
4.10. All tissue establishments authorised by 31/12/2011 (more than	Musculo-skeletal tissue establishments
1 answer possible):	Ocular tissue establishments
i answer possione).	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?	13
4.10.2.2. How many private musculo-skeletal tissue establishments?	0
4.10.3.1. How many public ocular tissue establishments?	1
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue establishments?	1
4.10.4.2. How many private cardiovascular tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	4
4.10.5.2. How many private HSC tissue establishments?	1
4.10.6.1. How many public cord blood tissue establishments?	3
4.10.6.2. How many private cord blood tissue establishments?	2
4.10.7.1. How many public ART tissue establishments?	12
4.10.7.2. How many private ART tissue establishments?	14
4.10.8.1. How many public multi-tissue establishments?	3
4.10.8.2. How many private multi-tissue establishments?	0
4.11. How many tissues and cells were distributed under the direct	Corneas 5
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	No
pursuant to the Directive been defined (Article 27)?	
4.17. Do you have any additional comments on accreditation,	Establishing and promoting an EU template for authorization will
authorisation, designation and licensing?	assist in the distribution of tissues/cells and encourage mutual
· , ···· · · · · · · · · · · · · · · ·	recognition between Member States.
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	103
	Inspection department of the Denick Medicines and Medicines
5.1.1. If yes, please specify the CA/Department of the CA in charge	Inspection department of the Danish Medicines and Medicines
of inspections.	Authority.
5.1.2. If yes, please specify staffing (how many inspectors).	1.5 whole time equivalents are dedicated to the tissue/cells sector.
	There are 16 inspectors in the inspection department for all types of
52 December 1997	GXP.
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training,	
Laborance autople etc. Le a compe increator teams comment training	

common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
5.2.1. If yes, prease specify. (more than I allower possible)	Organs
	Pharmaceuticals
	Advanced therapies
	1
	Medical devices
5.3. How many routine inspections of tissue establishments for non-	9
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	7
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	2
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
was the number of hispections carried out where major shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	9
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	7
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	2
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
	V
establishments followed by suspension of authorisation?	0
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	

5.5 Which time of routing ingrestions January 1. 1	Concret gratem enjoyted increastions
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	Routine inspections are typically planned for two year intervals and
	subsequently evaluated on a risk based approach with current
	information.
5.7. Until 2011, did you implement the requirement concerning the	No
time interval between two inspections (Art. 7.3.)?	
5.7.1. Why not?	Resources.
5.7.2. How do you prioritise tissue establishments to be inspected?	Risk based approach and evaluation of current information.
5.8. How many TEs were inspected at least twice between 2008-	Eleven
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	1
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	
•	Not practical or justified on the curent information.
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, $3 = good$ , $4 = very good$ , $5 = essential$ )?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	No
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.17.1. Could you please explain why not?	Complexities of auditing TE's in third countries and priorities to
our jou preuse explain why not:	fulfill requirements at national level.
5.18. Do you have any additional comments on inspections?	The frequency of inspections should be based on a risk assessment
2.10. 20 you have any additional comments on hispections:	scheme instead of a required 2 years frequency
( I(A	Sometime instead of a required 2 years frequency
6. Import/export (Article 9 Directive 2004/23/EC)	V
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	9
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	9
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	By the routine inspection of the SOP's according to generic
the equivalent standards of quality and safety for importation of skin	principles.
from third countries.	

6.5. Please specify which procedures you have in place for verifying	Not specific.
the equivalent standards of quality and safety for importation of	1 tot specifie.
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	Not specific.
the equivalent standards of quality and safety for importation of	
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	Not specific.
the equivalent standards of quality and safety for importation of	
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	Not specific.
the equivalent standards of quality and safety for importation of	
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	N
6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord	Not specific.
blood from third countries.	
6.10. Please specify which procedures you have in place for	Not specific.
verifying the equivalent standards of quality and safety for	Not specific.
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	Corneas 6
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	A. Export of tissues/cells is authorised only after checking that
and self-sufficiency? (more than 1 answer possible)	local/national needs are fulfilled.
	C. Export of tissues/cells is authorised irrespective of national needs
	D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled
6.14.1. If A or D were selected, please explain how you quantify	Advised by the tissue establishment.
local/national needs.	Advised by the tissue establishment.
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	163
6.15.1. If yes, please specify the number of cases and for which type	Corneas 6
of tissues/cells.	
6.16. Do you have any additional comments on import/export?	None.
7. Distribution/intra community exchanges (Article 23 Directive 20	04/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	
	Responsible Person shall demonstrate they have established any
and safety measures established by other Member States? Please	supplementary national requirements of the receiving EU country,
and safety measures established by other Member States? Please specify.	
	supplementary national requirements of the receiving EU country,
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	supplementary national requirements of the receiving EU country, and demonstrate they meet them.
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.  Inspection of the procedures for distribution
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.  Inspection of the procedures for distribution  Yes, no restrictions apply
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.  Inspection of the procedures for distribution
specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	supplementary national requirements of the receiving EU country, and demonstrate they meet them.  Yes  Response to enquiries by sending the TE information on our national requirements.  Inspection of the procedures for distribution  Yes, no restrictions apply

tissue/cells between your country and other EU MS?	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	Yes
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.7.1. Please describe the legal requirements and your role (if any) as	Specific legislation not specified at this time. Our CA informs the
a Competent Authority, in their authorisation/monitoring or	brokerage company on the principles of TE legislation and
inspection.	periodically monitors their activities.
7.8. Are brokers actively supplying health	Yes
professionals/establishments in your country?	
7.8.1. Where are the brokers located?	Your country
7.9. Do you have any additional comments on distribution?	Suitable draft legislation for brokerage companies should be
	developed to ensure quality, safety and traceability.
8. Register of tissue establishments and reporting obligations (Arti	cle 10. Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	No
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.1.1. If no, why not?	Report format and style varies slightly from year to year.
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	100/0 (dil)
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	Yes
	1.46//1
8.4.1. Please insert the link to the published national annual report.	http://laegemiddelstyrelsen.dk/da/service-
	menu/produktomraader/vaev-og-celler/register-over-godkendte-
	vaevscentre
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	1.46//1
8.5.1. If yes, please provide us with the link to the register's web site.	http://laegemiddelstyrelsen.dk/da/service-
	menu/produktomraader/vaev-og-celler/register-over-godkendte-
	vaevscentre
8.6. Do you provide data regarding tissues and cells activities to the	No
EUROCET registry (non-mandatory reporting)?	
8.6.2. If no, why not?	Data request for clinical information on tissues/cells is not part of
	our work activities.
8.7. Do you have any additional comments on reporting?	Individual reports (see 8.3) on activities of a TE are not deemed
	beneficial.
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Tissue establishment
possible)	
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	• •
9.4. How do you ensure that the 30 years data storage requirement is	Verification by routine inspections of tissue establishments.
respected (Directive 2006/89/EC, Art. 9)? Please specify.	
9.5. Do you have any additional comments on traceability?	None.
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the	
	Yes
reporting of serious adverse events and reactions (Article 11(1))?	Design Week and Medical And all
10.1.1. If yes, which CA/institution is responsible?	Danish Health and Medicines Authority.
10.1.2. If yes, please provide a short description of its organisation.	The vigilance coordinator has responsibility for the receipt,
	management and assessment of SAR/E's to our Agency. In collaboration with internal colleagues a strategy is developed to
	1 11-b

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	investigate probable cause and implement corrective actions as
	appropriate. The vigilance officer is fluent with the protocol and
	procedures of the RATC system, when applicable.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	Yes
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in 2011 the	<50%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	we have a procedure for ART
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at national level?	
10.7.2. Please specify why not.	Low statistics at this time.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at EU level?	
10.8.2. Please specify why not.	Resources.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	Two, sperm straws, genetic.
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	No
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.2. If no, please specify why not.	Our national system is effective for notifying the TE's, which
10.11.2. If no, pieuse speeify why not.	thereafter have responsibility for contacting the procurement
	centre/s.
10.12. Do you have in place a system/procedure to notify Tissue	No
Establishments and procurement sites when a rapid alert is issued via	INO
the EU RATC platform?	
10.12.2. If no, please specify why not.	Our national system is effective for notifying the TE's, which
	thereafter have responsibility for contacting the procurement
	centre/s.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	Resources.
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Medical devices
usually contacted. (more than 1 answer possible)	
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	4
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	·
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	A technical report of the SAR/E's at EU level, with
10.10. Do you have any additional comments on SAKE reporting?	recommendations/corrective actions, would be a useful tool to issue
	direct to tissue establishments.
11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)	
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	Different types of consent must be complied with (e.g. for donation,

tissue/cell donation.	for treatment, for storage, etc)
11.2. What consent system for deceased tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	Explicit consent (opt-in)
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	I hat degree relatives (merading spouse)
tissue donation? (more than 1 answer possible)	
11.4. Is the consent system for deceased tissue donation the same as	No
for organs?	
11.4.1. If no, please describe the difference.	Different perspectives apply here.
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	,
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	, , , , , , , , , , , , , , , , , , ,
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	This is the responsibility of the TE and different control systems
recipients remain unidentifiable when access is given to third parties	apply.
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	This is the responsibility of the TE and the treatment clinic to
identity of the receipient is not disclosed to the donor and vice versa.	ensure. by their own hospital procedures.
11.9. Does your national legislation allows disclosure of donor data	Yes
in case of gametes donation?	
11.10. Do you have any additional comments on consent and data	None.
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
12.5 D	Medical records of the donor
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	140
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
12 Quality management respectible account of the transfer	( 17 10 Directive 2004/22/EC)
13. Quality management, responsible person, personnel (Article 16	5, 17, 18 Directive 2004/25/EC)

have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	A di i di i
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	
13.3. How do you ensure an appropriate training for the personnel	Inspections
directly involved in the activities of tissue establishments? (more	
than 1 answer possible)	
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	An independent organization performs a one day course, which is
13.4.1. If yes, piease specify.	
10.5 1 152 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	available for all types of tissue establishments.
13.5. Any additional comments on quality management, responsible	None.
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	D-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	1
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
	COD- for all annual official and the first of the first o
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	None.
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
	165
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	Examples of circumstances are where; a) infectious marker testing is
	performed at a different testing centre, b) the TE arranges
	responsibility for stored tissue/cells and traceability data to a third
	party, if they should close, c) another third party performs
	specialized processing on behalf of the TE, d) the TE has an IT
	system and the software updates, the storage of data (ie patient files,
	lab results, materials in contact, etc are performed by an
	independent third party, e) the TE uses the courier services of a third
	party to fulfill distribution requirements. f) another TE in a different
	EU country performs earlier specified activities
	(donation/procurement/testing) and our TE continues with later
	specified activities.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	A specific evaluation of the contractual agreements (see 15.1.1.1
Competent Auhtority(ies) in your MS? Please specify.	above) to ensure details and responsibilities of both parties are
composed runtority (100) in your 1110: Floure specify.	specified, and agreement is signed and dated. This evaluation is
	performed at routine inspections and are specified in the TE dossier
	prior to the visit.
15.2. Any additional comments on third party agreements?	None.

16. General comments - implementation	16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field	Yes	
(e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)?		
16.1.1. Please specify.	NAT testing for deceased donors, specified in a guidance document.	
16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below.	Testing provisions Distribution provisions Import-export Inspections	
16.2.1. For all selected options in question 16.2., please provide a short description.	Status of testing laboratories in other countries and some national requirements are different in Europe Distribution; Interpretation is different across Europe. Import-eksport: Issues are being addressed in working group Inspections: The 2 year interval is a challenge to fulfill	
16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible)	Directive 2004/23/EC Directive 2006/17/EC Directive 2006/86/EC	
16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC?	Identify proposals for further consideration, review these in a working group to develop recommendations, then present the information to CA/Commission meetings.	
16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC?	Identify proposals for further consideration, review these in a working group to develop recommendations, then present the information to CA/Commission meetings.	
16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC?	Identify proposals for further consideration, review these in a working group to develop recommendations, then present the information to CA/Commission meetings.	

## A.1.8. Survey response Estonia

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	State Agency of Medicines
1.1.2. Address of NCA 1:	Nooruse 1, 50411 Tartu, Estonia
1.1.3. Telephone (central access point):	+372 737 4140
1.1.4. E-mail (central access point):	info@ravimiamet.ee
1.1.5. Website:	http://www.ravimiamet.ee/
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	State Agency of Medicines is a governmental body under the
organisation of the National Competent Authority(ies) (e.g.	Ministry of Social Affairs. Its main responsibility is the protection
departments, staffing, number of senior and junior inspectors, staff	and promotion of public and animal health, through the supervision
working on EU affairs and legal matters, vigilance officers, budget,	of medicines for human and veterinary use. Among other goals State
independence from government etc.).	Agency of Medicines aims to ensure that cells, tissues and organs
	used in the treatment of humans in Estonia are proven to be safe and
	of high quality. Department of Biologicals is a part of State Agency of Medicines. The staff consists of three persons who are all
	involved in EU affairs, legal matters and biovigilance. The
	inspections can also be carried out by all members of the department
	with the help of a senior inspector whose main focus is
	pharmaceutical manufacturing. As Department of Biologicals is a
	part of the State Agency of Medicines, it gets funded by the agency,
	which is funded by approximately ten percent by the government.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	11
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	No Regional Competent Authority(ies)
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	Other
than 1 answer possible)	
Please specify 'other':	In Estonia only tissue establishments and special medical care
	providers in contract with tissue establishments are allowed to
	procure tissues. Tissue establishment is responsible for the
	procurement and conditions and documentation associated with
	procurement in the tissue establishment are inspected.
2.1.2. How many such authorisations were granted in 2011 (01/01-	Two tissue establishments renewed their licences.
31/12/2011)?	The second disease of 11' 1 and 21' 2
2.2.1 Please provide the number of procurement centres in which	There were three tissue establishments responsible for procurement
procurement of "traditional tissues and cells" (skeletal tissues,	of "traditional tissues and cells" in 2011.
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	There were two tissue establishments responsible for procurement of
procurement of haematopoietic stem cells (bone marrow, PBSC,	haematopoietic stem cells in 2011.
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	nacmatopolette stem cens in 2011.
2.2.3 Please provide the number of procurement centers in which	There were five tissue establishments responsible for procurement
procurement of gametes, embryos and other reproductive tissues	of gametes, embryos and other reproductive tissues in 2011.
were carried out in 2011 (01/01-31/12/2011).	5. 5ametes, emeryos una omer reproductive tissues in 2011.
2.2.4. Please provide the number of procurement centers in which	0.
procurement of tissues/cells for ATMP manufacturing were carried	·.
processment of tibbaco, conditor Arrivir manufacturing were carried	

out in 2011 (01/01 21/12/2011)	
out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	Analysis of the mandatory documentation
conditions accredited, designated, authorised, licensed) ? (more than	
1 answer possible)	N-
2.4. Are you also responsible for the accreditation, designation,	No
authorisation or licensing of laboratories performing donor testing?	T. L. C.
2.4.2. Which National Authority is in charge of this activity?	Laboratories are accredited by Estonian Accreditation Centre.
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	- East-Tallinn Central Hospital Ltd 25.06.2012 (first accred.
authorised or licensed in your country (e.g. number, year of	18.12.07) Detailed description -
accreditation/authorisation/license, which donor tests are performed	http://www.eak.ee/dokumendid/pdf/kasitlusala/L199.pdf - North
etc.).	Estonia Medical Centre Ltd Laboratory (03.06.2010) Detailed
	description –
	http://www.eak.ee/dokumendid/pdf/kasitlusala/L232.pdf
	Quattromed HTI Laborid Ltd - 20.05.2009 (first accred. 20.05.04)
	Detailed description -
	http://www.eak.ee/dokumendid/pdf/kasitlusala/L159.pdf Tartu
	University Clinics United Laboratories - 03.02.2010 (first accred.
	03.02.05) Detailed description -
	http://www.eak.ee/dokumendid/pdf/kasitlusala/L167.pdf - West
	Tallinn Central Hospital Ltd Laboratory of Clinic of Diagnostics
	26.02.2009 (first accred. 26.02.04) Detailed description -
	http://www.eak.ee/dokumendid/pdf/kasitlusala/L155.pdf
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	<u> </u>
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	NAT HIV 1
1 /	HBs AG
	Anti HBc
	Anti HCV-Ab
	Anti HCV-Ab NAT HCV
	NAT HCV
3.2 Please specify laboratory tests required for donors of	NAT HCV Treponema Pallidum
3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2
	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1
reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG
reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc
reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab
reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV
reproductive tissues and cells in your Member State. (more than 1	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia
reproductive tissues and cells in your Member State. (more than 1 answer possible)	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and
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reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and
reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and the cost-benefit has to be taken into account.
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reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and the cost-benefit has to be taken into account.
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reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT HCV NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and the cost-benefit has to be taken into account.  No  Yes  Anti-HTVL-I for donors coming from high risk areas or whose
answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.5.1. Please specify.	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and the cost-benefit has to be taken into account.  No  Yes  Anti-HTVL-I for donors coming from high risk areas or whose sexual partners come from high risk areas.
answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.5.1. Please specify.  3.6. Are any other laboratory tests required for donors of	NAT HCV Treponema Pallidum Anti-HIV 1 Anti-HIV 2 NAT HIV 1 HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum The use is encouraged, but the resources of tissue establishments and the cost-benefit has to be taken into account.  No  Yes  Anti-HTVL-I for donors coming from high risk areas or whose sexual partners come from high risk areas.

testing laboratories?  4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)  4. Lo you have a system of designation, authorisation and accreditation or licensing for all types of tissue establishments under your responsability?  4. En inspection a perrequisite for the designation, authorisation, accreditation or licensing of all types of tissue establishments?  4. 2. I. Ilmo many impections were performed in 2011 for authorising/accrediting/licensing/designating TEs?  4. 3. Any expensation processes authorised?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were suspended in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisation/saccreditation/licenses were evoked in 2011?  4. Following inspections very sample of the saccreditation of the saccredi	3.7. Do you request/use international accreditation systems for	No
3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)  4. I. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?  4. 2. Is inspection a percequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4. 2. I. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?  4. 3. Are preparation processes authorised?  4. 4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were asspended in 2011?  4. 5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were asspended in 2011?  4. 5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4. 6. Do you require TEs to be certified by an external entity to a quality system standard (eg. ISO, JACIE, FACT)?  4. 6. Whistory of tissue/cells establishments authorised by the NCA  4.7. Tissue establishments with authorisations pending approval at 2011/2011 (more than 1 answer possible):  4. 7. Pissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4. 9. Please specify the type of tissues/cells and how many.  4. 9. Please specify the type of tissues/cells and how many.  4. 9. Please specify the type of tissues/cells and how many.  4. 10. All issue establishments authorised by 31/12/2011 (more than 1 answer possible):  4. 10. 7. How many public multi-issue establishments?  4. 10. 8. How many public multi-issue establishments?  4. 10		NO
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4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If yes, please specify staffing (how many inspectors).  5.1.4. If yes, please specify staffing (how many inspectors).  5.1.5. If yes, please specify staffing (how many inspectors).	1 /	
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5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  State Agency of Medicines, Department of Biologicals within the structure of the agency.  5.1.2. If yes, please specify staffing (how many inspectors).  3 in the Department of Biologicals (all multi-functional) and also 1	authorisation, designation and licensing?	
measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  State Agency of Medicines, Department of Biologicals within the structure of the agency.  5.1.2. If yes, please specify staffing (how many inspectors).  3 in the Department of Biologicals (all multi-functional) and also 1	5. Inspections (Article 7, Directive 2004/23/EC)	
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of inspections. structure of the agency. 5.1.2. If yes, please specify staffing (how many inspectors). 3 in the Department of Biologicals (all multi-functional) and also 1		
5.1.2. If yes, please specify staffing (how many inspectors).  3 in the Department of Biologicals (all multi-functional) and also 1	5.1.1. If yes, please specify the CA/Department of the CA in charge	State Agency of Medicines, Department of Biologicals within the
	*	6 3
from another department of the agency (department for supervision	5.1.2. If yes, please specify staffing (how many inspectors).	
month displacement of the agency (department for supervision		from another department of the agency (department for supervision
over medicinal products; support to tissue establishment		over medicinal products; support to tissue establishment
inspections).		inspections).
5.2. Does the inspection scheme interact or overlap with the Yes		Yes
inspection scheme of other activities, for example blood,		
pharmaceuticals, etc. (e.g. same inspector team, common training,		
common documentation, etc.)? (more than 1 answer possible)	common documentation, etc.)? (more than 1 answer possible)	
common documentation, etc.)? (more than 1 answer possible)	common documentation, etc.)? (more than 1 answer possible)	

5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
3.2.1. 11 yes, picase specify. (more than 1 answer possible)	Organs
	Advanced therapies
	Others
Please specify other.	General inspection process has been established on the level of the
Please specify other.	State Agency of Medicines, the agency supervises tissues and cells
	and pharmaceuticals.
5.2. How many routing increasing of tiggue actablishments for any	and pnarmaceuticals.
5.3. How many routine inspections of tissue establishments for non-	4
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	1
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	4
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	2
establishments (from 1/1/2011 to 31/12/2011)?	_
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	1 - Inspection of premises and conditions prior to first authorisation
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	(new ART site).
blower)? Please specify.	(new river site).
5.4.3. Outcome of inspections of ART tissue establishments carried	0
=	V
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	2
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0

establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
5.6. How do you decide which type of routine inspection to conduct?	Depends on the results of the last inspection and/or changes in the facilities and handling practices in the tissue establishment.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?	6 - including inspections prior to first authorisations.
5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?	No
5.9.2. If no, why not?	Authorised tissue establishments in Estonia are themselves responsible for fulfilling the conditions for procurement.
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	State Agency of Medicines is not obligated to inspect third parties on routine basis. Also, laboratories performing the donor testing are accredited by Estonian Accreditation Centre.
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in	No
collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	NO
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	Lv
6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries?	Yes
6.2. Please specify the number of tissue establishments authorised to	6. Only authorized tissue establishments are allowed to
import tissues and cells from third countries (recorded by 31/12/2011).	import/export tissues from/to third countries.
6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).	6
6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.	There are currently no tissue establishments authorized to handle skin in Estonia.
6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third	Only authorized tissue establishments are allowed to import tissues from third countries.

aguntrias	
countries.  6.6. Please specify which procedures you have in place for verifying	Only authorized tissue establishments are allowed to import tissues
the equivalent standards of quality and safety for importation of	from third countries.
ophtalmic (cornea, sclera, etc) tissues from third countries.	nom time countries.
6.7. Please specify which procedures you have in place for verifying	Only authorized tissue establishments are allowed to import tissues
the equivalent standards of quality and safety for importation of	from third countries.
	from time countries.
cardio vascular tissues from third countries.	0-1444
6.8. Please specify which procedures you have in place for verifying	Only authorized tissue establishments are allowed to import tissues
the equivalent standards of quality and safety for importation of	from third countries.
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	There are currently no tissue establishments authorized to handle
the equivalent standards of quality and safety for importation of cord	cord blood in Estonia.
blood from third countries.	
6.10. Please specify which procedures you have in place for	Only authorized tissue establishments are allowed to import tissues
verifying the equivalent standards of quality and safety for	from third countries.
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	19 unrelated bags of HPC. Countries of origin: 15 from Germany, 2
number/volume of imported tissues and cells by country of origin.	from Finland, 2 from Israel. 249 sperm straws. Country of origin:
	Denmark.
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.12.1. If yes, please provide the data concerning the	26 units of cord blood. Countries of destination: 25 to Lithuania, 1 to
number/volume of exported tissues and cells by country of	United Kingdom.
destination.	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	C. Export of tissues/cells is authorised irrespective of national needs
and self-sufficiency? (more than 1 answer possible)	F. Other
Please specify 'other':	Import of tissues/cells is authorised irrespective of national needs.
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 20	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	Tissue establishments themselves are responsible for meeting the
	=
and safety measures established by other Member States? Please	quality and safety measures established by Member States they want
specify.	to export to.
7.1.2. If yes, do you have more stringent quality and safety measures	No
than in other Member States?	
7.2. How do you ensure that tissues establishments fulfil the	The conditions of transport are in the responsibility of the tissue
requirements of Art. 23 of Directive 2004/23/EC regarding quality	establishment and the means of establishing the proper conditions
of tissues and cells during distribution? Please specify.	are controlled during routine inspections.
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, but only via an authorised TE in my MS
from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination, type of	26 units of cord blood. Countries of destination: 25 to Lithuania, 1 to
tissue/cell and number of units distributed) concerning distribution	United Kingdom.
to other MS in 2011 (01/01/2011-31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	19 unrelated bags of HPC. Countries of origin: 15 from Germany, 2
tissue/cell and number of units distributed) concerning distribution	from Finland, 2 from Israel. 249 sperm straws. Country of origin:
to other MS in 2011 (01/01/2011-31/12/2011)	Denmark.
1 10 011101 1113 111 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which may	No

	,
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Arti	cle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	
8.4.1. Please insert the link to the published national annual report.	http://www.ravimiamet.ee/rakkude-kudede-ja-elundite-2012-aasta-
paonona amadi report	k%C3%A4itlemisandmete-kokkuv%C3%B5te
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	100
8.5.1. If yes, please provide us with the link to the register's web site.	http://www.ravimiamet.ee/en/list-licensed-handlers-cells-tissues-
6.5.1. If yes, prease provide as with the fink to the register's web site.	and-organs-tissue-establishments
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	165
8.6.1. If yes, what data are provided to EUROCET? Please specify.	State Agency of Medicine completes forms for tissues, HPC and
6.0.1. If yes, what data are provided to EUROCE 1? Flease specify.	State Agency of Medicine completes forms for ussues, fire and
	ART.
8.7. Do you have any additional comments on reporting?	ART.
8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	ART. 6/86/EC)
8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2009.1. Was the donor identification system (Art. 8(2)) implemented in	ART.
8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2009.1. Was the donor identification system (Art. 8(2)) implemented in your country?	ART.  6/86/EC)  Yes
8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2009.1. Was the donor identification system (Art. 8(2)) implemented in your country?  9.2. Who assigns the unique code for each donation? (only 1 answer	ART. 6/86/EC)
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collecting SAR/E from all TEs?	<u> </u>
10.5. How many tissue establishments provided in 2011 the	100%
SAR/SAE data as requested (please provide the % from the total	100/0
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	No
centres when reporting SAR/SAE to the TEs which distributed the	NO
tissues/cells (Art 11.2)?	
10.6.2. If no, how do you ensure that SAR/SAE are reported to the	There is no mandatory procedure but the transplantation centre is
TEs? 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	required by the law to report SAR/SAE to the TE concerned.  Yes
at national level?	Yes
	Visitana administra and administration with a first fi
10.7.1. Please specify.	Vigilance activities are reported biannually on the website of State
10.0 D	Agency of Medicines.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?	
10.8.1. Please specify.	EU level serious adverse reactions and adverse events will be
	included in the biannual overview, if Estonia was directly
	concerned.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	Four cases of hyperviscosity of apheresis product (HPC).
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	Tissue establishments concerned will be informed by e-mail and
system/procedure.	over the phone.
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	Tissue establishments concerned will be informed by e-mail and
system/procedure.	over the phone.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	We complete the SANCO "Serious Adverse Reaction(s) and
	Event(s)" questtionnaire.
10.14. Do you notify alerts communicated via these tissues and cells	No
national vigilance system also to other national vigilance/alert	
systems?	
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	4
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	Donor has to explicitly agree to donate. This is separate for each
tissue/cell donation.	donation.
11.2. What consent system for deceased tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	No further authorisation is needed
donations, please specify who is giving the authorisation for the	
tissue donation? (more than 1 answer possible)	
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	
and not possible)	1

11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	Only trained personnel is allowed to provide such information
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	Handling of the documentation is based on the data protection act and only authorized persons are allowed to access the data.
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	Handling of the documentation is based on the data protection act.
11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	Yes
11.10. Do you have any additional comments on consent and data protection?	The personal data of a donor shall not be disclosed upon artificial insemination, except in the case where the ovum donor is a relative of the woman who wishes to undergo artificial insemination.
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible)	Inspections of TEs and procurement sites
12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible)	Inspections of ART centres
12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC?	No
12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible)	Interview with the donor's family or a person who knew the donor well  Medical records of the donor Autopsy report Other
Please specify 'other'.	Any other relevant tests.
12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	No
12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC?	No
12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?	No
12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011))	Inspection of tissue establishment
12.9. Do you have any additional comments on selection, evaluation and procurement?	
13. Quality management, responsible person, personnel (Article 16	5, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).	Authorisation requirement Inspections

13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	_ *
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	A competent person shall have the following qualifications: 1) an
	academic degree in medicine or biology or specialities relating to
	biology acquired in a university or a foreign qualification equal
	thereto; 2) at least two years of practical work experience in the field
	of handling cells, tissues and organs.
13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions)	Inspections of tissue establishments Other
of Directive 2004/23/EC? (more than 1 answer possible)	Other
Please specify 'other'.	Short description of storage conditions is mandatory for
Trease specify other.	authorisation.
14.4. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 22 (labelling, documentation and	Other
packaging) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	
Please specify 'other'.	Short description of labelling and packaging procedures is
	mandatory for authorisation.
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	This corresponds to the article 24 in 2004/23/EC - e.g. donor testing,
	transport of the material etc.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	During inspections of tissue establishments. List of third parties
Competent Auhtority(ies) in your MS? Please specify.	performing the contractual services related to the tissue handling and
	the nature of these services is added to the application for
150 A 150 A	authorisation.
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	N. 1.00 L.
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	N. 1.00. 10.
16.2.1. For all selected options in question 16.2., please provide a	No difficulties.
short description.  16.3. In your opinion, in which of the following Directives are there	No shorteomings
	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	

## A.1.9. Survey response Finland

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Finnish Medicines Agency
1.1.2. Address of NCA 1:	P.O. Box 55, FI-00034 FIMEA, FINLAND
1.1.3. Telephone (central access point):	+358 29 522 3341
1.1.4. E-mail (central access point):	registry@fimea.fi / personal addresses: firstname.lastname@fimea.fi
1.1.5. Website:	www.fimea.fi
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
(	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on ELI officirs and legal matters, vigilance officers, budget	The Finnish Medicines Agency (Fimea) is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health it
working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.).	promotes the health and safety of the population by regulating medicinal, blood and tissue products, and by developing the pharmaceuticals sector. Fimea's organisation is structured around
	three core processes: Supervision and licenses, Assessment of medicinal products, and Assessment of pharmacotherapies. The Supervision and licenses -process includes Inspectorate unit and Laboratory unit. The Inspectorate is responsible for authorisation
	and inspection of tissue establishments, and for vigilance functions.  About 20 inspectors/experts are working in the Inspectorate. Two senior inspector are responsible for the authorisation and inspection
	of tissue establishments, and for vigilance actions. In addition, the Assessment of medicinal products -process provides medical
	expertise at need (mostly in vigilance). Legal expertise is provided by the process of internal services.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	No decentralised systems nor regional competent authorities for
Regional Competent Authority(ies) and their relation with the	tissues and cells.
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	Other
Please specify 'other':	Procurement sites are listed on each TE license and inspected as a part of routine TE inspection.
2.1.2. How many such authorisations were granted in 2011 (01/01-	None. Almost all Finnish TEs and their procurement sites were
31/12/2011)? 2.2.1 Please provide the number of procurement centres in which	authorized year 2007-2008.
• •	J
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	5
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	No separate procurement sites for gametes and embryos. All 23
procurement of gametes, embryos and other reproductive tissues	fertility clinics (TEs) are responsible also for procurement of

were carried out in 2011 (01/01-31/12/2011).	gametes and embryos.
2.2.4. Please provide the number of procurement centers in which	gametes and emoryos.
procurement of tissues/cells for ATMP manufacturing were carried	1
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	inspections of the site/centre
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed)? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	No
authorisation or licensing of laboratories performing donor testing?	
2.4.2. Which National Authority is in charge of this activity?	Regional authorities and The National Institute for Health and
2.1.2. Which i tutional i tutionity is in change of this activity.	Welfare (THL) are responsible for licensing of all clinical
	microbiology laboratories in Finland. THL keeps the registry of
	laboratories.
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	In Finland any licensed clinical microbiology laboratory can perform
authorised or licensed in your country (e.g. number, year of	donor testing. THL is a national registration authority and keeps the
accreditation/authorisation/license, which donor tests are performed	registry. Exact number of donor testing laboratories was not
etc.).	available during survey. The estimate is 20-30 laboratories (clinical
	laboratories of university hospitals and central hospitals as well as
	some private laboratories).
2.7. Do you have any additional comments on procurement?	,
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
	NAT HIV 1
	HBs AG
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
	NAT HIV 1
	HBs AG
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	The Finnish Medicines Agency will update the Administrative
please indicate whether you intend to make it mandatory or to	Regulation 3/2012 in 2013. The Finnish Medicines Agency is
encourage its use? Please specify why or why not (e.g. number of	introducing more stringent protective testing requirements: viral
additional cases detected, cost-benefit etc.).	PCR tests required for living and deceased donors -except donors of
	reproductive cells). The more stringent national requirements are
	being notified (Commission Directive 98/34/EC; the notification
2.4 Do you have concerns an account of the state of the s	identification is 2013/0349/FIN).
3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?	Yes
3.4.1. Please specify why:	All allogenic donors (both living and deceased) should be tested as
3.4.1. I lease specify why.	carefully (both serology and PCR).
	carefully (both scrology and I CK).
3.5 Are any other laboratory tests required for donors of non	
3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?	Yes

3.5.1. Please specify.	Risk groups (HTLV, malaria, etc)
3.6. Are any other laboratory tests required for donors of	Yes
reproductive tissues and cells in your Member State?	
3.6.1. Please specify.	Risk groups (HTLV, malaria, etc)
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing of tissue e	stablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	2
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in	
2011?	0
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in 2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	110
4bis. Overview of tissue/cells establishments authorised by the NC	4
4.7. Tissue establishments with authorisation pending approval at	Musculo-skeletal tissue establishments
01/01/2011 (more than 1 answer possible):	Other tissue establishments
4.7.2. How many musculo-skeletal tissue establishments?	1
4.7.9. Please specify the type of tissues/cells and how many.	mesenchymal stem cells (ATMP)
4.8. Tissue establishments with authorisations pending approval by	Other tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.9. Please specify the type of tissues/cells and how many.	All TEs were authorised by 31.12.2011
4.9. Tissue establishments first time authorised between 01/01/2011	Musculo-skeletal tissue establishments
and 31/12/2011 (more than 1 answer possible):	Other tissue establishments
4.9.2. How many musculo-skeletal tissue establishments?	1
4.9.9. Please specify the type of tissues/cells and how many.	mesenchymal stem cells
4.10. All tissue establishments authorised by 31/12/2011 (more than	Skin tissue establishments
1 answer possible):	Musculo-skeletal tissue establishments
	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.1.1. How many public skin tissue establishments?	1
4.10.1.2. How many private skin tissue establishments?	0
4.10.2.1. How many public musculo-skeletal tissue establishments?	22
4.10.2.2. How many private musculo-skeletal tissue establishments?	1
4.10.3.1. How many public ocular tissue establishments?	2
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue establishments?	1
4.10.4.2. How many private cardiovascular tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	11
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	1
4.10.6.2. How many private cord blood tissue establishments?	0

4.10.0.1 TI 15.5 (11.1 (0)	Ι,
4.10.8.1. How many public multi-tissue establishments?	1
4.10.8.2. How many private multi-tissue establishments?	0
4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many.	1: mesenchymal stem cells (for ATMP)
4.10.9.2. Please specify the type of 'other' private tissues/cells	0
establishements and how many.	0
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	O Company
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	165
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Fimea's organisation is structured around three core processes:
of inspections.	Supervision and licenses, Assessment of medicinal products, and
•	Assessment of pharmacotherapies. The Supervision and licenses -
	process includes Inspectorate unit and Laboratory unit. The
	Inspectorate is responsible for authorisation and inspection of tissue
	establishments, and for vigilance functions.
5.1.2. If yes, please specify staffing (how many inspectors).	2
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Advanced therapies
5.3. How many routine inspections of tissue establishments for non-	17
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)? 5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	U C C C C C C C C C C C C C C C C C C C
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	17
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
1155465/20115 CONGREGA IN 2011 (01/01/2011 to 51/12/2011). What	

was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	8
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	8
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted?	0
· ·	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?  5.4.8. What was the number of other inspections of ART	
establishments? Please specify.	0
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	On-site inspections are carried out at least every four years. Desk-
3.6. How do you decide which type of fourthe hispection to conduct?	based inspections can be used at the time of an intermediate
	evaluation between on-site inspections, if there have been no
	significant changes in TE.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	59
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	11
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	In Finland there are quite a few third parties which act as suppliers
, ,	of critical services to TEs. So far inspections of the TE have
	indicated no non-compliance with the written agreement by a third
	party.
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
Tarana and the same and the sam	No
5.14. Did you receive/organise an inspection of a tissue	110
establishment in your country at the request of another MS in	

5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	NO
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	NO
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	No
inspections should be understood as inspections of tissue	NO
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.17.1. Could you please explain why not?	Limited HR
5.18. Do you have any additional comments on inspections?	Elillica TIK
6. Import/export (Article 9 Directive 2004/23/EC)	v.
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	17
6.2. Please specify the number of tissue establishments authorised to	16
import tissues and cells from third countries (recorded by	
31/12/2011).	16
6.3. Please specify the number of tissue establishments authorised to	16
export tissues and cells from third countries (recorded by	
31/12/2011).	No importation of skin
6.4. Please specify which procedures you have in place for verifying	No importation of skin
the equivalent standards of quality and safety for importation of skin from third countries.	
	Add Trr Tr Tr Tr Tr
6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of	Authorised TE is responsible for import procedures. Procedures are inspected douring routine TE inspection. TEs report number of
	-
musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.	import/export tissues and cells annually.
6.6. Please specify which procedures you have in place for verifying	Authorised TE is responsible for import procedures. Procedures are
the equivalent standards of quality and safety for importation of	inspected douring routine TE inspection. TEs report number of
ophtalmic (cornea, sclera, etc) tissues from third countries.	import/export tissues and cells annually.
6.7. Please specify which procedures you have in place for verifying	No importation of cardio vascular tissues
the equivalent standards of quality and safety for importation of	110 Importation of cardio vascalar lissues
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	Authorised TE is responsible for import procedures. Procedures are
the equivalent standards of quality and safety for importation of	inspected douring routine TE inspection. TEs report number of
haematopoietic stem cells (HSC) (other than cord blood) from third	import/export tissues and cells annually.
countries.	r r
6.9. Please specify which procedures you have in place for verifying	Authorised TE is responsible for import procedures. Procedures are
the equivalent standards of quality and safety for importation of cord	inspected douring routine TE inspection. TEs report number of
blood from third countries.	import/export tissues and cells annually.
6.10. Please specify which procedures you have in place for	Authorised TE is responsible for import procedures. Procedures are
verifying the equivalent standards of quality and safety for	inspected douring routine TE inspection. TEs report number of
importation of reproductive cells (sperm, egg cells) from third	import/export tissues and cells annually.
importation of reproductive cells (sperm, egg cells) from third countries.	import/export tissues and cells annually.
1 1 1 2 1	import/export tissues and cells annually.  Yes
countries. 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
countries. 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? 6.11.1. If yes, please provide the data concerning the	
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.	Yes
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes  HSC: 7 grafts from USA, 1 graft from Israel.
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may	Yes  HSC: 7 grafts from USA, 1 graft from Israel.
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between	Yes  HSC: 7 grafts from USA, 1 graft from Israel.  No
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?	Yes  HSC: 7 grafts from USA, 1 graft from Israel.  No
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?  6.14. What is the relation between import/export of tissues and cells	Yes  HSC: 7 grafts from USA, 1 graft from Israel.  No
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?  6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)	Yes  HSC: 7 grafts from USA, 1 graft from Israel.  No  No  F. Other
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?  6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)  Please specify 'other':	Yes  HSC: 7 grafts from USA, 1 graft from Israel.  No  No
countries.  6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.  6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?  6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?  6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)	Yes  HSC: 7 grafts from USA, 1 graft from Israel.  No  No  F. Other

6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 20	1004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	All grafts must fulfill minimum requirements. In exceptional cases,
and safety measures established by other Member States? Please	Fimea can grant permission to import/export graft nor fulfilling the
specify.	requirements (health reasons, benefits outwigjt the risks).
7.1.2. If yes, do you have more stringent quality and safety measures	No
than in other Member States?	110
7.2. How do you ensure that tissues establishments fulfil the	Authorised TE is responsible for ensuring that the other TE fulfill
requirements of Art. 23 of Directive 2004/23/EC regarding quality	the requirements.
of tissues and cells during distribution? Please specify.	the requirements.
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, but only via an authorised TE in my MS
from TEs in another MS? (only 1 answer possible).	1 cs, but only via all authorised 12 in my ivis
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	110
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	165
7.5.1. Please provide us with data (country of destination, type of	HSC: 4 grafts to Germany and Sweden Amniotic membrane: 14
tissue/cell and number of units distributed) concerning distribution	grafts to Ireland
to other MS in 2011 (01/01/2011-31/12/2011).	grans to netand
7.5.2. Please provide us with data (country of origin, type of	HSC: 79 grafts from Germany, 1 from UK, 1 from Portugese, 1 from
tissue/cell and number of units distributed) concerning distribution	France Sclera: 15 from Netherlands Tendons: 63 from Netherlands
to other MS in 2011 (01/01/2011-31/12/2011)	Sperms: Denmark
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	NO
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	110
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Arti	(clo 10. Directive 2004/23/FC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	1 es
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	100/6 (dil)
•	
possible)  8.2. Are those reports publish evailable? (Article 10(1))	No
8.3. Are these reports publicly available? (Article 10(1)) 8.4. Do you publish a national annual report of the consolidated	Yes
	105
activities of all tissue establishments in your country?	http://www.fimea.fi/download/21482 Kudoslaitostoiminta Suomess
8.4.1. Please insert the link to the published national annual report.	
0.5 T. d	a_vuonna_2011.pdf Yes
x 3 to there a publicly accomple register of outborised trans	1 65
8.5. Is there a publicly accessible register of authorised tissue	
establishements in place? (Article 10(2))	
	http://www.fimea.fi/download/23600_FI_Lista_Suomessa_toimivist
establishements in place? (Article 10(2)) 8.5.1. If yes, please provide us with the link to the register's web site.	a_kudoslaitoksista_10-7-2013.pdf
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the	
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?	a_kudoslaitoksista_10-7-2013.pdf Yes
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.	a_kudoslaitoksista_10-7-2013.pdf Yes All
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?	a_kudoslaitoksista_10-7-2013.pdf Yes  All The role of EUROCET should be clarify (mandatory or non-
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?	a_kudoslaitoksista_10-7-2013.pdf Yes  All The role of EUROCET should be clarify (mandatory or non-mandatory reporting).
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	a_kudoslaitoksista_10-7-2013.pdf Yes  All The role of EUROCET should be clarify (mandatory or non-mandatory reporting).  6/86/EC)
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2009).  9.1. Was the donor identification system (Art. 8(2)) implemented in	a_kudoslaitoksista_10-7-2013.pdf Yes  All The role of EUROCET should be clarify (mandatory or non-mandatory reporting).
establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	a_kudoslaitoksista_10-7-2013.pdf Yes  All The role of EUROCET should be clarify (mandatory or non-mandatory reporting).  6/86/EC)

possible)	
1 /	D-4h
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	
9.4. How do you ensure that the 30 years data storage requirement is	During inpections particular attention is paid to the identification
respected (Directive 2006/89/EC, Art. 9)? Please specify.	systems, traceability and registries (IT systems and paper
	documentation).
9.5. Do you have any additional comments on traceability?	
10. Notification of serious adverse events and reactions (Article 11	Directive 2004/23 Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in place (for the	Yes
	165
reporting of serious adverse events and reactions (Article 11(1))?	r.
10.1.1. If yes, which CA/institution is responsible?	Fimea
10.1.2. If yes, please provide a short description of its organisation.	Fimea's organisation is structured around three core processes:
	Supervision and licenses, Assessment of medicinal products, and
	Assessment of pharmacotherapies. The Supervision and licenses -
	process includes Inspectorate unit and Laboratory unit.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	Yes
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in 2011 the	100%
*	10070
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	No
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.2. If no, how do you ensure that SAR/SAE are reported to the	TEs give instructions to the transplantaion centers.
TEs?	
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at national level?	
10.7.1. Please specify.	Annual summary is published.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?	
10.8.1. Please specify.	We give feedback to those TEs which are involved in particular
10.0.1. I lease specify.	event.
10.0 Do you magning your TEs to have a recall presending?	Yes
10.9. Do you require your TEs to have a recall procedure?	
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	We notify TEs by phone or e-mails.
system/procedure.	
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	We notify TEs by phone or e-mails.
system/procedure.	I was a priorie of a mano.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
	110
registry (non-mandatory reporting)?	We already provide data a Lin - CAD/CAD / 1 C
10.13.2. If no, please specify why not.	We already provide data regarding SAR/SAE to the Comission.
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Pharmacovilance

	Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	4
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	Donors must give informed written consent to the removal of an
tissue/cell donation.	organ or tissue. Before giving written consent, donors must be
	provided with an explanation of the significance of the procedure for
	themselves and the recipients, and be informed that their consent can
	be withdrawn.
11.2. What consent system for deceased tissue/cell donation do you	Presumed consent (opt-out)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other relatives
tissue donation? (more than 1 answer possible)	Non-marital partners
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	Coding systems for donors. Restrict access to registries.
recipients remain unidentifiable when access is given to third parties	
(Art. 14(1)). Please specify.  11.8. Please specify what measures are in place to ensure that the	Coding systems for donors. Restrict access to registries.
identity of the receipient is not disclosed to the donor and vice versa.	Couling systems for dollors. Restrict access to registries.
11.9. Does your national legislation allows disclosure of donor data	Yes
in case of gametes donation?	163
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20)	04/23: Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	inspections of 120 and provincing sites
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
	Medical records of the donor
	Interview with the treating physician
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	

Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Inspection of the centre of human application (e.g. transplantation
tissue establishments in your country (Art 15(1), Annex IV of	centre, ART centre)
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
13. Quality management, responsible person, personnel (Article 16	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	A d · · ·
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?	No
13.4.2. If no, in which country(ies) is your personnel trained?	EU countries
13.4.2.1. Please specify EU-countries.	ESHRE EATB etc.
13.5. Any additional comments on quality management, responsible	251112 500
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	No
notified third party agreements?	
15.2. Any additional comments on third party agreements?	

16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	Yes
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.1.1. Please specify.	Tissue Act 101/2001: No donor or assignee of a donor may be
	promised or paid a fee for the removal and use of an organ or tissue
	as laid down in this Act, or for the donation of a cadaver.
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	No difficulties.
short description.	
16.3. In your opinion, in which of the following Directives are there	Directive 2006/17/EC
shortcomings (if any)? (more than 1 answer possible)	
16.3.2. How would you suggest to solve these issues in Directive	All allogenic donors (both living and deceased) should be tested as
2006/17/EC?	carefully (both serology and PCR). Oocyte and sperm donors (non-
	partner) should have same test requirements (if there is no
	quarantine: PCR-tests for HIV, HBV, HCV and Chlmaydia)

## A.1.10. Survey response France

1. Public information	
1.1. Name of National Competent Authority	Ministry of health
(NCA) 1:	
1.1.2. Address of NCA 1:	14, avenue duquesne 75700 PARIS France
1.1.3. Telephone (central access point):	00 33 1 40 56 50 61
1.1.4. E-mail (central access point):	genevieve.liffran@sante.gouv.fr
1.1.5. Website:	www.sante.gouv.fr
1.1.6. The NCA is responsible for? (more than 1	Non-reproductive tissues and cells
answer possible)	Reproductive tissues and cells
	Blood and blood components
	Human organs Pharmaceuticals
	Medical devices
	Other
Please specify 'other':	cosmetic products, tatoo ink, biocides, ancillary products, milk breast, medicinal
rease speerly other.	products, medicinal products (human, paediatric, veterinary medicinal products)
1.1.7. What are the role/tasks of the NCA? (more	Other
than 1 answer possible)	
Please specify 'other':	The ministry of health draws rules and regulations according to the law applying to
- constant of constant	the activities on organs, tissues and cells. It designs the strategic orientations of these
	areas.It manages the health alerts.
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Agence nationale de sécurité du médicament et des produits de santé (ANSM)
1.2.2. Address of NCA 2:	143/147, Boulevard Anatole France 93285 SAINT DENIS CEDEX 3 FRANCE
1.2.3. Telephone (central access point):	00 33 1 55 87 40 41
1.2.4. E-mail (central access point):	fewzi.teskrat@ansm.sante.fr
1.2.5. Website:	www.ansm.sante.fr
1.2.6. The NCA is responsible for? (more than 1	Non-reproductive tissues and cells
answer possible)	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
	Medical devices
	Other
Please specify 'other':	cosmetic products, tatoo ink, breast milk, microorganisms and toxins, biocide
	products, all kinds of medicinal products (including ATMPs), cellular
	products,contraceptive products,contact lenses
`	Accreditation, authorisation, licensing of TEs
`	Accreditation, authorisation, licensing of TEs Inspection
`	Accreditation, authorisation, licensing of TEs Inspection Vigilance
than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other
than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the
than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and
than 1 answer possible)  Please specify 'other':	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM) 1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:  1.3.6. The NCA is responsible for? (more than 1)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr www.agence-biomedecine.fr Reproductive tissues and cells
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:  1.3.6. The NCA is responsible for? (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr  www.agence-biomedecine.fr Reproductive tissues and cells Human organs
than I answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:  1.3.6. The NCA is responsible for? (more than I answer possible)  1.3.7. What are the role/tasks of the NCA? (more	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr  www.agence-biomedecine.fr Reproductive tissues and cells Human organs Inspection
1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:  1.3.6. The NCA is responsible for? (more than 1 answer possible)  1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr  www.agence-biomedecine.fr  Reproductive tissues and cells Human organs Inspection Vigilance
than 1 answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:  1.3.6. The NCA is responsible for? (more than 1 answer possible)  1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr  www.agence-biomedecine.fr Reproductive tissues and cells Human organs Inspection Vigilance Other
than I answer possible)  Please specify 'other':  1.3. National Competent Authority 3?  1.3.1. Name of National Competent Authority 3:  1.3.2. Address of NCA 3:  1.3.3. Telephone (central access point):  1.3.4. E-mail (central access point):  1.3.5. Website:  1.3.6. The NCA is responsible for? (more than I answer possible)  1.3.7. What are the role/tasks of the NCA? (more	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other drawing decisions, recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system, regulatory discussion at national and european level under the supervision of the health Ministry.  Yes Agence de la biomédecine (ABM)  1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE 00 33 1 55 93 65 09 francoise.merlet@biomedecine.fr  www.agence-biomedecine.fr  Reproductive tissues and cells Human organs Inspection Vigilance

	safety in the fields of organs, tissues, reproductive and non reproductive cells procurement, donation and use. It plays an essential role in the promotion and the development of these activities. It has an operational task in allocation of appropriate organs or cells in the purpose of transplantation.
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.).	The Health Ministry is in charge of drafting the general policy of public health according to the legal framework applying to the activities on organs, tissues and cells (ethical, medical and legal aspects). It also defines the main orientations for the development of these activities. It implements policies for improving the quality and the health security regarding health cares, health products and medical trials. The "Agence nationale de sécurité du médicament et des produits de santé (ANSM)" is responsible for the evaluation, authorisation, inspection and control of whole health products and establishments which process them (for more information: http://www.ansm.fr) The Agence de la biomedecine (ABM) provides expertise in order to improve the quality and safety in four fields: organ procurement, assisted reproduction, embryology and genetics, and haematopoietic stem cells. It plays an essential role in the promotion and the development of these activities. It also has operational tasks in allocation of organs and HSC to the matched recipient in vue of transplantation. Given its expertise in these fields, the ABM is the CA for all medical and scientific aspects relating to these issues. It should be pointed out that in the vigilance field, ANSM is the competent authority for biovigilance and materio vigilance in relation with the Agence de la biomédecine whereas ABM is fully
	competent for ART vigilance.
1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection
1.7. Could you please describe the	The regional competent authorities (Agences régionales de santé : ARS) are in charge
competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	of authorization and inspection of procurement and transplantation of organs, tissues and cells establishments, including hematopoietic stem cells (HSC) and Assisted Reproductive Techniques (ART) centres. ABM provides the regional agencies with an expertise advice in the process of the authorisation.
2. Procurement (Article 5 Directive 2004/23/EC)	enpende du rice in the process of the dumorisation.
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of	Other
procurement"? (more than 1 answer possible)	
Please specify 'other':	These conditions are evaluated during the product evaluation where procurement conditions are described in the dossier.
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	4
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	168 authorized procurement centers (among these 168, 22 authorized procurement centers don't perform this procurement activity)
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	32 bone marrow collection and apheresis centres and 9 cord blood banks.
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	In France, in 2011, 104 IVF centres (composed of a biological unit and a clinical unit in an unique site in an establishment for health) and 95 labs for insemination (just a biological site) have performed ART activities.
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	Data not available because the procurement site authorizations are not linked to the regulatory status of the final product. (cell/tissues/ATMP)
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5	Inspections of the site/centre Analysis of the mandatory documentation

	,
of Directive 2004/23/EC and its implementing	
Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised,	
licensed) ? (more than 1 answer possible)	
2.4. Are you also responsible for the accreditation,	No
designation, authorisation or licensing of	
laboratories performing donor testing?	
2.4.2. Which National Authority is in charge of this	In 2020, all the French laboratories must be fully accredited by the comité français
activity?	d'accréditation (COFRAC), designed as the national accreditation body in France
	(2008 decree).
2.5. How do you ensure, as CA for T&C, that	Analysis of the mandatory documentation requested from the tissue establishment
tests required for donors are carried out only by	Other
qualified laboratories accredited, designated,	
authorised or licensed Art. 5(2))? (more than 1	
answer possible)	
Please specify 'other':	Only medical laboratories authorized by regional health competent authorities realize
26 8	the donor qualification .
2.6. Please provide data on qualified laboratories	We have about 200 accredited qualified laboratories but It's impossible to provide
accredited, authorised or licensed in your country	precise data about the ones which perform donor testing: there are private or public
(e.g. number, year of	laboratories: some of them depend on hospitals (private and public), Some of them
accreditation/authorisation/license, which donor	depend on blood transfusion establishments. Sometimes these establishments have
tests are performed etc.).	agreements with private accredited laboratories which carry out the donor tests
2.7. Do you have any additional comments on procurement?	HSC donors procurement centres associated to the national registry are accredited by the WMDA. HLA labs performing HLA typing on donors and CB units are EFI
procurement?	accredited. Regarding ART, there are two separate processes: the first one is the legal
	framework of authorisation and inspection by the regional competent authorities for both clinical and biological activities, the second one is the legal accreditation process
	required for all the French laboratories and validated by Cofrac on all their activities
	including biological ART activities. About testing of gametes donors, the tests are not
	performed in the reproductive lab where the donors are recruited but by medical labs
	wich all are in the process of accreditation.
2 Testing (Aut A Appears I II and III of Directiv	-
3. Testing (Art. 4, Annexes I, II and III of Directiv	e 2006/17/EC)
3.1. Please specify laboratory tests required for	re 2006/17/EC) Anti-HIV 1
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2
3.1. Please specify laboratory tests required for	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2 Ag HIV
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC)  Anti-HIV 1  Anti-HIV 2  Ag HIV  NAT HIV 1  HBs AG  Anti HBc
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC) Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in	e 2006/17/EC)  Anti-HIV 1  Anti-HIV 2  Ag HIV  NAT HIV 1  HBs AG  Anti HBc  NAT HBV  Anti HCV-Ab  NAT HCV  Treponema Pallidum
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 1 Anti-HIV 2
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 1 Anti-HIV 2 Ag HIV
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 1 Anti-HIV 2
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your	e 2006/17/EC)  Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your	e 2006/17/EC)  Anti-HIV 1  Anti-HIV 2  Ag HIV  NAT HIV 1  HBs AG  Anti HBc  NAT HBV  Anti HCV-Ab  NAT HCV  Treponema Pallidum  HTLV-2  Anti-HIV 1  Anti-HIV 2  Ag HIV  HBs AG  Anti HBc  Anti HBc  Anti HBc  Anti HBc  Anti HCV-Ab
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)	e 2006/17/EC)  Anti-HIV 1  Anti-HIV 2  Ag HIV  NAT HIV 1  HBs AG  Anti HBc  NAT HBV  Anti HCV-Ab  NAT HCV  Treponema Pallidum  HTLV-2  Anti-HIV 1  Anti-HIV 2  Ag HIV  HBs AG  Anti HBc  Anti HBc  Anti HBc  Anti HCV-Ab  NAT Chlamydia  Treponema Pallidum
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your	e 2006/17/EC)  Anti-HIV 1  Anti-HIV 2  Ag HIV  NAT HIV 1  HBs AG  Anti HBc  NAT HBV  Anti HCV-Ab  NAT HCV  Treponema Pallidum  HTLV-2  Anti-HIV 1  Anti-HIV 2  Ag HIV  HBs AG  Anti HBc  Anti HCV-Ab  NAT Chlamydia
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HBV Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients ; it is performed according to the medical context and the general recommendations. However for egg donation, NAT
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT HOV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients ; it is performed according to the
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HBV Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients; it is performed according to the medical context and the general recommendations. However for egg donation, NAT HIV is mandatory immediately before the collection of eggs as a second
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HBV Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients; it is performed according to the medical context and the general recommendations. However for egg donation, NAT HIV is mandatory immediately before the collection of eggs as a second
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3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HOV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients; it is performed according to the medical context and the general recommendations. However for egg donation, NAT HIV is mandatory immediately before the collection of eggs as a second determination of the viral status of the donor.
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HOV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients; it is performed according to the medical context and the general recommendations. However for egg donation, NAT HIV is mandatory immediately before the collection of eggs as a second determination of the viral status of the donor.
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased	Anti-HIV 1 Anti-HIV 2 Ag HIV NAT HIV 1 HBs AG Anti HBc NAT HBV Anti HCV-Ab NAT HCV Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HBV  Anti-HIV 1 Anti-HIV 2 Ag HIV HBs AG Anti HBc NAT HBC Anti HCV-Ab NAT Chlamydia Treponema Pallidum Nat testing is not mandatory for ART patients; it is performed according to the medical context and the general recommendations. However for egg donation, NAT HIV is mandatory immediately before the collection of eggs as a second determination of the viral status of the donor.

your Member State?	
3.5.1. Please specify.	For cells qualification: -cytomegalovirus virus '-Epstein-Barr-Toxoplasma gondii
3.6. Are any other laboratory tests required for	Yes
donors of reproductive tissues and cells in your	
Member State?	
3.6.1. Please specify.	Actually, required testing differs between ART couples or non partner donor. For
5.0.1. I lease specify.	ART couples (both male and female partners, even if gametes from donors are used):
	Anti HIV1 and 2, Anti HCV, anti HBS, Anti HBC, Ag HBV and treponema pallidum.
	If necessary: Nat HCV, Nat HIV, or HTLV depending on the context and for women,
	Rubella and toxo For gamete donors, the same and in addition: Anti CMV and Nat
	HIV
3.7. Do you request/use international accreditation	No
systems for testing laboratories?	140
3.8. Do you have any additional comments on	no
testing?	
	ensing of tissue establishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation,	Yes
authorisation, accreditation or licensing for all	
types of tissue establishments under your	
responsability?	
4.2. Is inspection a prerequisite for the designation,	No
authorisation, accreditation or licensing of tissue	
establishments?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1	During inspections organised for this purpose
answer possible)	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4,	0
Directive 2004/23/EC), how many	
authorisations/accreditation/licenses were	
suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4,	1
Directive 2004/23/EC), how many	
authorisations/accreditation/licenses were revoked	
in 2011?	
4.6. Do you require TEs to be certified by an	Yes
external entity to a quality system standard (e.g.	
ISO, JACIE, FACT)?	
4.6.1. What is the relation between the indpendent	Optional, but TEs are encouraged to get a certification
certification(s) (e.g. ISO, JACIE, FACT) and the	Other
CA authorisation of the tissue establishments?	
(more than 1 answer possible)	
Please specify 'other':	Cord blood unit must be USA IND qualified for the shipment (NMDP sponsor)
4bis. Overview of tissue/cells establishments author	orised by the NCA
4.7. Tissue establishments with authorisation	Musculo-skeletal tissue establishments
pending approval at 01/01/2011 (more than 1	
answer possible):	
4.7.2. How many musculo-skeletal tissue	2
establishments?	
4.8. Tissue establishments with authorisations	Musculo-skeletal tissue establishments
pending approval by 31/12/2011 (more than 1	
answer possible):	
4.8.2. How many musculo-skeletal tissue	1
establishments?	
4.9. Tissue establishments first time authorised	Musculo-skeletal tissue establishments
between 01/01/2011 and 31/12/2011 (more than 1	
answer possible):	
4.9.2. How many musculo-skeletal tissue	1
establishments?	
4.10. All tissue establishments authorised by	Skin tissue establishments
31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
1 /	1

	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.10.1.1. How many public skin tissue	10
establishments?	
4.10.1.2. How many private skin tissue	0
establishments?	
4.10.2.1. How many public musculo-skeletal tissue	17
establishments?	
4.10.2.2. How many private musculo-skeletal	7
tissue establishments?	
4.10.3.1. How many public ocular tissue	16
establishments?	
4.10.3.2. How many private ocular tissue	1
establishments?	
4.10.4.1. How many public cardiovascular tissue	12
establishments?	
4.10.4.2. How many private cardiovascular tissue	1
establishments?	
4.10.5.1. How many public HSC tissue	36
establishments?	
4.10.5.2. How many private HSC tissue	2
establishments?	
4.10.6.1. How many public cord blood tissue	9
establishments?	
4.10.6.2. How many private cord blood tissue	0
establishments?	
4.10.7.1. How many public ART tissue	42 IVF centres
establishments?	
4.10.7.2. How many private ART tissue	62 IVF centres and 92 IUI labs
establishments?	
4.10.8.1. How many public multi-tissue	16
establishments?	
4.10.8.2. How many private multi-tissue	0
establishments?	
4.11. How many tissues and cells were distributed	1402 (bone marrow + PBSC + cord blood + lymphocytes)
under the direct agreement of the Competent	
Authority according to Art. 6(5) during 2011?	
Please provide number(s) per type tissues/cells.	
4ter. Sanctions	<del></del>
4.16. Have penalties for infringements of the	Yes
national provisions pursuant to the Directive been	
defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on	Actually, in the field of reproductive cells, 104 IVF centres and 92 IUI labs are
accreditation, authorisation, designation and	authorised and had an ART activity in 2011. Among the IUI labs, near 100% are
licensing?	private. Among the IVF centres, it is about 40% which have a public status. Some of
	them have both status private and public (different status between the clinical unit
	and the biological unit). A legal provision set that only the public or if private, non
	profit establishments, are authorised to manage non parner donors.
5. Inspections (Article 7, Directive 2004/23/EC)	<u> </u>
5.1. Is a system in place for organising inspections	Yes
and control measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of	The CA in charge of inspection of TE (non reproductive tissues and cells) is ANSM.
the CA in charge of inspections.	The division in charge of inspection is "INSBIO" (inspection of biological products).
and of the charge of hispections.	For ART, the regional agencies are in charge of inspection. The ABM must publish a
	mandatory annual report on inspections performed by the regional agencies, according
	mandatory annual report on inspections performed by the regional agencies, according

	to their inspection reports they send to ABM.
5.1.2. If yes, please specify staffing (how many	4 inspectors in ANSM. Regarding ART, there are 22 regional agencies with at least 2
inspectors).	inspectors trained in ART per agency in order to inspect every two years all the ART
- <b>r</b>	centres.
5.2. Does the inspection scheme interact or overlap	Yes
with the inspection scheme of other activities, for	
example blood, pharmaceuticals, etc. (e.g. same	
inspector team, common training, common	
documentation, etc.)? (more than 1 answer	
possible)	
5.2.1. If yes, please specify. (more than 1 answer	Others
possible)	
Please specify other.	Common trainings about the general inspection practises, the frame of the inspection
	report, the common inspection procedures, the graduation of the shortcomings based
	on a risk approach etc
5.3. How many routine inspections of tissue	27
establishments for non-reproductive tissues/cells	
were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues	0
establishments for non-reproductive tissues/cells	
were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or	
reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of	0
tissues establishments for non-reproductive	
tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-	0
reproductive tissues/cells conducted in 2011	
(01/01/2011 to 31/12/2011): What was the number	
of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-	27
reproductive tissues/cells conducted in 2011	
(01/01/2011  to  31/12/2011): What was the number	
of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-	8
reproductive tissues/cells conducted in 2011	
(01/01/2011 to 31/12/2011): What was the number	
of inspections carried out where major	
shortcomings were noted? 5.3.6. Outcome of inspections of TEs for non-	0
*	U
reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number	
of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-	0
reproductive tissues/cells conducted in 2011	U
(01/01/2011 to 31/12/2011): What was the number	
of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-	0
reproductive tissues/cells conducted in 2011	V
(01/01/2011 to 31/12/2011): What was the number	
of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted	32
in ART establishments (from 1/1/2011 to	32
31/12/2011)?	
J1/12/2011):	1

T	
5.4.1. How many inspections were conducted in	1
ART establishments following serious adverse	
events or reactions, or suspicion thereof (from	
1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were	0
conducted on ART establishments (from 1/1/2011	
to 31/12/2011) (e.g. due to a whistle-blower)?	
Please specify.	
5.4.3. Outcome of inspections of ART tissue	0
establishments carried out in 2011 (01/01/2011 to	
31/12/2011): What was the number of inspections	
carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried	32
-	32
out in ART establishments where minor	
shortcomings were noted?	
5.4.5. What was the number of inspections carried	32
out in ART establishments where major	
shortcomings were noted?	
5.4.6. What was the number of inspections carried	0
out in ART establishments followed by suspension	
of authorisation?	
5.4.7. What was the number of inspections carried	0
out in ART establishments followed by closure of	
respective establishments?	
5.4.8. What was the number of other inspections of	0
ART establishments? Please specify.	
5.5. Which type of routine inspections do you	General system-oriented inspections
conduct? (more than 1 answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine	The type of routine inspection is decided according a risk based inspection
inspection to conduct?	programme. Regarding ART, routine inspections are planned every two years
	according to a national inspection programm. However the lack of ressources leads to
	real difficulties to respect the interval of two years between two inspections.
5.7. Until 2011, did you implement the requirement	Yes
concerning the time interval between two	
inspections (Art. 7.3.)?	
-F ()	
5.8 How many TEs were inspected at least twice	In the field of reproductive cells the TEs inspected twice were TEs with major
5.8. How many TEs were inspected at least twice	In the field of reproductive cells the TEs inspected twice were TEs with major
5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?	shortcomings. 14 TEs were inspected twice. The total number of inspections was
between 2008-2011 (01/01/2008-31/12/2011)?	shortcomings. 14 TEs were inspected twice. The total number of inspections was 163.
between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of	shortcomings. 14 TEs were inspected twice. The total number of inspections was
between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?	shortcomings. 14 TEs were inspected twice. The total number of inspections was 163.  No
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between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?  5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational	shortcomings. 14 TEs were inspected twice. The total number of inspections was 163.  No  The agences régionales de santé (ARS) are in charge of the inspection of the procurement establishments. ANSM, time to time, inspect procurement establishments when there is doubt about the quality and safety of the products. Regarding ART, centers carry out both procurement and clinical applications of gametes and embryos. The regional agencies must inspect the ART centres for both clinical and biological activities.  Yes
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between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?  5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used	shortcomings. 14 TEs were inspected twice. The total number of inspections was 163.  No  The agences régionales de santé (ARS) are in charge of the inspection of the procurement establishments. ANSM, time to time, inspect procurement establishments when there is doubt about the quality and safety of the products. Regarding ART, centers carry out both procurement and clinical applications of gametes and embryos. The regional agencies must inspect the ART centres for both clinical and biological activities.  Yes  It depends on the kind of implemented process of tissues and cells  No  For inspections ,we use the national good tissues and cells practices (the 27th october 2010 ANSM decision), ISO norms, GMP, aide memoire , decree and ministerial orders. Regarding ART, routine inspections are based on the control of the compliance with the regulations in force in France and particularly with the rules of

guidelines/inspections.	Good practices in ART:
	http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022809674&dateTexte=&categorieLien=id National guide for ART centres inspection: http://www.agence-biomedecine.fr/Referentiel-inspection-AMP
5.12. Did you send any of your inspectors to the	Yes
training courses organised by EU-funded projects	103
(e.g. EUSTITE, SOHO V&S)?	
5.12.1. If yes, how would you rate the usefulness	5
and efficacy of these training courses on a scale	
from 1 to 5 (1 = not important, $2 = \text{sufficient}$ , $3 =$	
good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a	Yes
tissue establishment in another MS in collaboration	
with the NCA in that MS (Art 7(6))?	
5.13.1. Could you please explain why?	In some cases, French national CAs needs to know the accuracy of the data provided by the MS, suppliers (distributors) of tissues and cells.
5.14. Did you receive/organise an inspection of a	No
tissue establishment in your country at the request	110
of another MS in collaboration with the NCA in	
that MS (Art 7(6))?	
5.15. Did you organise any inspections of	Yes
procurement centres or tissue establishments in	
third countries from which tissues and/or cells	
were imported in your country (as recorded by 31/12/2011)?	
5.15.1. If yes, please specify why.	In some cases, the French national CAs needs to know the accuracy of the data
	provided by the procurement establishment or provided by the tissue establishments,
	importer of tissues and cells
5.16. Have you asked another MS, or have you	Yes
been requested by any other MS, on the results and	
control measures of your inspections, as part of an	
enquiry/investigation? 5.16.1. If yes, please specify.	Some European member states (poland, Danemark, Portugal, Estonia, etc)
5.17. Would you be interested in developing joint	Yes
inspections? Joint inspections should be	
understood as inspections of tissue establishments	
conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third	
countries.	
5.18. Do you have any additional comments on	There is a need of organizing a legal framework in the field of joint inspections
inspections?	especially when tissues and cells are imported within EU countries.
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue	Yes
establishments that are explicitly authorised to	
perform import/export of tissues and celles from/to third countries?	
6.2. Please specify the number of tissue	tissues:1; HSC: all the 36 HSC centers
establishments authorised to import tissues and	about 1, 1150. un un 50 1150 contois
cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue	tissues :5; HSC :all the 36 centres,
establishments authorised to export tissues and	
cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in	1. through the import/export authorisation procedure where the CA authorizes the
place for verifying the equivalent standards of	product based on the assessment of the data provided by the importer in the dossier submitted to the CA 2. through the documents accompanying each import and sent to
quality and safety for importation of skin from third countries.	the importing TE; 3. through inspections of the supliers of tissues and cells in third
uma countries.	countries. Currently no product authorization has been granted for this type of tissues
	imported from a third country.
6.5. Please specify which procedures you have in	the same as 6.4 Currently no product authorization has been granted for this type of
	1

tissues imported from a third country.
the same as 6.4 Currently no product authorization has been granted for this type of
tissues imported from a third country.
the same as 6.4 Currently no product authorization has been granted for this type of
tissues imported from a third country.
ussues imported from a time country.
through the import/export authorization procedure where the CA authorizes the
product based on the assessment of the data provided by the importer in the dossier
submitted to the CA. An authorization is granted on a case by case basis for this type
of cells
the same as 6.8
Import of reproductive cells in France from third country or EU MS must be
individually authorised by the ABM. A specific file with available data on the
conditions of the procurement, donation, testing, etc is submitted to ABM by the
French ART centre requesting an authorization. ABM makes its decision on a case by
case basis depending on the data provided and the respect of French legal and ethical
principles during the whole process.
Yes
1 CS
tissue: 0; HSC = 283; Reproductive cells = 4. the data per country of origin are not
tissue: 0; HSC = 283; Reproductive cells = 4. the data per country of origin are not available.
available.
available. Yes
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of
available. Yes
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other
available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA
available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.
available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA
available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No
available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No  In the field of HSC, import and export are necessary to comply with the medical need
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No  In the field of HSC, import and export are necessary to comply with the medical need for matching between donor and recipient. 75% of HSC are imported in France.
available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No  In the field of HSC, import and export are necessary to comply with the medical need
available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No  In the field of HSC, import and export are necessary to comply with the medical need for matching between donor and recipient. 75% of HSC are imported in France.  Direct import by hospital or clinics are not allowed in France.
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available.  Yes  tissues = 0 ; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No  In the field of HSC, import and export are necessary to comply with the medical need for matching between donor and recipient. 75% of HSC are imported in France.  Direct import by hospital or clinics are not allowed in France.  e 23 Directive 2004/23/EC)  Yes  The problem is that when a 6.2 authorisation is granted by another Member-state we
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available.  Yes  tissues = 0; HSC = 64 Reproductive cells = 7 (the data per countries of destination are not available)  No  F. Other  No tissues are imported from a third country - imported cells are based on HLA compatibility.  No  In the field of HSC, import and export are necessary to comply with the medical need for matching between donor and recipient. 75% of HSC are imported in France. Direct import by hospital or clinics are not allowed in France.  12 23 Directive 2004/23/EC)  Yes  The problem is that when a 6.2 authorisation is granted by another Member-state we don't know how they have performed their assessment ,which were their safety criteria In the field of HSC, international registries follow WMDA standards.
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quality requirements? Please specify.	
7.2. How do you ensure that tissues establishments	-through the evaluation of the file of the TE authorization submitted to the NCAs and
	which contains data about distribution such as the requirements to provide a
fulfil the requirements of Art. 23 of Directive	*
2004/23/EC regarding quality of tissues and cells	description of the organization set up to ensure the distribution; - also through
during distribution? Please specify.	inspections on site carried out on the basis of the good tissues and cell practices.
7.3. Do you allow direct distribution to	No
hospitals/clinics in your MS from TEs in another	
MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the	Yes
recipient of specific tissues and cells (Art. 6,	
Directive 2006/17/EC)?	
7.4.1. If yes, how many authorisations were given	For HSC = 607; For reproductive cells = 49
in 2011 (01/01/2011 to 31/12/2011)?	1 of fiber 607, 1 of reproductive cens 47
	HSC = Bone marrow, PBSC, cord blood and lympho; Reproductive cells = gametes,
7.4.2. If yes, for which tissues/cells?	
7.5 D. H. (1)	embryos.
7.5. Do you collect data regarding the cross-border	Yes
exchange of tissue/cells between your country and	
other EU MS?	
7.5.1. Please provide us with data (country of	- for tissues (skin ,bones ,vessels etc) : 1643 distributions to others MS For HSC,
destination, type of tissue/cell and number of units	see EBMT: exchanges within the UE or the world according to the needs of
distributed) concerning distribution to other MS in	matching For reproductive cells, the main part of exchange is represented by export
2011 (01/01/2011-31/12/2011).	of cryopreserved sperm to Spain, in order to obtain an ART with donated eggs. We
	know that this represents a very small part of the patients who travel abroad for egg
	donation.
7.5.2. Please provide us with data (country of	- For tissues (skin ,bones ,vessels etc) : 4480 distributions from others MS - For
origin, type of tissue/cell and number of units	HSC, see EBMT. Exchanges within the UE or the world according to the needs of
distributed) concerning distribution to other MS in	matching in 9 cases, autorizations are given by ABM for import gametes from a
2011 (01/01/2011-31/12/2011)	EU MS, probably because of the legal restrictions about embryo transfers in
	Switzerland and Germany. In other few cases, authorisations are given because
	patients intend to move while gametes or embryos are cryopreserved.
7.6. Are you aware of any significant changes in	No
2012 which may invalidate the 2011 data on cross-	
border exchanges of tissues/cells between your	
country and other EU MS?	
7.7. Do you allow brokerage companies for either	No
distribution in EU and/or import/export of	
tissues/cells? In this context, a brokerage company	
means a body that arranges transactions between a	
supplier (tissue establishment/company selling	
tissues or cells) and a buyer (a tissue	
establishment/a hospital or clinic/an individual)	
without undertaking activities of processing,	
preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on	
distribution?	
	obligations (Article 10 Directive 2004/22/EC)
8. Register of tissue establishments and reporting	
8.1. Do you have an annual report model/template	No
on the activities of tissue establishments in your	
Member State? (Article 10(1)). If yes, please	
upload the template.	
8.1.1. If no, why not?	in progress.
8.2. How many tissue establishments submitted	100% (all)
annual reports of their activities during 2011.	
Please provide an estimation. (1 answer possible)	
8.3. Are these reports publicly available? (Article	No
	110
10(1))	V
8.4. Do you publish a national annual report of the	Yes
consolidated activities of all tissue establishments	
in your country?	1

8.4.1. Please insert the link to the published national annual report.	http://ansm.sante.fr/var/ansm_site/storage/original/application/79a989c66ec609a6c7a 60db3464f9636.pd ; http://www.agence.biomedecine.fr/AMP ; http://www.agence.biomedecine.fr/CSH
8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2))	Yes
8.5.1. If yes, please provide us with the link to the register's web site.	http://ansm.sante.fr/var/ansm_site/storage/original/application/b9b896c06d836783486 5273951775d4b.pdf; http://www.agence.biomedecine.fr/Autorisation-des-centres; http://www.agence.biomedecine.fr/Les-etablissements-autorises.73
8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?	Yes
8.6.1. If yes, what data are provided to EUROCET? Please specify.	Data about tissues and cells etablishment activities, about the processed products and about the authorised ART centers and activities performed, activities and results (pregnancies, children) in partner and non partner donation.
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; a	nd Directive 2006/86/EC)
9.1. Was the donor identification system (Art. 8(2))	Yes
implemented in your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer possible)	Tissue establishment
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	by inspections Only electronic files in HSC centres and national registry in ABM
9.5. Do you have any additional comments on traceability?	
	tions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in	Yes
place (for the reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	ABM is leading the Assisted Reproductive Techniques (ART) vigilance system, in relation with ANSM - ANSM for biovigilance (including organs, tissues and cells) in relation with ABM
10.1.2. If yes, please provide a short description of its organisation.	In tissues and cells field other than reproductive At the top of the system there's the ANSM which coordinates the actions of the stakeholders who play a part in the biovigilance system. ANSM receives all the notifications of adverse events/reactions and takes the adequate safety measures. Then, in each public or private tissues or cells establishment, there is a local biovigilant correspondent who sends the dedicated form of adverse events/reactions to the ANSM.An assessment is performed for each report by the local biovigilant,the ANSM assessors in link with the Agence de la biomedecine.Based on the findings,corrective actions are implemented locally or nationally. The ART VS is organised according to 2 levels: - National level: Agence de la biomedecine × Leads the national ART VS × Designs methods and tools (documents, grading scale, I.S. etc.) × Collects adverse event and reactions (AER) × Analyses AER × Coordinates investigation and monitor corrective measures × Implements national guidelines × Reports to Ministry of Health and professionals × Coordinates nationally with other VS - Local level: ART clinical centers and lab × Identify a local correspondent for ART VS (mandatory) × ART professionals inform the CLA of AER × The CLAs notify the ABM and coordinates locally with other VS
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	No
10.2.1. If no, what template do you use? You are welcome to upload the template if you wish.	The principles included in the common Approach Document developed for the Annual reporting to the EC were already in place in the french proceedings. No, ABM does not use the SAR/E templates developed by EC since it is not really appropriate for reproductive cells and embryos

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10.3. Do you use the Common Approach	Yes
Document developed for the Annual reporting to	
the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in	Yes
charge of collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in	100%
2011 the SAR/SAE data as requested (please	100/0
provide the % from the total number of TEs	
authorised in your country).	
10.6. Do you have a mandatory procedure for the	Yes
transplantation centres when reporting SAR/SAE	
to the TEs which distributed the tissues/cells (Art	
11.2)?	
10.6.1. If yes, please provide a brief description.	http://ansm.sante.fr/var/ansm
10.0.1. If yes, piease provide a orier description.	site/storage/original/application/bcef203df79ae53c65ff2277f9bc52f5.pdf In each ART
	center, the local ART vigilance correspondant notifies the SARE using a specific
	form. Information related to SARE collected are defined by law.
10.7. Do you give feedback to the TEs regarding	Yes
SAR/SAE recorded at national level?	
10.7.1. Please specify.	Only if the SAR/SAE could impact their own activities.
10.8. Do you give feedback to the TEs regarding	Yes
SAR/SAE recorded at EU level?	
	Outsifets CAD/CAE sould immed their survivier
10.8.1. Please specify.	Only if the SAR/SAE could impact their own activities.
10.9. Do you require your TEs to have a recall	Yes
procedure?	
10.10. How many recalls related to safety and	see annual biovigilance report (www.ansm.sante.fr)
quality of tissues/cells were issued in your country	
in 2011? Please specify the number and which	
tissues were recalled and why (e.g. missing	
consent, quality defects etc).	
10.11. Do you have in place a system/procedure to	Yes
notify Tissue Establishments and procurement sites	
in case of a national rapid alert?	
10.11.1. If yes, please give a short description of	All procurements sites and TE must designate a local biovigilance correspondant and
the system/procedure.	both state their coordinates (mail and fax). In case of alert, one is sent by mailing list
· · · · · · · · · · · · · · · · · · ·	and depending on its severity, coupled with a fax. In the field of ART, any alert could
	be communicated through a specific and secure I.S.
10.12 D	
10.12. Do you have in place a system/procedure to	Yes
notify Tissue Establishments and procurement sites	
when a rapid alert is issued via the EU RATC	
platform?	
10.12.1. If yes, please give a short description of	All procurements sites and TE must designate a local biovigilance correspondant and
the system/procedure.	both state their coordinates (mail and fax). In case of alert, one is sent by mailing list
Joseph procedure.	and depending on its severity, coupled with a fax. In the field of ART, any alert could
	be communicated through a specific and secure I.S.
10.12 B	
10.13. Do you provide data regarding SAR/SAE to	No
the EUROCET registry (non-mandatory	
reporting)?	
10.13.2. If no, please specify why not.	
10.14. Do you notify alerts communicated via	Yes
these tissues and cells national vigilance system	
also to other national vigilance/alert systems?	
· ·	TTii
10.14.1. If yes, please specify which of the	Haemovigilance
following systems are usually contacted. (more	Pharmacovilance
than 1 answer possible)	Medical devices
	Other
Please specify 'other'.	nosocomial infection surveillance
10.15. Did you send a vigilance officer/contact	Yes
point to the trainings organised by the EU-funded	
project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness	4

and efficacy of these trainings on a scale from 1	
(insufficient) - 2 (sufficient) 3 (good) - 4 (very	
good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	In France not only severe SARE are collected but also SARE. The national ART VS requires also to notify all AR related to ART activities not only those related to the quality of reproductive cells. We consider the notification templates presented in the tools I the 2006/86 EUTCD is not appropriate for ART
11. Consent and personal data protection (Article	13 and 14, Directive 2004/23/EC)
11.1. What consent system for living tissue/cell	Explicit consent (opt-in)
donation do you have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	It is a legal requirement for donation of soho. We think that it's the best way to guarantee the donor's freedom and will because the condition of this consent is a clear information provided to the donor, particualry regarding all the medical consequences of his donation.
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed consent (opt-out)
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	No further authorisation is needed
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Interviews with personnel Interviews with relatives of deceased donors
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	Only trained personnel is allowed to provide such information
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	It's a principle set in the French bioethical Law: the article L.1211-5 (code de la santé publique) lays down that "no information allowing to identify at the same time the one who donated an element or a product of his body and the one who received it cannot be revealed".
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	there are two measures: 1) the first one mentionned above lays down that no information allowing to identify at the same time the one who donated an element or a product of its body and the one who received it cannot be revealed". 2) the second one is mentionned in the article R.1211-19 of the french health code (code de la santé publique) which states that "traceability is ensured by a codification which is also uses to guarantee the anonymity of the two persons involved in a procurement and a transplantation.
11.9. Does your national legislation allows disclosure of donor data in case of gametes	No
donation?  11.9.1. If no, please specify the circumstances and measures in place.	An anonymous code is allocated as the donor is recruited at the ART center level and this code will be kept during the whole procedure untill gametes are distributed. No information concerning the donor (position, hobbies etc) is given to the recipients in order to avoid to reveal potentially identifying data. Staff dealing with recruitement of donors are specifically trained. Registries of donors and donations are strictly kept at a local level and have validated protection against intrusion and are controlled by the CNIL and during inspections.
11.10. Do you have any additional comments on consent and data protection?	
12. Selection, evaluation and procurement (Article	e 15 Directive 2004/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive	Stadardised questionnaires at national levels Inspections of TEs and procurement sites
2006/17/EC)? (more than 1 answer possible)	

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12.2. How do you ensure that all requirements	Standardised questionnaires at national level
related to the evaluation and selection of donors of	Inspections of ART centres
reproductive cells are respected in your country	Audit documentation
(Art 15 (1), Annex III of Directive 2006/17/EC)?	
(more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor	No
selection than those listed in Annex I of the	
Directive 2006/17/EC?	
12.4. What sources are required in your MS for the	Interview with the donor's family or a person who knew the donor well
evaluation of a deceased donor of tissues/cells?	Medical records of the donor
(more than 1 answer possible)	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
12.5. Do you have more stringent criteria for	No
selection of donors of reproductive cells than those	
listed in Annex III of the Directive 2006/17/EC?	
12.6. Do you have more stringent criteria for	No
autologous donation than those listed in Annex I of	
the Directive 2006/17/EC?	
12.7. Do you require more information on the	No
donation of tissues/cells than the mandatory one as	
laid down in the Annex of Directive 2004/23/EC	
(Art 15(3)?	
12.8. How do you ensure that all requirements	Inspection of tissue establishment
regarding tissues and cells' procurement, packaging	Audit of tissue establishment
and transport are complied with by tissue	Inspection of the centre of human application (e.g. transplantation centre, ART centre)
establishments in your country (Art 15(1), Annex	Audit of the centre of human application
IV of Directive 2006/17/EC? (more than 1 answer	
possible)(For this question "audit" means a	
documented review of procedures, records,	
personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate	
adherence to the written SOP, standards or	
governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance	
for the Transplantation of Organs, Tissues and	
Cells, 2011))	
12.9. Do you have any additional comments on	
selection, evaluation and procurement?	
13. Quality management, responsible person, pers	onnel (Article 16, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments	Authorisation requirement
in your country have in place a quality system	Inspections
respecting the provisions of the Directive	Internal audits
2004/23/EC Art 16.1? (more than 1 answer	External audits
possible). (For this question "audit" means a	
documented review of procedures, records,	
personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate	
adherence to the written SOP, standards or	
governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance	
for the Transplantation of Organs, Tissues and	
Cells, 2011)).	
13.2. How do you ensure that tissue establishments	Authorisation requirement
have a responsible person fulfilling the	Inspections
requirements of Art. 17(1)? (more than 1 answer	Regular evaluation of personnel
possible)	Mandatory trainings
13.3. How do you ensure an appropriate training	Authorisation requirement
for the personnel directly involved in the activities	Inspections
of tissue establishments? (more than 1 answer	Regular evaluation of personnel
possible)	Mandatory trainings

13.4. Do you have national/regional/local training	Ver
	Yes
programmes for the personnel of tissue	
establishments?	
13.4.1. If yes, please specify.	ABM organizes different trainings for health professionals working in the fields of
	organs, tissues and HSC procurement and transplantation .It has experimented this
	year a learning management system. It also organises different trainings on quality
	management, legal and ethical aspects in ART or also for midwives involved in ART
	activities. The programs are available on the website of ABM. Moreover ABM
	proposes several annual meetings for the different kinds of health professionals
	working in organs, tissues and HSC procurement and transplantation and in ART(for
	example the annual meeting of the correspondents in ART vigilance during the
	national congress in ART).
13.5. Any additional comments on quality	,
management, responsible person, personnel?	
14. Reception, processing, storage, labelling and p	ackaging (Art 19.22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments	National regulation/policy for reception of tissues/cells
in your country fulfill the requirments of the Art.	Inspections of tissue establishments
19 (Tissue and cell reception) of Directive	Internal audits of tissue establishments
2004/23/EC and Annex IV of Directive	External audits of tissue establishments (e.g. ISO)
2006/17/EC? (more than 1 answer possible)	
14.2. How do you ensure that tissue establishments	SOPs for all processes affecting quality and safety are mandatory for authorisation
in your country fulfill the requirements of the Art.	Inspections of tissue establishments
20 (Tissue and cell processing) of Directive	Internal audits of tissue establishments
2004/23/EC? (more than 1 answer possible)	External audits of tissue establishments (e.g. ISO)
14.3. How do you ensure that tissue establishments	SOPs for procedures associated with storage of tissues and cells are mandatory for
in your country fulfill the requirements of Art. 21	authorisation
(tissue and cell storage conditions) of Directive	Inspections of tissue establishments
2004/23/EC? (more than 1 answer possible)	Internal audits of tissue establishments
( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( ( (	External audits of tissue establishments (e.g. ISO)
14.4. How do you ensure that tissue establishments	SOPs for procedures associated with labelling and packaging are mandatory for
in your country fulfill the requirements of Art. 22	authorisation
(labelling, documentation and packaging) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive	Internal audits of tissue establishments
2006/17/EC? (more than 1 answer possible)	External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception,	All the questions are related to the presence of procedures and not on their contents,
processing, storage, labelling and packaging?	what is assessed regarding the quality of the tissues and cells procured, processed and
	controlled.
15. Third party agreements (Art. 24 Directive 200	4/23/EC)
15.1. Are third party agreements foreseen/allowed	Yes
in your national legislation?	
15.1.1. If yes, have tissue establishments in your	Yes
Member State notified third party agreements?	
15.1.1.1. Under which circumstances and for which	When third parties provide good or services which might have an impact on the
responsibilities?	quality and safety of the products. The agreement clearely states the responsabilities
1.	of each part of the agreement and particularly it describes the tasks entrusted with the
	third party and the way it has to carry out them.
15.1.1.2. How are third party agreements	At the beginning through the dossier submitted for the authorization of tissue
controlled (Art 6.2) by the Competent	establishment and after that through inspections.
Auhtority(ies) in your MS? Please specify.	HCC
15.2. Any additional comments on third party	HSC centres have an agreement with FDA. ABM has an agreement with a transport
agreements?	company for CB unit shipments.
16. General comments - implementation	
16.1. Do you have at national level more stringent	Yes
quality and safety requirements than those	
requested by the EU legislation in this field (e.g.	
restrictions concerning the donation/use of certain	
tissues/cells, mandatory unpaid donation etc.)?	
16.1.1. Please specify.	Because quality and safety are directly linked with the conditions of recrutment of
1 ,	donors, the French law set ethical provisions. Among them: - the recruitment of
	donors must be managed through a non profit organisation which can evaluate the
	The state of managed and again a non-profit organization which can evaluate the

	needs at a national level and organize on a non-profit basis the promotion and the evaluation of the donors; - payment of donors for donation is totally forbidden except in the cases of duly justified therapeutic interest, donation is anonymus and it's done for all the patients who need a transpalntation: for this reason the private autologous cord blood banks are not authorized in France Key principles should be reasserted at the UE level: the products of the human body should not be a source of financial gain. Some compensation practices relate to payment and leads to ethical abuses.
16.2. Has your Member State encountered any	ART provisions
difficulties in implementing the requirements in the	Testing provisions
EU Tissues and Cells Directives? Please choose	Import-export
from the options below.	Vigilance
	Inspections
16.2.1. For all selected options in question 16.2.,	Terminology not appropriate for the field of reproductive cells. Difficulties to strictly
please provide a short description.	apply the periodicity of two years between two inspections of the same ART center.
	The French system of ART vigilance takes care of women exposed to complications of ovarian hyperstimulation and surgical collection of eggs which are not taken into account in the European system as they don't have consequences on the quality of reproductives cells. D.2006-17: the requirements for testing have to be revised for both partner and non partner donations (genetics and virological testing) D 2006-86: the requirements about quality of air in the facilities should be discussed in the context of ART (class D classification cannot be applied for ART field due to some processes contrainst)
16.3. In your opinion, in which of the following	Directive 2004/23/EC
Directives are there shortcomings (if any)? (more	Directive 2006/17/EC
than 1 answer possible)	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC?	1) In the tissues and cells field There is a need: - to extend the scope of the directive to the tissues and cells collected and transplanted back to the same patient, within the same surgical procedure, after being subject to a manipulation at the surgical unit or in the patient's room so that the cells or tissues are not intended to be used for the same essential function; -to clarify the legal status of the dehydrated human placenta and the status of certain products for which it's difficult to determine which is the relevant legal field (directive 2004/23; medical device directives; ATMP regulation) -to extend the scope of the inspection organized, at the request of the competent authorities of another member-state whenever there are grounds for suspecting non compliance with the principles of the directive; - to add a provision which excludes a competent authority which is as the same time a tissue establishment; -to change the frequency of the inspection of tissue establishment (between two inspections the intervall should not exceed 3 years (instead of two years) -to harmonize the process assessment for tissues and cells to avoid as much as possible the differences on the quality of the tissues and cells prepared in the different meember-states via a standardized format of dossier and via guidelines -to develop rules and guidelines applying to ATMP with hospital exemptions -to apply the international santards (FACT,JACIE,AABB) in all cord blood banks (private/public,autologous/allogenic) 2) In the field of ART threis a need to foresee a specific technical directive for reproductive tissues and cells.
16.3.2. How would you suggest to solve these	- the requirements for testing have to be revised for both partner and non partner
issues in Directive 2006/17/EC?	donations (genetics and virological testing)
16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC?	- In order to guarantee the harmfulness and the therapeutic efficiency of the tissues and cells ,by providing that in certain cases the CA can require the implementation of clinicals trials for new tissues and cells products results the requirements about quality of air in the facilities should be discussed in the context of ART (class D classification cannot be applied for ART field due to some processes contrainst) - to harmonize the process assessment for tissues and cells to avoid as much as possible the differences on the quality of the tissues and cells prepared in the different
	meember-states via a standardized format of dossier and via guidelines

## A.1.11. Survey response Germany

1. Public information	I was a second of the second o
1.1. Name of National Competent Authority (NCA) 1:	Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und
	biomedizinische Arzneimittel
1.1.2. Address of NCA 1:	Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany
1.1.3. Telephone (central access point):	+49 6103 77 0
1.1.4. E-mail (central access point):	pei@pei.de
1.1.5. Website:	www.pei.de
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Blood and blood components
	Pharmaceuticals
	Other
Please specify 'other':	Other biomedicinal products such as sera, vaccines, allergens,
	advanced therapy medicinal products and xenogenic medicinal
	products
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	Vigilance
	Other
Please specify 'other':	Marketing authorisation of tissue products and their vigilance
	including tissue vigilance inspections
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	The Paul-Ehrlich-Institut is the "Federal Institute for Vaccines and
organisation of the National Competent Authority(ies) (e.g.	Biomedicines", thus a higher competent authority of the Federal
departments, staffing, number of senior and junior inspectors, staff	Republic of Germany. It reports to the "Bundesministerium für
working on EU affairs and legal matters, vigilance officers, budget,	Gesundheit" (Federal Ministry of Health). The Paul-Ehrlich-Institut
independence from government etc.).	is the National Competent Authority for Tissues and Cells. Most of
	its activities relate to the various duties laid down in German and
	European medicinal product legislation, such as for example the
	approval of clinical trials and the marketing authorization of
	particular groups of medicinal products. The legal responsibilities of
	the Paul-Ehrlich-Institut relate to biological medicinal products such
	as vaccines for humans and animals, medicinal products containing
	antibodies, allergens used for therapy and in diagnostics, plasma-
	derived medicinal products and medicinal products for gene therapy
	somatic cell therapy and xenogeneic cell therapy, i.e. for processes
	in the latest forms of biomedical treatment. Product responsibilities
	extend to blood and blood products for transfusion medicine and as
	well as tissue and cell products. The Paul-Ehrlich-Institut's
	organization entails 7 product-related divisions performing research
	and regulatory activities. The division "Safety of Medicinal Product
	and Medical Devices" performs tasks related to pharmacovigialnce,
	hemovigilance and tissue vigilance. The sections "EU-
	Cooperation/Biological Medicinal Products", "Legal Affairs",
	"Clinical Trials", "Microbial Safety", "Viral Safety" and
	"Biostatistics", for example, provide support for assessment and
	regulation of all vaccines and biomedicines. The division
	"Administration" provides administrative support. For further detail
	see the Annual Report of the Paul-Ehrlich-Institut
	(http://www.pei.de/DE/institut/jahresberichte/jahresberichte-
	node.html). As a public body, the Paul-Ehrlich-Institut is subject to
	the principles of national budget law (laid down mainly in the
	Constitution), a number of other relevant laws, and the Annual
	Budget Act. The Paul-Ehrlich-Institut receives an annual budget
	from the government that is not affected by the amount of collected
	fees. The Paul-Ehrlich-Institut's budget and finance plan are divided
	into types of expenditure for personnel expenses, tangible expenses
	(including expenses for consumables, facility management, staff
	training, travels etc.) and investment expenses. For further details

	see the Annual Report of the Paul-Ehrlich-Institut
	(http://www.pei.de/DE/institut/jahresberichte/jahresberichte-
	node.html).
1.6. In case of MS with federal or decentralised systems, please	Accreditation, authorisation, licensing of TEs
indicate the roles/tasks of the Regional Competent Authority(ies).	Inspection
(more than 1 answer possible)	Vigilance
•	Other
Please specify 'other':	The Regional Competent Authorities in the German Länder are
	basically entrusted with the task of supervising and continuously
	monitoring the compliance with legal provisions. For this purpose,
	they grant authorisations.
1.7. Could you please describe the competence/mandate of the	There is a splitted competence between the National Competent
Regional Competent Authority(ies) and their relation with the	Authority (PEI) and the Regional Competent Authorities of the
National Competent Authority(ies) for tissues and cells:	Länder. Generally spoken, the Regional Competent Authorities are
	responsible for activities in matters of Article 5 and 6 of the
	Directive 2004/23/EC well as for granting import authorizations,
	Article 9 of the Directive 2004/23/EC. Furthermore, it is their
	regional responsibility to continuously monitor the compliance with
	legal provisions. In case of noncompliance, they also have the power
	to impose penalties/sanctions. The PEI is responsible for the
	marketing authorisation of tissue products as well as for the
	fulfilment of pharmacovigilance duties . Both, the Regional
	Competent Authorities and the PEI work together, e.g. in the field of
	inspections. The German Federal Government as well as the Paul-
	Ehrlich-Institut have no authority to issue directives opposite the
	Länder. For further information regarding the Regional Competent
	Authorities of the Länder see annex.
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	By inspecting the documentation associated with procurement that is
• /	available in the tissue establishment working with procurement
	centres
212 H	
2.1.2. How many such authorisations were granted in 2011 (01/01-	226
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	226
31/12/2011)?	
31/12/2011)? 2.2.1 Please provide the number of procurement centres in which	226 345
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues,	
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
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31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	983
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3.1/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	983  208  234  Inspections of the site/centre Analysis of the mandatory documentation  Yes  207 In Germany, the Regional Competent Authorities are
3.1/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	983  208  234  Inspections of the site/centre Analysis of the mandatory documentation  Yes  207 In Germany, the Regional Competent Authorities are responsible for this authorisation.
3.1/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?  2.4.1. Please provide the number of the laboratories performing donor testing.	983  208  234  Inspections of the site/centre Analysis of the mandatory documentation  Yes  207 In Germany, the Regional Competent Authorities are responsible for this authorisation.  Inspections of the laboratories
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	983  208  234  Inspections of the site/centre Analysis of the mandatory documentation  Yes  207 In Germany, the Regional Competent Authorities are responsible for this authorisation.

possible)	Other
Please specify 'other':	Authorisation of the laboratories by inspection of the laboratories
	and analysis of the mandatory documentation in the laboratories.
2.6. Please provide data on qualified laboratories accredited,	173 The performed donor tests in the qualified laboratories depend
authorised or licensed in your country (e.g. number, year of	on the scope of the authorisation. Most of the laboratories provide
accreditation/authorisation/license, which donor tests are performed	the following tests: HIV1, HIV2 (including NAT-tests), Hepatitis B,
etc.).	Hepatitis C (including NAT-tests), HTLV-1/2, Treponema pallidum,
,	Chlamydien. Laboratories also provide the subsequent mentioned
	tests: - Hepatitis A - CMV (including NAT-test) - Epstein-Barr-
	Virus - Toxoplasma - Malaria - Rubella - Trypanosoma cruzi -
	Parvovirus B 19 (including NAT-test) - Gonorrhoea (including
	NAT-test) - RV - VZV - HSV (including NAT-test) - Measles
	(including NAT-test) - RhD - HLA-typing - blood-typing
2.7. Do you have any additional comments on procurement?	No.
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT testing is not mandatory by German law, however, it is an
please indicate whether you intend to make it mandatory or to	additional requirement imposed by the national competent authority.
encourage its use? Please specify why or why not (e.g. number of	According to current scientific knowledge viruses can be transmitted
additional cases detected, cost-benefit etc.).	by cardiovascular and highly blood supplied tissues (e.g. HBV and
	HCV). Therefore, the competent authority PEI requires in addition
	to serological testing and as a further safety measure HIV-, HBV-,
	and HCV-NAT for deceased donors (exceptions for cornea and skin)
	. Since for cardiovascular and highly blood contaminated tissues
	effective virus inactivation is not possible (preservation of tissue
	morphology necessary) the advantage of NAT is apparent (reduction
	of diagnostic window period).
3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?	Yes
r	All aggregatams intended to be used for the detection of infections
3.4.1. Please specify why:	All assay systems intended to be used for the detection of infections with HIV, HCV and HBV used in the European Union have to
	comply with the requirements of Directive 98/79/EC and with the
	Common Technical Specifications (CTS). The CTS require
	investigations on the sensitivity and specificity of the assays which are fulfilled for all devices bearing the CE-mark. These
	investigations are to be carried out using serum and plasma. In
	general, the CE-marked assays are not validated for the use of
	cadaveric specimens. After death, rapid changes due to autolysis,
	haemolysis, bacterial growths etc. occur in the blood specimens. The
	latter complicate the determination of infection markers and may
	eventually lead to unspecific reactions and, as a consequence, to
	false-positive results or to loss of reactivity and false-negative
	results. In addition, the pre-mortal administration of blood and blood
	products may lead to significant dilution effects of the blood which
	could also diminish sensitivity. Therefore, the Paul-Ehrlich-Institut
	as competent authority recommends validating the assay systems
	before use on cadaveric samples.
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	110
reproductive disaces and cens in your member state!	1

3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	Commission Directive 2006/17/EC requires HTLV-I antibody
	testing for donors living in, or originating from, high-incidence areas
	or with sexual partners originating from those areas or where the
	donor's parents originate from those areas. Since it is very difficult
	to determine what a HTLV-I high-incidence area is and more data
	on prevalence are available than data on incidence, the Commission
	Directive should be amended in regard of replacing the references
	"high-incidence" to references "high-prevalence". The competent
	authority completely agrees with this science-based specification.
	Additional testing referred to medical directives or guidelines (e.g.
	of the German Federal Medical Association /
	"Bundesärztekammer"), e.g. aminotransferase for bone tissue banks
	as state of the scientific and technical knowledge.
4. Accreditation, designation, authorisation or licensing of tissue es	
4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under	Yes
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	98
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	During inspections organised for this purpose
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	3
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011? 4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	NO
4bis. Overview of tissue/cells establishments authorised by the NC.	A
4.7. Tissue establishments with authorisation pending approval at	Skin tissue establishments
01/01/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
r r	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	ART tissue establishments
	Other tissue establishments
4.7.1. How many skin tissue establishments?	1
4.7.2. How many musculo-skeletal tissue establishments?	58
4.7.3. How many ocular tissue establishments?	19
4.7.4. How many cardiovascular tissue establishments?	2
4.7.5. How many HSC tissue establishments?	12
4.7.7. How many ART tissue establishments?	113
4.7.9. Please specify the type of tissues/cells and how many.	16 (e.g. chondrozytes, reproductive tissue, fetal tissue, amnion)
4.8. Tissue establishments with authorisations pending approval by	Skin tissue establishments
31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
	Ocular tissue establishments Cardiovascular tissue establishments
	HSC tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments

4.0.1 How many skin tig	1
4.8.1. How many skin tissue establishments?	1
4.8.2. How many musculo-skeletal tissue establishments? 4.8.3. How many ocular tissue establishments?	39
,	14
4.8.4. How many cardiovascular tissue establishments?	
4.8.5. How many HSC tissue establishments?	9
4.8.7. How many ART tissue establishments?	87
4.8.8. How many multi-tissue establishments?	
4.8.9. Please specify the type of tissues/cells and how many.	10 (e.g. chondrocytes, reproductive tissue, fetal tissue, amnion)
4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments Ocular tissue establishments
and 31/12/2011 (more than 1 answer possible).	Cardiovascular tissue establishments
	HSC tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.9.2. How many musculo-skeletal tissue establishments?	17
4.9.3. How many ocular tissue establishments?	5
4.9.4. How many cardiovascular tissue establishments?	2
4.9.5. How many HSC tissue establishments?	4
4.9.7. How many ART tissue establishments?	37
4.9.8. How many multi-tissue establishments?	2
4.9.9. Please specify the type of tissues/cells and how many.	34 (e.g. arms, hands, amnion)
4.10. All tissue establishments authorised by 31/12/2011 (more than	Skin tissue establishments
1 answer possible):	Musculo-skeletal tissue establishments
i diower possiole).	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.1.1. How many public skin tissue establishments?	2
4.10.1.2. How many private skin tissue establishments?	9
4.10.2.1. How many public musculo-skeletal tissue establishments?	23
4.10.2.2. How many private musculo-skeletal tissue establishments?	96
4.10.3.1. How many public ocular tissue establishments?	8
4.10.3.2. How many private ocular tissue establishments?	6
4.10.4.1. How many public cardiovascular tissue establishments?	3
4.10.4.2. How many private cardiovascular tissue establishments?	3
4.10.5.1. How many public HSC tissue establishments?	22
4.10.5.2. How many private HSC tissue establishments?	29
4.10.6.1. How many public cord blood tissue establishments?	2
4.10.6.2. How many private cord blood tissue establishments?	11
4.10.7.1. How many public ART tissue establishments?	14
4.10.7.2. How many private ART tissue establishments?	105
4.10.8.1. How many public multi-tissue establishments?	2
4.10.8.2. How many private multi-tissue establishments?	8
4.10.9.1. Please specify the type of 'other' public tissues/cells	1
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	2
establishements and how many.  4.11. How many tissues and cells were distributed under the direct	4
agreement of the Competent Authority according to Art. 6(5) during	<b>+</b>
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	165
4.16.1. Have penalties already been imposed?	Yes
4.16.1.1 How many penalties have been imposed in 2011 (from	In 2011 there has been one penalty imposed under the
01/01/2011-31/12/2011)?	Transplantation Act.

4.16.1.2 What 4	
4.16.1.2. What were the reasons for imposing the penalties? Please describe.	The statistics do not specify the infringement. It cannot be said, whether the infringement was in relation to organs or tissues and cells. Beside, there are no specific statistical data available relating to infringements against tissue regulation.
4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)	The penalty imposed was a financial penalty.
4.17. Do you have any additional comments on accreditation,	No.
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	l v
5.1. Is a system in place for organising inspections and control measures of tissue establishments?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	The Regional Competent Authorities in the German Länder are entrusted with the task of inspections; they are supported by the Paul-Ehrlich-Institute. For further information see answer 1.7.
5.1.2. If yes, please specify staffing (how many inspectors).	No further data available.
5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	Yes
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Pharmaceuticals
	Advanced therapies
	Medical devices
	Others
Please specify other.	Whole salers, brokers, pharmacies and GCP/GLP- Surveillance/License
5.3. How many routine inspections of tissue establishments for non-	56
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify.	8
5.3.3. Outcome of inspections of TEs for non-reproductive	16
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted?	46
5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted?	9
5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation?	1
5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure?	0
5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify.	4
5.4. How many routine inspections were conducted in ART	32
5.4. How many fourne inspections were conducted in AKT	34

actablishments (from 1/1/2011 to 21/12/2011)9	
establishments (from 1/1/2011 to 31/12/2011)?  5.4.1. How many inspections were conducted in ART establishments	1
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	8
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	34
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	13
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	4
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
5.6. How do you decide which type of routine inspection to conduct?	Risk-based approach referred to the outcome of the last inspection.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	62
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	50
	<del></del>
5.10. Did you carry out inspections of third parties?	Yes
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many?	
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for	Yes
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement	Yes 63
5.10. Did you carry out inspections of third parties? 5.10.1. If yes, how many? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission	Yes 63
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	Yes 63 No
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at	Yes 63 No No Not mandatory, but recommended as a guideline, additional
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?	Yes 63 No No Not mandatory, but recommended as a guideline, additional guideline as aide memoire.
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these	Yes 63 No Not mandatory, but recommended as a guideline, additional guideline as aide memoire. Aide memoire «Surveillance of procurement establishments and
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?	Yes 63 No Not mandatory, but recommended as a guideline, additional guideline as aide memoire. Aide memoire «Surveillance of procurement establishments and laboratories » (No. 07122501),
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these	Yes 63 No Not mandatory, but recommended as a guideline, additional guideline as aide memoire. Aide memoire «Surveillance of procurement establishments and laboratories » (No. 07122501), https://www.zlg.de/arzneimittel/deutschland/qualitaetssystem.html
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	Yes 63 No Not mandatory, but recommended as a guideline, additional guideline as aide memoire. Aide memoire «Surveillance of procurement establishments and laboratories » (No. 07122501), https://www.zlg.de/arzneimittel/deutschland/qualitaetssystem.html (no open resource)
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	Yes 63 No Not mandatory, but recommended as a guideline, additional guideline as aide memoire. Aide memoire «Surveillance of procurement establishments and laboratories » (No. 07122501), https://www.zlg.de/arzneimittel/deutschland/qualitaetssystem.html
5.10. Did you carry out inspections of third parties?  5.10.1. If yes, how many?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	Yes 63 No Not mandatory, but recommended as a guideline, additional guideline as aide memoire. Aide memoire «Surveillance of procurement establishments and laboratories » (No. 07122501), https://www.zlg.de/arzneimittel/deutschland/qualitaetssystem.html (no open resource)
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inspections, as part of an enquiry/investigation?	
5.16.1. If yes, please specify.	Requirements, conditions and data basis of an import licence granted by HTA (UK) for a tissue preparation of a US tissue. Information to other MS because of tissue import from the Ukraine and USA conducted by a German holder of import license.
5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries.	Yes
5.18. Do you have any additional comments on inspections?	No.
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries?	Yes
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).	37
6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).	Ocular, limbal 1 Cardiovascular, pericardium 1 Musculoskeletal, bone, femoral 17 Musculoskeletal, soft tissue 2 Musculoskeletal, bone, preparation 2 Musculoskeletal, cartilage 32 Skin 3 Reproductive, sperm 13 Note: In Germany, there is no authorisation for export of tissues and cells, but the export of tissue and cells has to be notifed annually by the tissue establishments.
6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.	Import authorisation and certification pursuant sec. 72b of the German Medicinal Products Act, granted by the Regional Competent Authorities, product-related marketing authorisation pursuant sec. 21a or sec. 21 of the German Medicinal Products Act, granted by the Paul-Ehrlich-Institut.
6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.	See answer 6.4.
6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries.	See answer 6.4.
6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.	See answer 6.4.
6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries.	See answer 6.4.
6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries.	See answer 6.4.
6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries.	Import authorisation and certification pursuant sec. 72b of the German Medicinal Products Act, granted by the Regional Competent Authorities.
6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.	The notification requirement according to section 8d of the German Transplantation Act (TPG) does not distinguish between import from third countries and import from member states of the European Union. The following table contains all tissues which were notified to the Paul-Ehrlich-Institut as being "imported" to Germany during 2011: Ocular, corneal 550 Cardiovascular, heart valves 128 Cardiovascular, vessels 12 Cardiovascular, membrane, pericardium 2410 Musculoskeletal, bone, complete 7914 Musculoskeletal, bone, femoral 1680 Musculoskeletal, bone, preparation 14056 Musculoskeletal, soft tissues 17822 Musculoskeletal, cartilage 176

	Skin (area in square centimeter) 3436004 Skin (number of pieces) 2
	Reproductive, sperm 325
6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
6.12.1. If yes, please provide the data concerning the	The notification requirement according to section 8d of the German
number/volume of exported tissues and cells by country of	Transplantation Act (TPG) does not distinguish between export to
destination.	third countries and export to member states of the European Union.
	The following table contains all tissues which were notified to the
	Paul-Ehrlich-Institut as being "exported" from Germany during 2011: Ocular, corneal 185 Ocular, limbal 3 Cardiovascular,
	membrane, pericardium 2131 Musculoskeletal, bone, complete 8985
	Musculoskeletal, bone, femoral 2850 Musculoskeletal, bone,
	preparation 119407 Musculoskeletal, soft tissues 12951
	Musculoskeletal, cartilage 180 Membrane, amniotic 130 Skin (area
	in square centimeter) 2825092 Reproductive, sperm 1463
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	F. Other
and self-sufficiency? (more than 1 answer possible)  Please specify 'other':	There is no information about this issue.
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	165
6.15.1. If yes, please specify the number of cases and for which type	31 (e.g. bone marrow stem cells, peripheral blood stem cells, coord
of tissues/cells.	blood, cardiac valves)
6.16. Do you have any additional comments on import/export?	No.
7. Distribution/intra community exchanges (Article 23 Directive 20	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	Certification by the Paul-Ehrlich-Institut before the first placing on
and safety measures established by other Member States? Please	the market pursuant to sec. 21a para. 9 of the German Medicinal
specify.	Products Act: Before issuing the certificate, the PEI examines
	whether the processing of the tissue preparations meet the
	requirements with respect to the removal and processing procedures including the donor selection procedures and the laboratory test
	methods, and whether the quantitative and qualitative criteria for the
	tissue preparations meet the requirements of the German Medicinal
	Products Act and its ordinances. The competent higher federal
	authority issues the certificate if the authorisation certificate or
	another certificate from the competent authority of the country of
	origin demonstrates the equivalence of the requirements pursuant to
	the German regulation and the proof of authorisation in the Member
	State of the European Union or in another State Party to the
7.1.2. If yes, do you have more stringent quality and safety measures	Agreement on the European Economic Area is submitted.  Yes
than in other Member States?	163
7.1.2.1. How do you address this difference for tissues and cells	In Germany human tissue preparations are regarded as medicinal
coming from a MS with minimum quality requirements? Please	products (according to section 4 number 30 of the Medicinal
specify.	Products Act; German Medicinal Product Act; AMG). Accordingly,
	authorizations for the manufacturing and placing on the market of
	tissue preparations are required. Industrially produced tissue
	preparations are regulated as pharmaceutical medicinal products,
	tissue preparations not produced using industrial processes,
	produced with methods well established and known in the EU, having functions or being associated with adverse reactions known
	from public literature are regulated according to the framework of
	Directive 2004/23/EC. Therefore, in Germany there are two different
	marketing authorizations depending on the classification of the
	product based on the AMG: 1.) authorization for "classical" human
	tissue preparations (regulated as medicinal products) according to
	section 21a AMG and 2.) marketing authorization according to
	section 21 AMG (regulated as medicinal products according to

	Directive 2001/83/EC). "Classical" human tissue preparations
	subject to authorization according to section 21a AMG which are
	intended to be placed on the market in a member state of the
	European Union shall require a certificate according to section 21a
	sub-section 9 AMG prior to the first placing on the market in
	Germany. Before issuing the certificate, the competent higher
	federal authority, Paul-Ehrlich-Institut, shall examine whether the
	processing of the tissue preparations meets the requirements with
	respect to the removal and processing procedures including the
	donor selection procedures and the laboratory examinations, and
	whether the quantitative and qualitative criteria for the tissue
	preparations meet the requirements of the AMG and its ordinances.
	Without the above mentioned marketing authorisation, authorisation
	or certification, respectively, the placing of human tissue
	preparations on the German market is not permitted.
7.2. How do you ensure that tissues establishments fulfil the	Authorisation pursuant sec. 20c of the German Medicinal Products
requirements of Art. 23 of Directive 2004/23/EC regarding quality	Act and inspections, granted by the Regional Competent Authorities.
of tissues and cells during distribution? Please specify.	The tissue establishments are supervised by the Regional Competent
	Authorities of the Länder. Technical requirements for processing,
	storage and distribution must be defined in the quality management
	system which is checked during the supervision.
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Other
from TEs in another MS? (only 1 answer possible).	
Please specify 'other'.	Before the first placing on the market a certificate, which is issued
	by the Paul-Ehrlich-Institut, is required (section 21a sub-section 9
	AMG). The certificate shall ensure that only equivalent products are
	introduced into the purview of the AMG (see answer 7.1.1.).
	Otherwise, in the case of non-equivalence, a "full marketing
	authorization" (authorization for tissue preparations regarding
	Section 21a AMG) must be obtained.
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
	Vac
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
tissue/cells between your country and other EU MS? 7.5.1. Please provide us with data (country of destination, type of	Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular,
tissue/cells between your country and other EU MS? 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution	Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular, heart valves 110 Cardiovascular, vessels 12 Musculoskeletal, bone,
tissue/cells between your country and other EU MS? 7.5.1. Please provide us with data (country of destination, type of	Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular, heart valves 110 Cardiovascular, vessels 12 Musculoskeletal, bone, complete 7.914 Musculoskeletal, bone, femoral 1.647
tissue/cells between your country and other EU MS? 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution	Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular, heart valves 110 Cardiovascular, vessels 12 Musculoskeletal, bone, complete 7.914 Musculoskeletal, bone, femoral 1.647 Musculoskeletal,, soft tissues 17.822 Musculoskeletal, bone,
tissue/cells between your country and other EU MS? 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution	Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular, heart valves 110 Cardiovascular, vessels 12 Musculoskeletal, bone, complete 7.914 Musculoskeletal, bone, femoral 1.647 Musculoskeletal, soft tissues 17.822 Musculoskeletal, bone, preparation 14.059 Musculoskeletal, cartilage 208 Skin (area in
tissue/cells between your country and other EU MS? 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution	Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular, heart valves 110 Cardiovascular, vessels 12 Musculoskeletal, bone, complete 7.914 Musculoskeletal, bone, femoral 1.647 Musculoskeletal,, soft tissues 17.822 Musculoskeletal, bone, preparation 14.059 Musculoskeletal, cartilage 208 Skin (area in square centimetre) 3.287.339 Skin (number of pieces) 61.511
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Competent Authorities acc. to sec. 52c of the German Medicinal Product Act. No experiences in implementing these regulations with regard to "classical tissues". Interdiction of commerce for "classical" tissues acc. to sec. 17 of the German Transplantation Act (Transplantationsgesetz – TPG), no commerce for germ cells due to
the German Embryo Protection Law (Embryonenschutzgesetz - ESchG).
No
No.
icle 10, Directive 2004/23/EC)
Yes
60-99%
No
Yes
http://www.pei.de/DE/infos/meldepflichtige/meldung-gewebe-8d-transplantationsgesetz/berichte-pei/berichte-meldung-8d-transplantationsgesetz-tpg-node.html
Yes
www.pharmnet-bund.de
Yes
1. Donation of ocular tissues, skin, heart valves, blood vessels, musculoskeletal tissues and placenta. 2. Procurement of cm² of skin retrieved. 3. Storage at 01/01/00:00, procession, discarding, distribution and storage at 31/12 24:00 of the above tissues (no. 1) completed by ovarian and testicular tissues (units). The musculoskeletal tissues are subdivided in whole or part of supporting bone (units), tendons / ligaments (units), cartilage (units), bone filling material (units) and other musculoskeletal (units) (i.e. ear ossicles). 4. Import- and Export of the above mentioned tissues (no.3)
The Register of tissue establishments is based on the German Transplantation Act (sec. 8f TPG) and was established in 2011 at the German Institut for Medicinal Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information – DIMDI). It is a publicly accessible register of tissue establishments specifying the acitivities for which they have been authorised by the Regional Competent Authority; it contains also the contact details of the tissue establishments. Due to the fact that DIMDI hosts this register since end of 2011, the data in the registry do not yet contain the whole dataset of tissue establishments that existed in Germany in the implied period of time. Final transplantation data cannot be provided because this is not part of the notification requirement according to section 8d para. 3 of the German Transplantation Act (TPG). Beside, there is no obligation pursuant to Article 10 of the Directive 2004/23/EC.
6/86/EC)
Yes
Procurement centre
Both paper records and electronic forms

9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?	Tissue establishments and organisations responsible for human application are required by law to retain the data for 30 years, in an appropriate and readable storage medium (sec. 41 AMWHV, sec. 15 para. 2 German Transplantation Act). The tissue establishments have to provide a solution for the case of closing the establishment in respect to storage of remained tissues as well as the data for purposes of traceability (e.g. by contract with another tissue establishment) (sec. 20c para. 7 German Medicinal Products Act, sec. 41 AMWHV). These aspects are part of the surveillance of inspections by the Regional Competent Authorities.  No.
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	The vigilance of tissue products is in the competence of the National Competent Authority (PEI) insofar tissue products require a marketing authorisation pursuant to sec. 21 or sec. 21 of the German Medicinal Products Act. The surveillance of the vigilance system of the procurement and tissue establishments (SOPs, reporting channels) is in the responsibility of the Regional Competent Authorities.
10.1.2. If yes, please provide a short description of its organisation.	Section 63i of the German Medicinal Products Act / documentation and notification obligations in respect of tissue preparations and tissues: (1) The holder of a marketing authorisation or authorisation for tissue preparations pursuant to section 21a, shall keep documents on all suspected serious incidents or serious adverse reactions in the Member States of the European Union or in the States party to the Agreement on the European Economic Area or in a third country, as well as on the number of recalls. (2) The holder of a marketing authorisation or authorisation for tissue preparations pursuant to subsection 1 shall, furthermore, document every suspected serious incident and every suspected serious adverse reaction and shall report them to the competent higher federal authority immediately, or at the latest within 15 days of acquiring this knowledge. The report shall contain all necessary information, especially the name or firm and address of the pharmaceutical entrepreneur, name and number or code of the tissue preparation, date and documentation of the emergence of the suspicion of the serious incident or the serious adverse reaction, date and place where the removal of the tissue took place, enterprises or facilities supplied as well as information on the donor. The incidents or reactions reported pursuant to sentence 1 are to be examined with respect to their causes and effects and subsequently evaluated and the results together with the measures to trace and protect both the donor and the recipient reported immediately to the competent higher federal authority. (3) In the case of tissue preparations and tissues which are not subject to marketing authorisation or authorisation, the tissue facilities shall notify the competent authority, immediately, of every suspected serious incident and every suspected serious adverse reaction. The notification shall contain all necessary information such as the name or firm and address of the donation or tissue facility, name and number or code of tissue preparation, d

	the basis of the obligations contained in sub-section 1, an updated report on the safety of the medicinal product immediately upon
	request or, where recalls, confirmed or suspected serious incidents or serious adverse reactions are involved, at least once a year. Sentence 1 shall not apply to parallel importers. (5) Section 62 sub-section 6
	shall apply mutatis mutandis to tissue facilities; Section 63b subsection 3 shall apply mutatis mutandis to the holder of an authorisation for tissue preparations. (6) A serious incident within
	the meaning of the foregoing provisions is any undesired event in connection with the procurement, testing, processing, preserving, storage or supply of tissues preparations which could lead to the
	transmission of an infectious disease, the death of a patient, a life- threatening state, disability or invalidity of patients, the need for or prolongation of hospitalisation or disease. A serious incident is also
	any incorrect identification or confusion of germ cells or impregnated egg cells within the framework of medically-assisted
	insemination measures. (7) A serious adverse reaction within the meaning of the foregoing provisions is an unintended reaction, including an infectious disease in the donor or recipient in
	connection with the procurement of tissues or the transplanting of tissue preparations, which is fatal or life-threatening or leads to disability or invalidity or requires hospitalisation or the prolongation
	of existing hospitalisation or causes or prolongs a disease.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	Yes
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	No
the Annual reporting to the EC also at national level?	The tienne cetablishments
10.3.1. If no, please specify what guidelines you use.	The tissue establishments are requested to use the notification form, which is available on the PEI homepage.
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	Yes
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	<50%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes
10.6.1. If yes, please provide a brief description.	According to the German Transplantation Act (TPG) there is an obligation for transplantation centers/ transplant doctors to report SARs to the Regional or National Competent Authority. They are asked to use the notification form available on the PEI homepage.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	No
10.7.2. Please specify why not.	At present there is no established feedback, but the PEI is planning to publish an annual tissue vigilance report.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	No
10.8.2. Please specify why not.	At present there is no established feedback, but the PEI is planning to include this issue in an annual tissue vigilance report.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and	0
which tissues were recalled and why (e.g. missing consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid alert?	
	The Comment of the side of the
10.11.1. If yes, please give a short description of the	The German competent authorities established a reporting system to

10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	The German competent authorities established a reporting system to
system/procedure.	inform the qualified person in each tissue establishment responsible
System procedure.	for quality and safety of the medicinal products.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	110
10.13.2. If no, please specify why not.	There is no obligation and no benefit for this procedure.
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	163
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
	Tes
organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	4
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	Cooperation with relevant third countries with regard to SARE
	reporting (e.g. USA, case Cryolife), Establishment of an interface
	for SARE reporting to other product areas, e.g. industrial tissue
	products in terms of the Directive 2001/83/EG or ATMP in terms of
	the Regulation (EC) 1394/2007 SOHO V&S Vigilance Guidance for
	Competent Authorities is helpful and should be updated if necessary.
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	In the case of living donation the explicit consent of the donor is
tissue/cell donation.	mandatory.
11.2. What consent system for deceased tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other relatives
tissue donation? (more than 1 answer possible)	Non-marital partners
	Friends
	Other
Please specify 'other'.	Section 4 of the Transplantation Act regulates the removal of organs
	with the consent of persons other than the donor: In cases where the
	physician who is supposed to remove the organ has neither written
	evidence of consent nor written evidence of objection by the
	potential donor, the latter's next-of-kin shall be asked whether he or
	she is aware of a declaration of donation on the part of the potential
	donor. If the next-of-kin has no knowledge of such a declaration
	either, removal under the provisions set forth in Section 3, paragraph
	1 numbers 2 and 3 as well as paragraph 2 shall only be admissible if
	a physician has informed the next-of-kin about a possible organ
	removal and has obtained his or her consent. In making the decision,
	the next-of-kin shall respect the presumed wishes of the potential
	donor. The physician shall inform the next-of-kin of this
	requirement. The latter may agree with the physician that his or her
	consent may be withdrawn within a specific, agreed deadline.
	Within the meaning of this Act, next-of-kin are, in the following
	order of priority: 1. the spouse, 2. children of full age, 3. the parents
	or, in so far as the potential donor was a minor at the time of death
	and the custody for his or her person was exercised at that time by
	only one parent, by a guardian or curator, then the person exercising
	this custody, 4. sisters and brothers of full age, 5. grand-parents.
	this custody, 4. sisters and brothers of full age, 5. grand-parents.  Next-of-kin are only authorised to make a decision pursuant to
	this custody, 4. sisters and brothers of full age, 5. grand-parents.

	The physician shall determine this fact by questioning the next-of-kin. In the case of several next-of-kin of equal rank, it is sufficient for one of them to be consulted under the terms of paragraph 1 and take a decision; however, an objection on the part of any of them is noteworthy. If a prior-ranking next-of-kin cannot be reached within an appropriate period of time, the consultation and decision of the next-of-kin of lower rank who can be reached next shall be sufficient. A person of full age who has evidently had an especially intimate personal relationship with the potential donor until the latter's death shall be of equal rank to the next-of-kin; such a person shall be on a par with the next-of-kin. In the event that the potential donor had delegated the decision regarding organ removal to a specific person, this person shall take the place of the next-of-kin.
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Interviews with personnel Other
Please specify 'other'.	Surveillance of SOPs, contracts between procurement and tissue establishments.
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
Please specify 'other'.	General information is also available within the national schemes on public awareness as well as information made available by medical associations.
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	According to Section 14 of the Transplantation Act are those persons involved in the disclosure or passing on of information pursuant to relevant sections of the Transplantations Act are not authorised to disclose the personal data of either the organ donor or the organ recipient. The personal data compiled within the framework of the Transplantation Act may not be processed or utilised for any purpose other than those stipulated in the Act. They may be processed and utilised for court proceedings the subject matter of which is the violation of any prohibition to disclose data pursuant to sentence 1 or 2. These provisions shall, in the case of the donation of semen, be without prejudice to the right of the child to have access to knowledge about his or her own parentage. In the case of a bone narrow transplantation, by way of derogation from sub-section 2, the identity of the tissue donor and that of the tissue recipient or of the relative in question may be mutually revealed if the tissue donor and the recipient or his or her legal representative have explicitly agreed to do so.
11.8. Please specify what measures are in place to ensure that the	See answer to question 11.7.
identity of the receipient is not disclosed to the donor and vice versa.  11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	Yes
11.10. Do you have any additional comments on consent and data protection?	No.
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible)	Inspections of TEs and procurement sites Audit of documentation Other
Please specify 'other'.	Authorisation of procurement establishments pursuant sec. 20b of the German Medicinal Products Act, surveillance of SOPs, quality management system and the training of the personnal (see sec. 33, 34 und 35 Arzneimittel- und Wirkstoffherstellungsverordnung / AMWHV, TPG-GewV). The determination of donor eligibility and the data from laboratory tests are carried out according to pre-

	established SOPs in accordance with good professional practice (sec.
12.2 How do you angure that all assessment and the de-	33 AMWHV).
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	Other
2006/17/EC)? (more than 1 answer possible)	
Please specify 'other'.	See question 12.1. (other)
12.3. Do you have more stringent criteria for donor selection than	Yes
those listed in Annex I of the Directive 2006/17/EC?	
12.3.1. If yes, please specify.	Donor selection: The exclusion criteria are adapted to the donor of a
5, 1 2.	specific tissue (for example donor for heart valves or vessels or
	cornea). Therefore, the donor selection criteria are sometimes more
	specific or stringent, respectively. As criteria for donor selection, the
	medical history of bacterial and protozoic diseases which can lead to
	chronically persistent infections, including tuberculosis, brucellosis,
	leprosis, melioidosis, Q fever, chlamydiosis, salmonellosis and
	tularaemia, should be considered by manufacturers. In this
	connection, specific attention should be paid on tick / arthropode
	borne diseases such as borreliosis, bartonellosis, rickettsiosis,
	trypanosomiasis, leishmaniasis, babesiosis and ehrlichiosis. The risk
	to transmit these infectious agents with specific tissues has to be
	assessed and negative effects for the recipient have to be excluded.
	Manufacturers are advised to refer to the German Guidelines on
	Hemotherapy, as published by the Federal Medical Association
	(Bundesärztekammer) in order to revise the donor questionnaire and
	to consider restrictions for specific tissue preparations.
	Procurement: Manufacturers are asked to provide a detailed
	procedure for the preparation and disinfection of the donor's skin.
	So far, in many cases this is not possible due to a multitude of
	different procurement sites with non-supervised disinfection
	procedures. Manufacturers are asked to revise all applied
	procedures. A standardized procedure for skin disinfection should be
	provided to all procurement sites by the tissue organisation or
	establishment in future. They should follow the recommended
	standards of practice used for surgical patients and should account
	for the elimination of bacterial spores as well as vegetative
	microorganisms and therefore include suitable disinfectants, their
	concentration and duration of exposure.
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
	Other
Please specify 'other'.	Post mortem physical examination as well as the results of the
	laboratory tests required according to Annex II of Directive
	2004/23/EC.
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	110
12.7. Do you require more information on the donation of	NT-
17 7 LIO VOIL require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?	
tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?  12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?  12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by	Inspection of tissue establishment Other
tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?  12.8. How do you ensure that all requirements regarding tissues and	
tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?  12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by	

personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.8.1. Please specify.	Authorisation of procurement establishments pursuant sec. 20b of the German Medicinal Products Act.
12.9. Do you have any additional comments on selection, evaluation	No.
and procurement?	
	15 10 D: (1 200 4/22/E/C)
13. Quality management, responsible person, personnel (Article 16,	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Other
	- P
Please specify 'other'.	Notification of changes, reservation of authorisation
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	Local training of the personnel by the tissue establishment or other
	providers.
13.5. Any additional comments on quality management, responsible	No.
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19-	-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirements of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	internal addits of tissue establishments
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	
	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Inspections of tissue establishments Internal audits of tissue establishments
	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials
	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed.
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed.  Testing methods should be able to detect relevant aerobic and
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed.  Testing methods should be able to detect relevant aerobic and anaerobic bacteria, as well as fungi, and have to take into account
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed.  Testing methods should be able to detect relevant aerobic and anaerobic bacteria, as well as fungi, and have to take into account possible specific contaminations of the tissue, for instance with
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed.  Testing methods should be able to detect relevant aerobic and anaerobic bacteria, as well as fungi, and have to take into account possible specific contaminations of the tissue, for instance with fastidious microorganisms such as Neisseria sp. or Mycobacterium
14.5. Any additional comments on reception, processing, storage,	Internal audits of tissue establishments  The requirements for microbiological testing of the source materials as well as of the final tissue product should be included:  Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed.  Testing methods should be able to detect relevant aerobic and anaerobic bacteria, as well as fungi, and have to take into account possible specific contaminations of the tissue, for instance with

temperatures. Other suitable samples may be taken from transport or washing solutions. In-process microbiological testing should be performed at relevant manufacturing steps, for instance after a stage of decontamination or inactivation, after washing or change of storage solution. For in-process control tests large amounts of spent storage solutions or cell culturing medium, or other suitable sample material should be used. Suitable microbiological control tests have to be applied on each batch of a final tissue or cell preparation. Whenever possible, a tissue or cell sample should be tested after final packaging, otherwise immediately prior to this step. In addition or in exceptional cases as an exclusive sample, spent storage or culturing medium or final washing solutions may be used for final testing. Every effort should be made to take representative samples. Tests for the detection of mycoplasmas should be performed as late as possible during the manufacturing process. If risk factors are present, it is desirable to perform additional tests for the detection of specific infectious agents. The need for endotoxin/pyrogen testing should be evaluated for each type of tissue or cell preparation. It depends on the intended route of administration, the usual endotoxin content of a preparation and the possible impact on the recipient. Sampling and testing methods have to be validated to show the representativeness of the sample and the suitability of the selected methods. Microbiological safety of tissues and cells should follow the concept of a risk-based approach. It is based on donor selection, the absence of initial contamination or surveillance of incoming bioburden in combination with the absence of specific microorganisms, respectively, and the therapeutic use of the preparation. This is supplemented by control and monitoring of the manufacturing process and the final preparation, and validated methods of disinfection, decontamination or inactivation of microorganisms during processing of tissues and cells. Treatment of tissues with antibiotics and antimycotics cannot be regarded as a safe procedure for elimination of viable microorganisms in cells and tissue preparations. Some microorganisms may survive the antibiotic treatment, but may be inhibited in growth and not detected by microbiological testing due to the sampling error, and can recover when conditions change. Therefore, if possible due to the nature of the starting material, a treatment with antimicrobial substances should not be performed, or should at least be restricted to a validated time as short as possible with subsequent processing steps without the use of such substances.

15. Third party agreements (Art. 24 Directive 2004/23/EC)		
15.1. Are third party agreements foreseen/allowed in your national	Yes	
legislation?		
15.1.1. If yes, have tissue establishments in your Member State	Yes	
notified third party agreements?		
15.1.1.1. Under which circumstances and for which responsibilities?	On the authority of the tissue establishments.	
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	They are controlled in the context of the authorisation of the tissue	
Competent Auhtority(ies) in your MS? Please specify.	establishment and the regular inspections.	
15.2. Any additional comments on third party agreements?	No.	
16. General comments - implementation		
16.1. Do you have at national level more stringent quality and safety	Yes	
requirements than those requested by the EU legislation in this field		
(e.g. restrictions concerning the donation/use of certain tissues/cells,		
mandatory unpaid donation etc.)?		
16.1.1. Please specify.	The German legislation has restrictions on the certain use of gametes	
	and embryotic stem cells which fall under Article 4 para. 3 of	
	Directive 2004/23/EC and are not covered by the scope of Art. 168	
	para. 4 letter a of the Treaty.	
16.2. Has your Member State encountered any difficulties in	Testing provisions	
implementing the requirements in the EU Tissues and Cells	Import-export	

Directives? Please choose from the options below.	Other
16.2.1. For all selected options in question 16.2., please provide a	For further details see letter from German Federal Ministry of Health
short description.	from 3th June 2013.
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC
	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive	Article 28 should be amended by requirements for an approach for
2004/23/EC?	microbiological testing on incoming material, in-process and final
	product samples.
16.3.2. How would you suggest to solve these issues in Directive	Directive 2006/17/EC should be amended by an article on
2006/17/EC?	microbiological testing on tissue as incoming material, in-process
	controls and final product testing, similar to Article 4 (laboratory
	tests required for donors) and corresponding annex.
16.3.3. How would you suggest to solve these issues in Directive	Directive 2006/86/EC should be amended by an article on
2006/86/EC?	microbiological testing on tissue as incoming material, in-process
	controls and final product testing, similar to Article 4 (laboratory
	tests required for donors) and corresponding annex.

## A.1.12. Survey response Greece

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	HELLENIC TRANSPLANT ORGANISATION & BONE MARROW
1.1. Traine of Tradional Competent Audionty (IVCA) 1.	DEPARTMENT
1.1.2. Address of NCA 1:	5, ANASTASIOU TSOHA STREET, ATHENS, 115 21, GREECE
1.1.3. Telephone (central access point):	0030 2016471200, 0030 2132027000
1.1.4. E-mail (central access point):	eom@eom.gr
1.1.5. Website:	www.eom.gr
1.1.6. The NCA is responsible for? (more than 1 answer possible)	
Non-reproductive tissues and cells	Yes
Reproductive tissues and cells	
Blood and blood components	
Human organs	Yes
Pharmaceuticals	
Medical devices	
Other	
Please specify 'other':	
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	
possible)	
Accreditation, authorisation, licensing of TEs	Yes
Inspection	Yes
Vigilance	Yes
Other	
THE PROCESS OF IDENTIFYING A SUITABLE	Search
HEMATOPOETIC STEM CELL DONOR FOR A PATIENT IN	
A NEED FOR TRANSPLANT	
1.2. National Competent Authority 2?	
1.2.1. Name of National Competent Authority 2:	
1.2.2. Address of NCA 2:	
1.2.3. Telephone (central access point):	
1.2.4. E-mail (central access point):	
1.2.5. Website:	
1.2.6. The NCA is responsible for? (more than 1 answer possible)	
Non-reproductive tissues and cells	
Reproductive tissues and cells	
Blood and blood components	
Human organs Pharmaceuticals	
Medical devices	
Other	
Please specify 'other':	
1.2.7. What are the role/tasks of the NCA? (more than 1 answer	
possible)*	
Accreditation, authorisation, licensing of TEs	
Inspection	
Vigilance	
Other	
Please specify 'other':	
1.3. National Competent Authority 3?	
Yes No	
1.3.1. Name of National Competent Authority 3	
1.3.2. Address of NCA 3:	
1.3.3. Telephone (central access point):	
1.3.4. E-mail (central access point):	
1.3.5. Website:	
1.3.6. The NCA is responsible for? (more than 1 answer possible)	
Non-reproductive tissues and cells	
Reproductive tissues and cells	
	·

Blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Other	
Please specify 'other':	
1.3.7. What are the role/tasks of the NCA? (more than 1 answer	
possible	
Accreditation, authorisation, licensing of TEs	
Inspection	
Vigilance	
Other	
Please specify 'other':	
1.4. National Competent Authority 4?	
Yes No	
1.4.1. Name of National Competent Authority 4:	
1.4.2. Address of NCA 4:	
1.4.3. Telephone (central access point):	
1.4.4. E-mail (central access point):	
1.4.5. Website:	
1.4.6. The NCA is responsible for? (more than 1 answer possible)	HTO is a non profit organisation granted from the Ministry of Health.
1.1.0. The field is responsible for (more than 1 answer possible)	It has three departments: solid organs department- 5 employees
	bone marrow department -5 employees
	administrative economical department - 3 employees and two
	lawyers working on legal matters
Non-reproductive tissues and cells	
Reproductive tissues and cells	
Blood and blood components	
Human organs	
Pharmaceuticals	
Medical devices	
Other	
Please specify 'other':	
1.4.7. What are the role/tasks of the NCA? (more than 1 answer	
possible)	
Accreditation, authorisation, licensing of TEs	
Inspection	
Vigilance	
Other	
Please specify 'other':	
1.5. Please give a short description of the legal status and	Periodically we have inspectors from the Ministry of Health
organisation of the National Competent Authority(ies)	·
(e.g. departments, staffing, number of senior and junior	
inspectors, staff working on EU affairs and legal matters,	
vigilance officers, budget, independence from government etc.).	
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent	
Authority(ies). (more than 1 answer possible)	
Accreditation, authorisation, licensing of TEs	
Inspection	
Vigilance	
Other	
Not applicable	
Please specify 'other':	
1.7. Could you please describe the competence/mandate of the	
Regional Competent Authority(ies) and their relation	
with the National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	

2.1.1 How do you authorist the "conditions of procurement"?  (more than 1 anose possible)  By inspecting all procurement centres  By inspecting all decumentation associated with procurement that is available in the tissue establishment working with procurement centres  Other  Please specify wher?  2.1.2 How many such authorisations were granted in 2011  (2010-13/12/2011)  2.2.1 Please provide the number of procurement centres in which procurement of states and cells'  ((alcelatal tissues, cardiovascalar tissues, skin, coular tissues, andipose tissue etc.) were carried out in 2011 (010-13/12/2011)  2.2.2 Please provide the number of procurement centres in which procurement of haematopoietic stem cells (bone  marrow, PBSC, cord blood etc.) were carried out in 2011 (010-13/12/2011)  2.2.3 Please provide the number of procurement centres in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.3 Please provide the number of procurement centers in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.4 Please provide the number of procurement centers in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.4 Please provide the number of procurement centers in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.3 Please provide the number of procurement centers in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.4 Please provide the number of procurement centers in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.4 Please provide the number of procurement centers in which procurement of gameles, enhyon and other reproductive tissues were carried out in 2011 (010-13/12/2011)  2.2.5 Ploa by our casic that procurement centers in which procurement of	Yes No	Yes
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By inspecting one procurement centres By inspecting one procurement centres By inspecting one procurement centres Officer By inspecting one procurement centres Officer Officer Please specify other?  2.1.2. How many such authorisations were granted in 2011 (0101-31/122011)  2.2.1.Please provide the number of procurement centres in which procurement of frauditional tissues, and cells' (skeletal tissues, cardiovascular tissues, askin, ocular tissues, andipose tissue etc.) were carried out in 2011 (0101-31/122011) 2.2.2. Please provide the number of procurement centers in which procurement of frauditional tissues, askin, ocular tissues, andipose tissue etc.) were carried out in 2011 (0101-31/122011) 2.2.2. Please provide the number of procurement centers in which procurement of haematopoicic stem cells (bone  marrow, PBSC, cord blood etc.) were carried out in 2011 (0101-31/122011) 2.2.3. Please provide the number of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (0101-31/122011). 2.3. How do you ensure that procurement centers comply with the requirements fail down in AT. 5 of Directive 2004/23/EC and its implementing Directive 2009/17/EC (e.g. trained personnel, conditions accepted, designated, authorised, licensed):  Ves  Ves  Ves  Ves  Ves  Ves  Ves  Ve		
Ves		
By impecting the documentation associated with procurement that is available in the issue establishment working with procurement centres  Other  Please specify other?  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)  2.2.1.Please provide the number of procurement centres in which procurement of traditional tissues and cells*  (skeletal tissues, curdiovascular tissues, sakin, ocular tissues, aminotic membrane, penerotate iskel, hepstocytes, adipose tissue cel. ) were carried out in 2011 (01/01-31/12/2011)  2.2.2. Please provide the number of procurement centres in which procurement of harnatopoietic stem cells (bone  marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011)  2.2.3. Please provide the number of procurement centers in which procurement of procurement of procurement centers in which procurement of procurement centers in which procurement of genetic procurement of procurement of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of genetic procurement of procurement centers in which procurement of genetic procurement of g		Yes
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Analysis of the mandatory documentation requested from the tissue establishment  Other  Please specify 'other':  6 LABORATORIES (ANTI -HIV, ANTI HTLV I + II, CMV/ ANTI	* '	
tissue establishment Other Please specify 'other': 6 LABORATORIES (ANTI -HIV, ANTI HTLV I + II, CMV/ ANTI	-	
Other  Please specify 'other':  6 LABORATORIES (ANTI -HIV, ANTI HTLV I + II, CMV/ ANTI		Yes
Please specify 'other':  6 LABORATORIES (ANTI -HIV, ANTI HTLV I + II, CMV/ ANTI	tissue establishment	
6 LABORATORIES (ANTI -HIV, ANTI HTLV I + II, CMV/ ANTI		
	Please specify 'other':	
CMV, HBS-Ag, ANTI- HBC, ANTI HCV, TREPONEMA		
		CMV, HBS-Ag, ANTI- HBC, ANTI HCV, TREPONEMA

	PALLIDUM)
year of accreditation/authorisation/license, which donor tests are	Tribbio(ii)
performed etc.).	
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive	
2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State.	
(more than 1 answer possible)	Yes
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Ag HIV	Yes
NAT HIV 1	Yes
HBs AG	Yes
Anti HBc	Yes
NAT HBV	Yes
Anti HCV-Ab	Yes
NAT HCV	Yes
Treponema Pallidum	Yes
HTLV-2	Yes
NAT HTLV-2	Yes
3.2. Please specify laboratory tests required for donors of	
reproductive tissues and cells in your Member State.	
(more than 1 answer possible)	
Anti-HIV 1	
Anti-HIV 2	
Ag HIV	
NAT HIV 1	
HBs AG	
Anti HBc	
NAT HBV	
Anti HCV-Ab	
NAT HCV	
HTLV-2	
NAT HTLV-2	
NAT Chlamydia	
Treponema Pallidum	
3.3. If NAT testing is not mandatory in your country, could you	NAT TESTING NOT MANDATORY, UNTIL NOW NAT TEST IS
please indicate whether you intend to make it	MANDATORY FOR BLOOD DONATION. WE TEND TO
1	EXTEND THE USE OF THIS METHOD TO TISSUE & CELL
	DONORS.
mandatory or to encourage its use? Please specify why or why not	
(e.g. number of additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and	
test procedures for deceased donors?	
Yes No	Yes
3.4.1. Please specify why:	
	Safety reasons , Quality & Traceability
3.5. Are any other laboratory tests required for donors of non-	
reproductive tissues and cells in your Member State?	
Yes No	No
3.5.1. Please specify.	
3.6. Are any other laboratory tests required for donors of	
reproductive tissues and cells in your Member State	
Yes No	
3.6.1. Please specify.	
3.7. Do you request/use international accreditation systems for	
testing laboratories?	

Yes No	Yes
	EUROPEAN FEDERATION FOR IMMUNOGENETICS (EFI)
	ELOT/ EN/ ISO 15015189:2007(2012)
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing of	
tissue establishments (Article 6, Directive 2004/23/EC)	
4.1. Do you have a system of designation, authorisation,	
accreditation or licensing for all types of tissue	
establishments under your responsability?	
Yes No	Yes
4.1.1. Why not?	
4.2. Is inspection a prerequisite for the designation, authorisation,	
accreditation or licensing of tissue establishments?	
Yes No	Yes
4.2.1. How many inspections were performed in 2011 for	1) BIOMETICS DENTAL 2) IAMEX ENDOLYSI 3) OPTIMUM
authorising/accrediting/licensing/designating TEs?	ORTOPEDICS 4) OPTHALMIATREIO OF ATHENS 5)
	UNIVERSITY HOSPITAL OF ALEXANDROUPOLIS
4.3. Are preparation processes authorised?	
1 1 1	
Yes No	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	
During routine inspections	
During inspections organised for this purpose	Yes
By review of a submitted application with supporting	Yes
documentation	
4.4. Following inspections/controls (Art. 6.4, Directive	1) OTHALMIATREIO OF ATHENS 2) UNIVERSITY
2004/23/EC), how many authorisations/accreditation/licenses	HOSPITAL OF ALEXANDROUPOLIS
were suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	-
2004/23/EC), how many authorisations/accreditation/licenses	
were revoked in 2011?	
4.6. Do you require TEs to be certified by an external entity to a	
quality system standard (e.g. ISO, JACIE, FACT)?	
Yes No	No
4.6.1. What is the relation between the indpendent certification(s)	
(e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue	
establishments? (more than 1 answer possible)	
Mandatory for authorisation	
Optional, but TEs are encouraged to get a certification	Yes
Inspections are conducted jointly by the CAs and independent	
certifying body	
No relation	Yes
Other	
Please specify 'other':	
-	
4bis. Overview of tissue/cells establishments authorised by the	
NCA	
(Establishments authorised for only one type of tissue should be	
included under the appropriate categories	
3.6.13.6.7.; establishments authorised for more than one type of	
tissue, should be included under "multi-tissue"	
establishments" - category 3.6.8.)	
In questions XX – XX please select the appropriate type(s) of	
tissue establishments in your country and then provide	
the requested numbers.	
4.7. Tissue establishments with authorisation pending approval at	
01/01/2011 (more than 1 answer possible):	
Skin tissue establishments	Yes
Musculo-skeletal tissue establishments	Yes
Ocular tissue establishments	Yes
	<u> </u>

C	
Cardiovascular tissue establishments	N.
HSC tissue establishments  Cord blood tissue establishments	Yes
ART tissue establishments	Yes
Multi-tissue establishments Other tissue establishments	
4.7.1. How many skin tissue establishments?	1
4.7.2. How many musculo-skeletal tissue establishments?	1) ASKLIPIEION HOSPITAL
4.7.3. How many ocular tissue establishments?	OCULAR 2
4.7.4. How many cardiovascular tissue establishments? 4.7.5. How many HSC tissue establishments?	
1	4
4.7.6. How many cord blood tissue establishments?	2
4.7.7. How many ART tissue establishments? 4.7.8. How many multi-tissue establishments?	
4.7.9. Please specify the type of tissues/cells and how many.	
4.8. Tissue establishments with authorisations pending approval	
by 31/12/2011 (more than 1 answer possible):	
Skin tissue establishments	Yes
Musculo-skeletal tissue establishments	Yes
Ocular tissue establishments	Yes
Cardiovascular tissue establishments  Cardiovascular tissue establishments	1 05
HSC tissue establishments	Yes
Cord blood tissue establishments	
ART tissue establishments	Yes
Multi-tissue establishments	
Other tissue establishments	
	0
4.8.1. How many skin tissue establishments?  4.8.2. How many musculo-skeletal tissue establishments?	17
4.8.3. How many ocular tissue establishments?	
-	20
4.8.4. How many cardiovascular tissue establishments?	
4.8.5. How many HSC tissue establishments?	4
4.8.6. How many cord blood tissue establishments?  4.8.7. How many ART tissue establishments?	2
4.8.8. How many multi-tissue establishments?	
4.8.9. Please specify the type of tissues/cells and how many.	
4.9. Tissue establishments first time authorised between	None
01/01/2011 and 31/12/2011 (more than 1 answer possible):	None
Skin tissue establishments	
Musculo-skeletal tissue establishments	
Ocular tissue establishments	
Cardiovascular tissue establishments	
HSC tissue establishments	
Cord blood tissue establishments	
ART tissue establishments	
Multi-tissue establishments  Multi-tissue establishments	
Other tissue establishments  Other tissue establishments	
4.9.1. How many skin tissue establishments?	
4.9.2. How many musculo-skeletal tissue establishments? 4.9.3. How many ocular tissue establishments?	
4.9.4. How many ocular tissue establishments? 4.9.4. How many cardiovascular tissue establishments?	
· · · · · · · · · · · · · · · · · · ·	
4.9.5. How many HSC tissue establishments?	
4.9.6. How many cord blood tissue establishments?	
4.9.7. How many ART tissue establishments?	
4.9.8. How many multi-tissue establishments?	
4.9.9. Please specify the type of tissues/cells and how many.	
4.10. All tissue establishments authorised by 31/12/2011 (more	
than 1 answer possible):  Skin tissue establishments	
Musculo-skeletal tissue establishments	

Ocular tissue establishments	Yes
Cardiovascular tissue establishments	165
HSC tissue establishments	
Cord blood tissue establishments	Yes
ART tissue establishments	168
Multi-tissue establishments	
Other tissue establishments	
4.10.1.1. How many public skin tissue establishments	
4.10.1.2. How many private skin tissue establishments?	NA
4.10.2.1. How many public musculo-skeletal tissue	1
establishments?	
4.10.2.2. How many private musculo-skeletal tissue	None
establishments?	
4.10.3.1. How many public ocular tissue establishments?	2
4.10.3.2. How many private ocular tissue establishments?	
4.10.4.1. How many public cardiovascular tissue establishments?	
4.10.4.2. How many private cardiovascular tissue establishments?	
4.10.5.1. How many public HSC tissue establishments?	
4.10.5.2. How many private HSC tissue establishments?	
4.10.6.1. How many public cord blood tissue establishments?	One public
4.10.6.2. How many private cord blood tissue establishments?	
4.10.7.1. How many public ART tissue establishments?	
4.10.7.2. How many private ART tissue establishments?	
4.10.8.1. How many public multi-tissue establishments?	
4.10.8.2. How many private multi-tissue establishments?	
4.10.9.1. Please specify the type of 'other' public tissues/cells	
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	
establishements and how many.	
4.11. How many tissues and cells were distributed under the	CORNEAS: 345 , HEMATOPOETIC STEM CELL: 78,
direct agreement of the Competent Authority according to Art.	HELLENIC CORD BANK OF ATHENS: 2
6(5) during 2011? Please provide number(s) per type tissues/cells.	The Best we could be will of the best of the
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	
pursuant to the Directive been defined (Article 27)?	Yes
pursuant to the Directive been defined (Article 27)? Yes No	Yes
yes No  4.16.1. Have penalties already been imposed?	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No	Yes No
pursuant to the Directive been defined (Article 27)?  Yes No 4.16.1. Have penalties already been imposed?  Yes No 4.16.1.1. How many penalties have been imposed in 2011 (from	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control	
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?	No No
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No	No Yes
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in	No No
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Yes A team fron the Ministry of Health authorized for inspections
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).	Yes A team fron the Ministry of Health authorized for inspections  Yes
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If no, please specify why not.	Yes A team fron the Ministry of Health authorized for inspections
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If no, please specify why not.  5.2. Does the inspection scheme interact or overlap with the	Yes A team fron the Ministry of Health authorized for inspections  Yes
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If no, please specify why not.  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example	Yes A team fron the Ministry of Health authorized for inspections  Yes
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If no, please specify why not.  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common	Yes A team fron the Ministry of Health authorized for inspections  Yes
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If no, please specify why not.  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer	Yes A team fron the Ministry of Health authorized for inspections  Yes
pursuant to the Directive been defined (Article 27)?  Yes No  4.16.1. Have penalties already been imposed?  Yes No  4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)?  4.16.1.2. What were the reasons for imposing the penalties?  Please describe.  4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  Yes No  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.1.3. If no, please specify why not.  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common	Yes A team fron the Ministry of Health authorized for inspections  Yes

5 2 1 If	
5.2.1. If yes, please specify. (more than 1 answer possible)	
Blood	
Organs	
Pharmaceuticals	
Advanced therapies	
Medical devices	
Hospitals	
Accreditation organisations (e.g. JACIE)	
Others	
Please specify other.	
5.3. How many routine inspections of tissue establishments for	Two corneas
non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	
reproductive tissues/cells were conducted in 2011 (from 1/1/2011	
to 31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues	
establishments for non-reproductive tissues/cells were conducted	
in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	Every two years
tissues/cells conducted in 2011 (01/01/2011 to31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	Every six months
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	Onr year
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major	
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	Two inspections
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	TI : .:
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	Three inspections
` '	
was the number of inspections carried out that were followed by closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	
establishments following serious adverse events or reactions,	
or suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on	
ART establishments (from 1/1/2011 to 31/12/2011) (	
e.g. due to a whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments	
carried out in 2011 (01/01/2011 to 31/12/2011): What was the	
number of inspections carried out where no shortcomings were	
observed?	
5.4.4. What was the number of inspections carried out in ART	
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	
establishments where major shortcomings were noted?	
comonomiento where major onorteonnings were noted:	

5.4.6. What was the number of inspections carried out in ART	
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more	
than 1 answer possible)	
General system-oriented inspections	
Thematic inspections	
Desk based reviews	
5.6. How do you decide which type of routine inspection to	
conduct?	
5.7. Until 2011, did you implement the requirement concerning	
the time interval between two inspections (Art. 7.3.)?	
Yes No	
5.7.1. Why not?	
5.7.2. How do you prioritise tissue establishments to be	A goording to the data of the request from the T.E.
	According to the date of the request from the T.E
inspected?	
5.8. How many TEs were inspected at least twice between 2008-	Two corneas
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	
outside tissue establishments?	
Yes No	Yes
5.9.1. If yes, how many?	Two in public tissue and none yet in private establishment
5.9.2. If no, why not?	- · · · · · · · · · · · · · · · · · ·
5.10. Did you carry out inspections of third parties?	
	N.
Yes No	No
5.10.1. If yes, how many?	
5.10.2. If no, why not?	Because we request a private contact between the T.E and the 3r d
	parties which reassures the safety and the quality system according to
	parties which reassures the safety and the quality system according to the Greek law
5.11. Do you use at national level the Operational Manual for	
5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell	
Competent Authorities on inspection of tissue and cell	
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for	
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No	
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses	the Greek law
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No 5.11.1. If no, which guidelines/regulations are used for inspections at national level? 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  4
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No	Yes Yes
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No  5.13.1. Could you please explain why?	Yes  Yes  Yes  4
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No	Yes  Yes  Yes  4
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No  5.13.1. Could you please explain why?  5.14. Did you receive/organise an inspection of a tissue	Yes  Yes  Yes  4
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No  5.13.1. Could you please explain why?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in	Yes  Yes  Yes  4
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No  5.13.1. Could you please explain why?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  No
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No	Yes  Yes  Yes  4
Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  Yes No  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  Yes No  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  1 2 3 4 5  5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  Yes No  5.13.1. Could you please explain why?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes  Yes  Yes  No

tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
Yes No	No
5.15.1. If yes, please specify why.	
5.16. Have you asked another MS, or have you been requested by	
any other MS, on the results and control	
measures of your inspections, as part of an enquiry/investigation?	
Yes No	No
5.16.1. If yes, please specify.	
5.17. Would you be interested in developing joint inspections?	
Joint inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more	
Member States' Competent Authorities on their territory or in	
third countries.	
Yes No	No
5.17.1. Could you please explain why not?	We are not ready yet
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
Import/export refers to the exchange of tissue/cells with non-EU	
Member States	
6.1. Do you have a register of authorised tissue establishments	
that are explicitly authorised to perform import/export of tissues	
and celles from/to third countries?	
Yes No	No
6.2. Please specify the number of tissue establishments authorised	
to import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised	
to export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for	
verifying the equivalent standards of quality and safety for importation of skin from third countries.	
6.5. Please specify which procedures you have in place for	
verifying the equivalent standards of quality and safety for	
importation of musculo-skeletal (bone, tendons, fascia etc.)	
tissues from third countries.	
6.6. Please specify which procedures you have in place for	DIRECTIVE 2008 & PRESIDENTIAL LAW 26/2008
verifying the equivalent standards of quality and safety for	BIRECTIVE 2000 & TRESIDENTINE ENTW 20/2000
importation of ophtalmic (cornea, sclera, etc) tissues from third	
countries.	
6.7. Please specify which procedures you have in place for	
verifying the equivalent standards of quality and safety for	
importation of cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for	
verifying the equivalent standards of quality and safety for	
importation of haematopoietic stem cells (HSC) (other than cord	
blood) from third countries.	
6.9. Please specify which procedures you have in place for	DIRECTIVE 2008 & PRESIDENTIAL LAW 26/2008
verifying the equivalent standards of quality and safety for	
importation of cord blood from third countries.	
6.10. Please specify which procedures you have in place for	
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	
(01/01/2011-31/12/2011)?	N.
Yes No	No
6.11.1. If yes, please provide the data concerning the	
number/volume of imported tissues and cells by country of origin.	

r	
6.12. Did you export tissues/cells from 3rd countries during 2011	
(01/01/2011-31/12/2011)?	
Yes No	No
6.12.1. If yes, please provide the data concerning the	
number/volume of exported tissues and cells by country of	
destination.	
6.13. Are you aware of any significant changes in 2012 which	
may invalidate the 2011 data on imports/exports of	
tissues/cells between your country and other third countries?*	
Yes No	
6.13.1. If yes, please specify.	
6.14. What is the relation between import/export of tissues and	
cells and self-sufficiency? (more than 1 answer	
possible)	
A. Export of tissues/cells is authorised only after checking that	Yes
local/national needs are fulfilled.	
B. Export of tissues/cells is authorised based on estimations	Yes
performed on an annual basis	165
C. Export of tissues/cells is authorised irrespective of national	
needs	
D. Import of tissues/cells is authorised only after checking that	Yes
local/national needs are not fulfilled	1 es
E. Import of tissues/cells is authorised based on estimations	
_ =	
showing that there is chronic deficiency of those tissues/cells	
1320 0000 0000	
F. Other	
Please specify 'other':	
6.14.1. If A or D were selected, please explain how you quantify	THERE IS A WAITING LIST FOR HCC & OCULAR
local/national needs.	
6.15. Did you authorise direct imports of tissues/cells to	
hospitals/clinics in your country?	
Yes No	NO
6.15.1. If yes, please specify the number of cases and for which	
type of tissues/cells.	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23	
Directive 2004/23/EC)	
For this question, distribution should be understood as cross-	
border exchanges of tissues/cells, and not between	
tissue establishments and centres of human application within the	
same MS.	
7.1. Do you have intra-community exchanges of tissues and cells?	
Yes No	YES
7.1.1. If yes, how do you address the possible more stringent	WE REQUEST FROM THE OTHER MS TO FOLLOW STRICTLY
quality and safety measures established by other	THE DIRECTIVE GUIDELINES
Member States? Please specify.	
7.1.2. If yes, do you have more stringent quality and safety	
measures than in other Member States?	
Yes No	NO
7.1.2.1. How do you address this difference for tissues and cells	WE INSIST TO FOLOOW THE DIRECTIVES GUIDELINES
coming from a MS with minimum quality requirements? Please	
specify.	1
7.2. How do you ensure that tissues establishments fulfil the	BY INSPECTIONS
requirements of Art. 23 of Directive 2004/23/EC regarding	
quality of tissues and cells during distribution? Please specify.	
7.3. Do you allow direct distribution to hospitals/clinics in your	
MS from TEs in another MS? (only 1 answer possible).	
Yes, no restrictions	
apply	
Yes, but only via an	
1 co, out only via all	

authorised TE in my MS	<u> </u>
-	NO
No / Other	NO
Please specify 'other'.	
7.4. Have you authorised direct distribution to the recipient of	
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	NO
Yes No	NO
7.4.1. If yes, how many authorisations were given in 2011	
(01/01/2011 to 31/12/2011)?	
7.4.2. If yes, for which tissues/cells?	
7.5. Do you collect data regarding the cross-border exchange of	
tissue/cells between your country and other EU MS?	
Yes No	YES
7.5.1. Please provide us with data (country of destination, type of	DONATION TWO CORD BLOOD UNITS TO UK IN 2011
tissue/cell and number of units distributed) concerning	
distribution to other MS in 2011 (01/01/2011-31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	PBSC: 2011 78, CORNEAS:
tissue/cell and number of units distributed) concerning	345 SCELETICAL TISSUES:
distribution to other MS in 2011 (01/01/2011-31/12/2011)	519
7.6. Are you aware of any significant changes in 2012 which may	
invalidate the 2011 data on cross-border exchanges of	
tissues/cells between your country and other EU MS?	
Yes No	NO
7.6.1. Please specify.	
7.7. Do you allow brokerage companies for either distribution in	
EU and/or import/export of tissues/cells?	
In this context, a brokerage company means a body that arranges	
transactions between a supplier (tissue	
establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual)	
without undertaking activities of processing, preservation or	
storage.	
Yes No	NO
7.7.1. Please describe the legal requirements and your role (if	ACCORDING TO THE DIRECTIVES
any) as a Competent Authority, in their authorisation/monitoring	
or inspection.	
7.8. Are brokers actively supplying health	
professionals/establishments in your country?	
Yes No	NO
7.8.1. Where are the brokers located?	
Your country Another country	
7.8.2. If the broker is located in another country, how	
easy/difficult is it to ensure that safety and quality requirements	
are met?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations	
(Article 10, Directive 2004/23/EC)	
8.1. Do you have an annual report model/template on the	
activities of tissue establishments in your Member State?	
(Article 10(1)). If yes, please upload the template.	
Yes No	NO
8.1.1. If no, why not	WE DO NOT HAVE AT THE MOMENT A TEMPLATE FOR EACH
	ASCTIVITY BUT WE KEEP DATA BASE IN PAPER FORM FROM THE T.E.
8.2. How many tissue establishments submitted annual reports of	
their activities during 2011. Please provide an	
estimation. (1 answer possible)	
100% (all) 60-99% 50-69% <50%	50-69%
8.3. Are these reports publicly available? (Article 10(1))	
Yes No	YES
8.3.1. If yes, please insert the link(s) to the report(s).	www.eom.gr / www.eae.gr
- J - J - F	

8.4. Do you publish a national annual report of the consolidated	
activities of all tissue establishments in your country?	
Yes No	NO
8.4.1. Please insert the link to the published national annual	110
report.	
8.4.2. If no, why not?	NO DUE TO FINANCIAL REASONS
8.5. Is there a publicly accessible register of authorised tissue	NO DOL TO I INANCIAL REASONS
establishements in place? (Article 10(2))	
Yes No	NO
8.5.1. If yes, please provide us with the link to the register's web	110
site.	
8.5.2. If no, why not?	NO DUE TO FINANCIAL REASONS
8.6. Do you provide data regarding tissues and cells activities to	NO DOE TO PINANCIAE REASONS
the EUROCET registry (non-mandatory reporting)?	
Yes No	YES
8.6.1. If yes, what data are provided to EUROCET? Please	HSC & CORNEAS DATA
specify.	IISC & CORNEAS DATA
8.6.2. If no, why not?	
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive	
2006/86/EC)	
9.1. Was the donor identification system (Art. 8(2)) implemented	
in your country?	
Yes No	YES
9.1.1. If no, why not?	TEG
9.2. Who assigns the unique code for each donation? (only 1	
answer possible)	
National Competent Authority	
Regional Authority	
Tissue establishment	YES
Procurement centre	TEG
Other	
Please specify 'other'.	
9.3. How is the data storage for traceability purposes organised in	
your tissue establishements (Art 8(4))? (only 1 answer	
possible)	
Only paper records Only electronic forms Both paper records and	BOTH PAPERS AND ELECTRONICS FORMS
electronic forms	BOTH THE ERG THAT ELECTROMES TORMS
9.4. How do you ensure that the 30 years data storage requirement	WE KEEP THEM IN A SEPARATE LOCKED SPACE WITH
is respected (Directive 2006/89/EC, Art. 9)?	LIMITED ACCESS
Please specify.	EMITED RECEIO
9.5. Do you have any additional comments on traceability?	
10. Notification of serious adverse events and reactions	
(Article 11 Directive 2004/23, Article 6 Directive 2006/76)	
10.1. Do you have a national vigilance system in place (for the	
reporting of serious adverse events and reactions	
(Article 11(1))?	
Yes No	YES
10.1.1. If yes, which CA/institution is responsible?	HTO
10.1.2. If yes, please provide a short description of its	HTO IS AN NON PROFIT ORGANISATION GRANTED FROM
organisation.	THE MINISTRY OF HEALTH.
10.1.3. If no, why not?	
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	
the SAR/E (to the CA (2006/76 art 6.4)) templates	
developed to the Annual reporting of the EC also at national	
level?	
Yes No	YES
10.2.1. If no, what template do you use? You are welcome to	
upload the template if you wish.	
10.3. Do you use the Common Approach Document developed	

for the Annual reporting to the EC also at national level?	
Yes No	YES
10.3.1. If no, please specify what guidelines you use.	
10.4. Do you have a dedicated vigilance officer in charge of	
collecting SAR/E from all TEs?	
Yes No	NO
10.4.1. Why not?	DUE TO THE STUFF LIMITATION
10.5. How many tissue establishments provided in 2011 the	
SAR/SAE data as requested (please provide the %	
from the total number of TEs authorised in your country).	
100% 70-99% 50-69% <50%	<50%
10.6. Do you have a mandatory procedure for the transplantation	
centres when reporting SAR/SAE to the TEs	
which distributed the tissues/cells (Art 11.2)?	
Yes No	YES
10.6.1. If yes, please provide a brief description.	WE DISTRIBUTE THE SURVEY FORMS TO BE COMPLETED
	BY THE T.E.'s
10.6.2. If no, how do you ensure that SAR/SAE are reported to	
the TEs?	
10.7. Do you give feedback to the TEs regarding SAR/SAE	
recorded at national level?	
Yes No	YES
10.7.1. Please specify.	WE GIVE SOME DIRECTIONS FOLLOWED BY INSPECTIONS
	TO THE T.E.'s
10.7.2. Please specify why not.	
10.8. Do you give feedback to the TEs regarding SAR/SAE	
recorded at EU level?	
Yes No	YES
10.8.1. Please specify.	
10.8.2. Please specify why not.	
10.9. Do you require your TEs to have a recall procedure?	
Yes No	YES
10.9.1. If no, please specify why not.	
10.10. How many recalls related to safety and quality of	
tissues/cells were issued in your country in 2011? Please specify	
the number and which tissues were recalled and why (e.g. missing	
consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	
Establishments and procurement sites in case of a national rapid	
alert?	
Yes No	NO
10.11.1. If yes, please give a short description of the	
system/procedure.	DUE TO THE CTHEFT I MITATION
10.11.2. If no, please specify why not.	DUE TO THE STUFF LIMITATION
10.12. Do you have in place a system/procedure to notify Tissue	
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	
Yes No	NO
10.12.1. If yes, please give a short description of the	NO .
system/procedure.	
10.12.2. If no, please specify why not.	DUE TO THE STUFF LIMITATION
10.12.2. If no, please specify why not.  10.13. Do you provide data regarding SAR/SAE to the	DOD TO THE STOTE ENVITATION
EUROCET registry (non-mandatory reporting)?	
Yes No	NO
10.13.1. If yes, please specify what data.	
10.13.2. If no, please specify what data.	
10.13.2. If no, piease specify why not.  10.14. Do you notify alerts communicated via these tissues and	
cells national vigilance system also to other national	
vigilance/alert systems?	
Yes No	YES
100110	1

	T
10.14.1. If yes, please specify which of the following systems are	
usually contacted. (more than 1 answer possible)	
Haemovigilance	YES
Pharmacovilance	
Medical devices	
Other	
Please specify 'other'.	
10.15. Did you send a vigilance officer/contact point to the	
trainings organised by the EU-funded project SOHO	
V&S?	
Yes No	NO
10.15.1. If yes, how would you rate the usefulness and efficacy of	
these trainings on a scale from 1	
(insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5	
(essential)?	
12345	
10.15.2. If no, please specify why not.	
10.16. Do you have any additional comments on SARE	
reporting?	
11. Consent and personal data protection (Article 13 and 14,	
Directive 2004/23/EC)	
11.1. What consent system for living tissue/cell donation do you	
have in place within your Member State?	
Presumed consent (opt-out) Explicit consent (opt-in)	Explicit consent
11.1.1. Please specify your choice of consent system for living	Z.Aprien Compone
tissue/cell donation.	
tissue/cen donation.	WE KEEP CONSENT FORMS FOR EACH TYPE OF TISSUE TO
	BE COMPLETED
11.2. What consent system for deceased tissue/cell donation do	DE COMI EL LED
you have in place within your Member State?	
Presumed consent (opt-out) Presumed (opt-out) and explicit (opt-	explicit consent
in) consent	explicit consent
,	
Explicit consent (ont-in)	
Explicit consent (opt-in)	
11.2.1. If you have chosen both consent systems for deceased	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	VES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation	
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation  Interviews with personnel	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation  Interviews with personnel  Interviews with relatives of deceased donors	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation  Interviews with personnel  Interviews with relatives of deceased donors  Interviews with living donors  Other	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation  Interviews with personnel  Interviews with relatives of deceased donors  Interviews with living donors  Other  Please specify 'other'.	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation  Interviews with personnel  Interviews with relatives of deceased donors  Interviews with living donors  Other  Please specify 'other'.  11.6. What measures are in place to ensure that	YES
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  First degree relatives (including spouse)  Other relatives  Non-marital partners  Friends  No further authorisation is needed  Other  Please specify 'other'.  11.4. Is the consent system for deceased tissue donation the same as for organs?  Yes No  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible  Analysis of documentation  Interviews with personnel  Interviews with relatives of deceased donors  Interviews with living donors  Other  Please specify 'other'.	YES

13(2)? (more than 1 answer possible)	
Only trained personnel is allowed to provide such information	YES
Information for donors are standardised at national/regional level	
Other	
Please specify 'other'.	
11.7. What measures are in place to ensure that both donors and	WE KEEP AN ANONIMITY FOR TWO YEARS
recipients remain unidentifiable when access is	WE KEEL THAT HOUSE HAVE TEACH
given to third parties (Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	WE GIVE CODE SYSTEM
identity of the receipient is not disclosed to the donor and vice	WE GIVE CODE STOTEM
versa.	
11.9. Does your national legislation allows disclosure of donor	
data in case of gametes donation?	
Yes No	
11.9.1. If no, please specify the circumstances and measures in	
place.	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive	
2004/23; Annexes I-IV Directive 2006/17)	
12.1. How do you ensure that all requirements related to the	
evaluation and selection of donors (except donors of reproductive	
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
Stadardised questionnaires at national levels	YES
Inspections of TEs and procurement sites	YES
Audit of documentation	YES
Regular evaluation of medical personnel	
Other	
Please specify 'other'.	
12.2. How do you ensure that all requirements related to the	
evaluation and selection of donors of reproductive cells	
are respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
Standardised questionnaires at national level	
Inspections of ART centres Audit documentation	
Regular evaluation of medical personnel Other	
Please specify 'other'.	
12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC?	
Yes No	
12.3.1. If yes, please specify.	
12.3.1. If yes, please specify.  12.4. What sources are required in your MS for the evaluation of	
a deceased donor of tissues/cells? (more than 1 answer possible)	
Interview with the donor's family or a person who knew the donor	YES
well	
Medical records of the donor	YES
Interview with the treating physician	YES
Interview with the general practitioner	
Autopsy report	YES
Other	
Please specify 'other'.	
12.5. Do you have more stringent criteria for selection of donors	
of reproductive cells than those listed in Annex III of the	
Directive 2006/17/EC?	
Yes No	
12.5.1. Please specify.	
12.6. Do you have more stringent criteria for autologous donation	

than those listed in Annex I of the Directive 2006/17/EC?	
Yes No	YES
12.6.1. If yes, please specify.	ACCORDING TO THE DIRECTIVES
12.7. Do you require more information on the donation of	
tissues/cells than the mandatory one as laid down in the	
Annex of Directive 2004/23/EC (Art 15(3)?	
Yes No	NO
12.7.1. If yes, please specify.	110
12.8. How do you ensure that all requirements regarding tissues	
and cells' procurement, packaging and transport are complied	
with by tissue establishments in your country (Art 15(1), Annex	
IV of Directive 2006/17/EC? (more than 1 answer possible) (For	
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities,	
and/or vendors in order to evaluate adherence to the written SOP,	
standards or governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
Inspection of tissue establishment	YES
Audit of tissue establishment	YES
Inspection of the centre of human application (e.g. transplantation	YES
centre, ART centre)	1LO
Audit of the centre of human application	YES
Other	
12.8.1. Please specify.	
12.9. Do you have any additional comments on selection,	
evaluation and procurement?	
13. Quality management, responsible person, personnel (Article	
16, 17, 18 Directive 2004/23/EC)	
13.1. How do you ensure that tissue establishments in your	
country have in place a quality system respecting the provisions	
of the Directive 2004/23/EC Art 16.1? (more than 1 answer	
possible). (For this question "audit" means a documented review	
of procedures, records, personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate adherence to the	
written SOP, standards or governments laws and regulations	
(from Council of Europe Guide to the Safety and Quality	
Assurance for the Transplantation of Organs, Tissues and Cells,	
2011)).	
Authorisation requirement	
Inspections	YES
Internal audits	YES
External audits	YES
Other	
Please specify 'other'.	
13.2. How do you ensure that tissue establishments have a	
responsible person fulfilling the requirements of Art. 17(1)?	
(more than 1 answer possible)	
Authorisation requirement	YES
Inspections	YES
Regular evaluation of personnel	YES
Mandatory trainings	YES
Other	
Please specify 'other'.	
13.3. How do you ensure an appropriate training for the personnel	
directly involved in the activities of tissue establishments? (more	
than 1 answer possible)	
Authorisation requirement	YES
Inspections	YES
Regular evaluation of personnel	YES
5	

Mandatory trainings	YES
Other	
Please specify 'other'.	
13.4. Do you have national/regional/local training programmes	
for the personnel of tissue establishments?	
Yes No	NO
13.4.1. If yes, please specify.	
13.4.2. If no, in which country(ies) is your personnel trained?	
EU countries Non-EU countries	EU countries
13.4.2.1. Please specify EU-countries.	EUSTITE, FACT NETCORD ,
. ,	JACKIE
13.4.2.2. Please specify non EU-countries.	
13.5. Any additional comments on quality management,	
responsible person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art	
19-22 Directive 2004/23/EC)	
14.1. How do you ensure that tissue establishments in your	
country fulfill the requirments of the Art. 19 (Tissue and cell	
reception) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	
National regulation/policy for reception of tissues/cells	YES
Inspections of tissue establishments	YES
Internal audits of tissue establishments	YES
External audits of tissue establishments (e.g. ISO)	YES
Other	
Please specify 'other'.	
14.2. How do you ensure that tissue establishments in your	
country fulfill the requirements of the Art. 20 (Tissue and cell	
processing) of Directive 2004/23/EC? (more than 1 answer	
possible)	
SOPs for all processes affecting quality and safety are mandatory	YES
for authorisation	
Inspections of tissue establishments	YES
Internal audits of tissue establishments	YES
External audits of tissue establishments (e.g. ISO)	YES
Other	
Please specify 'other'.	
14.3. How do you ensure that tissue establishments in your	
country fulfill the requirements of Art. 21 (tissue and cell storage	
conditions) of Directive 2004/23/EC? (more than 1 answer	
possible)	
SOPs for procedures associated with storage of tissues and cells	YES
are mandatory for authorisation	
Inspections of tissue establishments	YES
Internal audits of tissue establishments	YES
External audits of tissue establishments (e.g. ISO)	YES
Other	-
Please specify 'other'.	
14.4. How do you ensure that tissue establishments in your	
country fulfill the requirements of Art. 22 (labelling,	
documentation and packaging) of Directive 2004/23/EC and	
Annex IV of Directive 2006/17/EC? (more than 1 answer	
possible)	
SOPs for procedures associated with labelling and packaging are	YES
mandatory for authorisation	
Inspections of tissue establishments	YES
Internal audits of tissue establishments	YES
External audits of tissue establishments(e.g. ISO)	YES
Other	110
Please specify 'other'.	
I least specify office.	

14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your	
national legislation?	
Yes No	YES
15.1.1. If yes, have tissue establishments in your Member State	TES
notified third party agreements?	
Yes No	YES
15.1.1.1. Under which circumstances and for which	CONTRACT
responsibilities?	CONTRACT
15.1.1.2. How are third party agreements controlled (Art 6.2) by	BY DOCUMENTATION PAPER
the Competent Auhtority(ies) in your MS?	BT DOCUMENTATION TALER
Please specify.	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and	
safety requirements than those requested by the EU	
legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation	
etc.)?	
Yes No	NO
16.1.1. Please specify.	NO
16.2. Has your Member State encountered any difficulties in	
implementing the requirements in the EU Tissues and	
Cells Directives? Please choose from the options below.	
ART provisions	
	VEC
Procurement provisions	YES
Testing provisions	
Storage provisions	
Distribution provisions	
Import-export	A TOPO
Vigilance	YES
Authorisation-accreditation-licensing of TEs	YES
Inspections	
Traceability	
Other	
No difficulties	
16.2.1. For all selected options in question 16.2., please provide a	STRUCTIONAL DIFFICULTIES & COMMUNICATION
short description.	PROBLEMS
16.3. In your opinion, in which of the following Directives are	
there shortcomings (if any)? (more than 1 answer possible)	
Directive 2004/23/EC Directive 2006/17/EC Directive	
2006/86/EC	L NO
No shortcomings	NO
16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC?	
16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC?	
16.3.3. How would you suggest to solve these issues in Directive	
2006/86/EC?	

## A.1.13. Survey response Hungary

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	National Public Health and Medical Officer Service - Office of the
	Chief Medical Officer (NPHMOS-OCMO)
1.1.2. Address of NCA 1:	2-6 Gyali ut, Budapest, H-1097, Hungary
1.1.3. Telephone (central access point):	+36-1-476-1100
1.1.4. E-mail (central access point):	igazgatas@oth.antsz.hu; tisztifoorvos@oth.antsz.hu
1.1.5. Website:	http://www.antsz.hu
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Pharmaceuticals
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	National Public Health and Medical Officer Service - Office of the
organisation of the National Competent Authority(ies) (e.g.	Chief Medical Officer (NPHMOS-OCMO) is responsible for the
departments, staffing, number of senior and junior inspectors, staff	professional management, coordination and control of public health,
working on EU affairs and legal matters, vigilance officers, budget,	epidemiology, health development (protection and maintenance of
independence from government etc.).	health, health education) and health administration activities, as well
	as the supervision (licencing and control) of healthcare. NPHMOS is
	directed by the Chief Medical Officer who fulfils his tasks under the
	direct supervision of the minister responsible for health. Department
	of Health Administration of NPHMOS-OCMO fulfils the CA tasks,
	there are about fifty officers in the country that can conduct
	inspections of TEs and other health care providers as well.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	N. ( 1' 11
1.7. Could you please describe the competence/mandate of the	Not applicable.
Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"?	By inspecting all procurement centres
(more than 1 answer possible)	By inspecting an production estates  By inspecting the documentation associated with procurement that is
(more than 1 this wer possible)	available in the tissue establishment working with procurement
	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	17
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	9
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	15
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	20
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	NA.
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed) ? (more	
than 1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	No

authorisation or licensing of laboratories performing donor testing?	
	National Authorities are district institutes of public health under the
2.4.2. Which National Authority is in charge of this activity?	National Authorities are district institutes of public health under the
O. S. IV. I. C.	direction of the government offices
2.5. How do you ensure, as CA for T&C, that tests required	Other
for donors are carried out only by qualified laboratories accredited,	
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
Please specify 'other':	Laboratories must be licenced as health care providers, they have to
	comply professional requirements prescribed by legal rules.
	Authorized authorities inspect and control if they fulfil the legal
	requirements.
2.6. Please provide data on qualified laboratories accredited,	Our databases do not contain all of data to answer this question, so we
authorised or licensed in your country (e.g. number, year of	cannot give exact numbers.
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
,	Anti HCV-Ab
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT testing can be done, but not compulsory.
please indicate whether you intend to make it mandatory or to	
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and	No
test procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	If it is necessary: RhD, HLA, malaria, CMV, Toxoplasma, EBV,
3.3.1. Fledde specify.	Trypanosoma cruzi
3.6. Are any other laboratory tests required for donors of	Yes
reproductive tissues and cells in your Member State?	103
3.6.1. Please specify.	Neisseria gonorrhoeae, Herpes genitalis, CMV, Chlamidia
5.6.1.1 loade specify.	trachomatis, Trichomonas vaginalis
3.7. Do you request/use international accreditation systems for	Yes
testing laboratories?	100
3.7.1. Please specify.	Using an international accreditation system is not mandatory for each
3.7.1. Picase specify.	
3.8. Do you have any additional comments on testing?	laboratory
4. Accreditation, designation, authorisation or licensing of tissue	
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments	
under your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	10
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	No
4.4. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many authorisations/accreditation/licenses were	
suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	0
*	·

0004/00/50)	
2004/23/EC), how many authorisations/accreditation/licenses were	
revoked in 2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NO	CA
4.7. Tissue establishments with authorisation pending approval at	Ocular tissue establishments
01/01/2011 (more than 1 answer possible):	Cardiovascular tissue establishments
4.7.3. How many ocular tissue establishments?	1
4.7.4. How many cardiovascular tissue establishments?	1
4.8. Tissue establishments with authorisations pending approval by	Cord blood tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.6. How many cord blood tissue establishments?	2
4.9. Tissue establishments first time authorised between 01/01/2011	Ocular tissue establishments
and 31/12/2011 (more than 1 answer possible):	Cardiovascular tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
4.9.3. How many ocular tissue establishments?	1
4.9.4. How many cardiovascular tissue establishments?	2
4.9.6. How many cord blood tissue establishments?	2
4.9.7. How many ART tissue establishments?	1
4.10. All tissue establishments authorised by 31/12/2011 (more	Skin tissue establishments
than 1 answer possible):	Musculo-skeletal tissue establishments
	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
4.10.1.1. How many public skin tissue establishments?	2
4.10.1.2. How many private skin tissue establishments?	0
4.10.2.1. How many public musculo-skeletal tissue establishments?	2
4.10.2.2. How many private musculo-skeletal tissue	0
establishments?	
4.10.3.1. How many public ocular tissue establishments?	1
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue establishments?	
4.10.4.2. How many private cardiovascular tissue establishments?	
4.10.5.1. How many public HSC tissue establishments?	1
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	4
4.10.6.2. How many private cord blood tissue establishments?	2
4.10.6.2. How many private cord blood tissue establishments? 4.10.7.1. How many public ART tissue establishments?	7
* *	
4.10.7.2. How many private ART tissue establishments?	10
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5)	
during 2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	No
pursuant to the Directive been defined (Article 27)?	
4.17. Do you have any additional comments on accreditation,	
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Officers of the National Public Health and Medical Officer Service -
of inspections.	Office of the Chief Medical Officer, Department of Health
	Administration conducts inspections of tissue establishments. Those
	of our officers working in large cities of the country, inspect TEs
	located in the area, participating of medical supervisors if needed
5.1.2. If yes, please specify staffing (how many inspectors).	There are about fifty officers in the country that can conduct
	inspections of TEs and other health care providers as well. At least
· · · · · · · · · · · · · · · · · · ·	

	two officers take part in an inspection, and one medical supervisor,
	the latter ones do not belong to the NPHMOS-OCMO, they are called
	upon for a single inspection by the NPHMOS-OCMO
5.2. Does the inspection scheme interact or overlap with the	No
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.3. How many routine inspections of tissue establishments for	10
non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011	
to 31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
	0
5.3.2. How many other type of inspections of tissues establishments	U
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	6
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
	U
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major	
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	2
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	2
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	0
establishments following serious adverse events or reactions, or	
suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a	
whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	1
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
=	V
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	4
and the second of the second o	1

establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than	General system-oriented inspections
1 answer possible)	
5.6. How do you decide which type of routine inspection to	In Hungary general system-oriented inspections are the common type
conduct?	of inspections
5.7. Until 2011, did you implement the requirement concerning the	No
time interval between two inspections (Art. 7.3.)?	
5.7.1. Why not?	According to Hungarian legislation inspections are carried out ,,regularly". In practice inspections are carried out yearly.
5.7.2. How do you prioritise tissue establishments to be inspected?	General inspections by central arrangement, tissue establishments under licencing process, inspection due to patient complaint.
	However, inspections can be conducted more frequent than two years,
5.0 H TE	due to some changing in activity of the TEs or other causes.
5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?	Most of TEs were inspected at least twice between 2008-2011.
5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?	No
5.9.2. If no, why not?	Each procurement site had to possess a cell or tissue establishment licence in 2011, even if it operated as a procurement site.
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	Because each establishment, which persuits activity connected with cells or tissues, must be a licenced tissue establishment.
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	5
these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?  5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections?	Yes
Joint inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	No
are explicitly authorised to perform import/export of tissues and celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised	0
to import tissues and cells from third countries (recorded by 31/12/2011).	
6.3. Please specify the number of tissue establishments authorised	0
to export tissues and cells from third countries (recorded by	
31/12/2011). 6.4. Please specify which procedures you have in place for	NA.
0.7. I lease specify which procedures you have in place for	IVA.

verifying the equivalent standards of quality and safety for	
importation of skin from third countries.	
6.5. Please specify which procedures you have in place for	NA.
verifying the equivalent standards of quality and safety for	
importation of musculo-skeletal (bone, tendons, fascia etc.) tissues	
from third countries.	
6.6. Please specify which procedures you have in place for	NA.
verifying the equivalent standards of quality and safety for	
importation of ophtalmic (cornea, sclera, etc) tissues from third	
countries.	
6.7. Please specify which procedures you have in place for	NA.
verifying the equivalent standards of quality and safety for	
importation of cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for	NA.
verifying the equivalent standards of quality and safety for	
importation of haematopoietic stem cells (HSC) (other than cord	
blood) from third countries.	
6.9. Please specify which procedures you have in place for	NA.
verifying the equivalent standards of quality and safety for	IVA.
importation of cord blood from third countries.	NA.
6.10. Please specify which procedures you have in place for	INA.
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	C. Export of tissues/cells is authorised irrespective of national needs
and self-sufficiency? (more than 1 answer possible)	
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 2	2004/23/FC)
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.2. How do you ensure that tissues establishments fulfil the	Inspections of the tissue establishments
	inspections of the dissue establishments
requirements of Art. 23 of Directive 2004/23/EC regarding quality	
of tissues and cells during distribution? Please specify.	W. L. L. J. J. J. J. MC
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, but only via an authorised TE in my MS
from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.5. Do you collect data regarding the cross-border exchange of	No
tissue/cells between your country and other EU MS?	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in	No
EU and/or import/export of tissues/cells? In this context, a	
brokerage company means a body that arranges transactions	
between a supplier (tissue establishment/company selling tissues or	
cells) and a buyer (a tissue establishment/a hospital or clinic/an	
individual) without undertaking activities of processing,	
preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
20 jou nave any additional comments on distribution!	

8. Register of tissue establishments and reporting obligations (Ar	ticle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	60-99%
their activities during 2011. Please provide an estimation. (1 answer	
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	The Hungarian law changed this summer, tissue establishments shall
	submit to the competent authority an annual report on these activities
	and this report shall be publicly available. The reports should be sent
	by 31 January next year.
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web	https://www.antsz.hu/bal_menu/igazgatas/sejt_es_szovetbank_nyt.ht
site.	ml V
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.	- tissues data - HPC data - ART data
	- tissues data - HPC data - AKT data
8.7. Do you have any additional comments on reporting?	ACIDCIDED
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 20	,
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	Tiggue ogtablishment
9.2. Who assigns the unique code for each donation? (only 1	Tissue establishment
answer possible)	Poth paper records and electronic forms
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement	30 years data storage requirement is prescribed for all health care
is respected (Directive 2006/89/EC Art 9)? Places specify	providers - including tissue establishments - in the Act VI VII of
is respected (Directive 2006/89/EC, Art. 9)? Please specify.	providers – including tissue establishments – in the Act XLVII of
is respected (Directive 2006/89/EC, Art. 9)? Please specify.	1997 on the Handling and Protection of Medical and Other Related
is respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?	
	1997 on the Handling and Protection of Medical and Other Related Data
9.5. Do you have any additional comments on traceability?	1997 on the Handling and Protection of Medical and Other Related Data
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1	1997 on the Handling and Protection of Medical and Other Related Data  1 Directive 2004/23, Article 6 Directive 2006/76)
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the	1997 on the Handling and Protection of Medical and Other Related Data  1 Directive 2004/23, Article 6 Directive 2006/76)
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	1997 on the Handling and Protection of Medical and Other Related Data  1 Directive 2004/23, Article 6 Directive 2006/76)  Yes
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	1997 on the Handling and Protection of Medical and Other Related Data  1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	1997 on the Handling and Protection of Medical and Other Related Data  1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Qualityand Organizational Development in Healthcare and Medicines. In
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute notifies the NPHMOS-OCMO. The NPHMOS-OCMO performs the
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute notifies the NPHMOS-OCMO. The NPHMOS-OCMO performs the needed actions.
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute notifies the NPHMOS-OCMO. The NPHMOS-OCMO performs the
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute notifies the NPHMOS-OCMO. The NPHMOS-OCMO performs the needed actions.
9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 1 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	1 Directive 2004/23, Article 6 Directive 2006/76)  Yes  National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO)  In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality-and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute notifies the NPHMOS-OCMO. The NPHMOS-OCMO performs the needed actions.  Yes
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	notifies the NPHMOS-OCMO. Legal rule determines the form of the
	report. The NPHMOS-OCMO then performs the needed actions.
10.7. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at national level?	
10.7.1. Please specify.	If NPHMOS-OCMO receives a report on SAR/SAE from a health
	care provider, NPHMOS-OCMO performs the needed actions
	including notifying the affected tissue establishment.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	If NPHMOS-OCMO receives a report on SAR/SAE from a EU
	member state, NPHMOS-OCMO performs the needed actions
	including notifying the affected tissue establishments.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of	0
tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing	
consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	In case of national rapid alert NPHMOS-OCMO performs the needed
system/procedure.	actions including notifying the affected tissue establishments and
	procurement sites.
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued	
via the EU RATC platform?	
10.12.1. If yes, please give a short description of the	In case of rapid alert from the EU, NPHMOS-OCMO performs the
system/procedure.	needed actions including notifying the affected tissue establishments and procurement sites.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	Yes
registry (non-mandatory reporting)?	165
10.13.1. If yes, please specify what data.	All data.
10.14. Do you notify alerts communicated via these tissues and	Yes
cells national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Pharmacovilance
	Medical devices
10.15. Did you send a vigilance officer/contact point to the	Yes
trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of	5
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	3
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direction)	ective 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	Basically, only a person with legal capacity may donate tissues,
tissue/cell donation.	except for some circumstances.
11.2. What consent system for deceased tissue/cell donation do you	Presumed (opt-out) and explicit (opt-in) consent
have in place within your Member State?	
11.2.1. If you have chosen both consent systems for deceased	Primely presumed consent (opt-out) system is the sole system in
tissue/cell dontation, please specify.	Hungary, but every person can declare an objection in written form.
	Tissues may only be removed from cadaver donors if the deceased
	did not make a declaration opposing donation during his lifetime. A
	person with legal capacity may make a declaration in writing, or
	verbally at his attending physician in case of inability to, or
	significant difficulty in making a written declaration. A person with restricted legal capacity may make an opposition declaration without
	his legal representative's involvement. Such opposition declaration
	10001 representative a involvement, out of opposition decidation

	may be made on behalf of a person with no legal capacity by his
	legal representative.
11.3. According to your national legislation, in case of deceased	Other
donations, please specify who is giving the authorisation for the	Cinci
tissue donation? (more than 1 answer possible)	
Please specify 'other'.	If the deceased is under age and no opposition declaration can be
,	found, the organ or
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	Interviews with living donors
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	Name of the donor cannot be recorded on the labelling of the tissue,
recipients remain unidentifiable when access is given to third	only an identity number. The institution that removes the tissue from
parties (Art. 14(1)). Please specify.	the donor, must apply the privacy rules of the health law. The
	competent authority controls if the institution applies the legal rules.
11.8. Please specify what measures are in place to ensure that the	Legal rule determines that that the identity of the recipient is not
identity of the receipient is not disclosed to the donor and vice	disclosed to the donor and vice versa. The competent authority
versa.	controls if the institution applies the legal rules.
11.9. Does your national legislation allows disclosure of donor data	Yes
in case of gametes donation?	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	004/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Medical records of the donor
deceased donor of tissues/cells? (more than 1 answer possible)	
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Inspection of the centre of human application (e.g. transplantation
tissue establishments in your country (Art 15(1), Annex IV of	centre, ART centre)
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP,	
standards or governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	
evaluation and procurement?	
13. Quality management, responsible person, personnel (Article 1	6, 17, 18 Directive 2004/23/EC)

13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible).	
(For this question "audit" means a documented review of	
procedures, records, personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate adherence to the	
written SOP, standards or governments laws and regulations (from	
Council of Europe Guide to the Safety and Quality Assurance for	
the Transplantation of Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Inspections
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	165
13.4.1. If yes, please specify.	Personnel of health care providers, including tissue establishments,
	have to take part in regular training programmes. Training
	programmes can be organized by medical universities, national
	professional institutes, health care providers.
13.5. Any additional comments on quality management,	
responsible person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 1	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing)	authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage	mandatory for authorisation
conditions) of Directive 2004/23/EC? (more than 1 answer	Inspections of tissue establishments
possible)	Transfer to the state of the st
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	N-
15.1. Are third party agreements foreseen/allowed in your national	No
legislation?	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and	No
safety requirements than those requested by the EU legislation in	
this field (e.g. restrictions concerning the donation/use of certain	
tissues/cells, mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	Other
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	The implementation of the Directive has only been completed this
short description.	summer, as the IT system of NPHMOS-OCMO had to be developed.
r····	The Hungarian law (Decree 18 of 1998 of the Minister of Health)
	changed this summer (from 01.07.2013), tissue establishments shall
	submit to the competent authority an annual report on these activities
	and this report shall be publicly available. The reports should be sent
	and this report shall be publicly available. The reports should be sent by 31 January next year.

16.3. In your opinion, in which of the following Directives are there	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	

## A.1.14. Survey response Ireland

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Irish Medicines Board
1.1.2. Address of NCA 1:	Irish Medicines Board, Kevin O Malley House, Earlsfort Centre, Earlsfort
	Terrace, Dublin 2, Ireland
1.1.3. Telephone (central access point):	00353 -1 - 6764971
1.1.4. E-mail (central access point):	compliance@imb.ie
1.1.5. Website:	www.imb.ie
1.1.6. The NCA is responsible for? (more than 1	Non-reproductive tissues and cells
answer possible)	Reproductive tissues and cells
answer possible)	Blood and blood components
	Human organs
	Pharmaceuticals
	Medical devices
	Other
Please specify 'other':	Vetinary Products, Cosmetic Products, Advanced Therapy Medicinal Products,
rease specify other.	Clinical Trials approval, Protection of Animals.
1.1.7. What are the role/tasks of the NCA? (more than	Accreditation, authorisation, licensing of TEs
	<u> </u>
1 answer possible)	Inspection Vigilance
	Other
DI:	
Please specify 'other':	Overseeing recalls, Advice to the Government, International Representation, Enforcement.
12 N. C. 10 4 4 4 1 1 20	
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status	There are four (4) departments directly involved in carrying out IMB's reglatory
and organisation of the National Competent	functions: 1:Compliance (Inspections and audits, Market compliance and
Authority(ies) (e.g. departments, staffing, number of	enforcement), 2: Human Products Authorisation and Registration (licensing of
senior and junior inspectors, staff working on EU	medicines for human use, designation and monitoring of notified bodies for
affairs and legal matters, vigilance officers, budget,	medical devices, registration of medical devices) 3: Human products monitoring
independence from government etc.).	(monitoring of safety of medicines for human use, blood and blood components,
	tissues and cells and medical devices), 4: Vetinary Sciences (licensing and safety
	of medicines for human use, scientific animal protection). There are three (3)
	departments which provide cross organisational support: 1: Finance and corporate
	affairs, 2: human resources, 3: IT management and an office of the Chief
	Executive. Overall there are approximately 300 staff working in the Irish
	Medicines Board. In the Compliance department there are currently
	approximately 21 inspectors working accross different specialities including
	GMP, GDP, GCP, Blood ,Tissues & Cells and Organs (BTO). There is a
	dedicated team for Tissues & Cells inspection comprised of the BTO manager,
	two BTO inspectors and a BTO scientific officer. The BTO manager and BTO
	inspectors represent the competent authority at an EU level through participation
	in European Commission competent authority meetings, EU working groups and
	the development of best practice guidance in the field of Tissues and Cells. The
	human products monitoring department is made up of pharmacovigilance,
	medical devices vigilance and human products vigilance assessment, comprising
	of approximately 40 staff, there is 1 dedicated Tissue & Cells vigilance officer.
	The Irish Medicines Board is 85% Self funded through licensing, inspection fees,
	The remainder is funded by the Irish Department of Health.
1.6. In case of MS with federal or decentralised	Not applicable
systems, please indicate the roles/tasks of the Regional	
Competent Authority(ies). (more than 1 answer	
possible)	
1.7. Could you please describe the	Not applicable
competence/mandate of the Regional Competent	
Authority(ies) and their relation with the National	
Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
,	I

	<u>,                                    </u>
2.1.1. How do you authorise the "conditions of	By inspecting all procurement centres
procurement"? (more than 1 answer possible)	
2.1.2. How many such authorisations were granted in	none
2011 (01/01-31/12/2011)?	
2.2.1 Please provide the number of procurement centres	4
in which procurement of "traditional tissues and cells"	
(skeletal tissues, cardiovascular tissues, skin, ocular	
tissues, amniotic membrane, pancreatic islet,	
hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers	6
in which procurement of haematopoietic stem cells	
(bone marrow, PBSC, cord blood etc.) were carried out	
in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers	9
in which procurement of gametes, embryos and other	
reproductive tissues were carried out in 2011 (01/01-	
31/12/2011).	
2.2.4. Please provide the number of procurement	1 - cartilage for extraction of chondrocytes for use in ATMP (processing
centers in which procurement of tissues/cells for	performed in another EU Member State)
ATMP manufacturing were carried out in 2011 (01/01-	performed in another Do Member State)
31/12/2011).	
2.3. How do you ensure that procurement centres	Inspections of the site/centre
comply with the requirements laid down in Art. 5 of	Analysis of the mandatory documentation
Directive 2004/23/EC and its implementing Directive	Amaryoro of the manuatory documentation
2006/17/EC (e.g. trained personnel, conditions	
accredited, designated, authorised, licensed) ? (more	
than 1 answer possible)	N.
2.4. Are you also responsible for the accreditation,	No
designation, authorisation or licensing of laboratories	
performing donor testing?	AND AND THE PROPERTY OF THE PR
2.4.2. Which National Authority is in charge of this	Irish National Accreditation Board (INAB)
activity?	
2.5. How do you ensure, as CA for T&C, that tests	Analysis of the mandatory documentation requested from the tissue establishment
required for donors are carried out only by qualified	Other
laboratories accredited, designated, authorised or	
licensed Art. 5(2))? (more than 1 answer possible)	
Please specify 'other':	All laboratories that perform tests required for donors are listed on each Tissue
	Establishment's Authorisation. Each laboratory is required to be accredited by the
	Irish National Accreditation Board.
2.6. Please provide data on qualified laboratories	11 testing laboritories in Ireland who perform tests required for donors; testing at
accredited, authorised or licensed in your country (e.g.	time of donation performed as per Directive requirements: AntiHIV1, AntiHIV2,
number, year of accreditation/authorisation/license,	HBsAG,Anti HBc, Anti- HCV-Ab, HTLV - 1 and 2 (when required) Treponema
which donor tests are performed etc.).	Pallidum must be excluded
2.7. Do you have any additional comments on	Where procurement occurs in Ireland, the activity is inspected and the site
procurement?	requires a Tissue Establishment Authorisation. If the procurement occurs outside
	Ireland, inspection of relevant documentation occurs onsite at the Irish Tissue
	Establishment.
3. Testing (Art. 4, Annexes I, II and III of Directive 20	06/17/EC)
3.1. Please specify laboratory tests required for donors	Anti-HIV 1
of non-reproductive tissues and cells in your Member	Anti-HIV 2
State. (more than 1 answer possible)	HBs AG
2 mars (more than 1 and 1 to possible)	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors	Anti-HIV 1
of reproductive tissues and cells in your Member State.	Anti-HIV 2
(more than 1 answer possible)	HBs AG
(more than I allower possible)	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
	LILLINGS CHA FAIRERE

3.3. If NAT testing is not mandatory in your country,	NAT testing would be encouraged by the NCA; However, a national decision
could you please indicate whether you intend to make it	would be required and currently no plans in place.
mandatory or to encourage its use? Please specify why	
or why not (e.g. number of additional cases detected,	
cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available	Yes
tests and test procedures for deceased donors?	
3.4.1. Please specify why:	Post mortem testing may be compromised due to hemolyis, autolysis or bacterial contamination which could lead to the detection of false negatives / positives.  There are currently no CE marked comercially available tests on the market.  However, no post mortem procurement of tissues and cells occurs in Ireland
3.5. Are any other laboratory tests required for donors	Yes
of non-reproductive tissues and cells in your Member	
State?	
3.5.1. Please specify.	HTLV-1 testing of donors living in or originating from areas of high prevalence
1 3	as per Directive
3.6. Are any other laboratory tests required for donors	Yes
of reproductive tissues and cells in your Member State?	
3.6.1. Please specify.	HTLV-1 testing of donors living in or originating from areas of high prevalence
5.0.1. Hease specify.	as per Directive. NAT chlamydia tesing is obligatory for non partner sperm donations as per Directive.
3.7. Do you request/use international accreditation	Yes
systems for testing laboratories?	
3.7.1. Please specify.	Yes, in Ireland, the Irish National Accreditation Board accredit such laboratories
	to the International Standard for Medical Testng Laboratories ISO15189.
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing	ng of tissue establishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation,	Yes
authorisation, accreditation or licensing for all types of	
tissue establishments under your responsability?	
4.2. Is inspection a prerequisite for the designation,	Yes
authorisation, accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011	No applications for Tissue Establishment Authorisation were received in 2011.
for authorising/accrediting/licensing/designating TEs?	All existing Tissue Estalishments had been authorised in 2011. 3 inspections were performed in relation to applications to vary /change the existing Tissue Establishment Authorisations. Routine (two yearly) inspections of tissue establishments were also performed.
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer	During routine inspections
possible)	During inspections organised for this purpose  By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many	none
authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	none
2004/23/EC), how many	
authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external	No
entity to a quality system standard (e.g. ISO, JACIE,	
FACT)?	
	d by the NCA
4 bis. Overview of tissue/cells establishments authorise	•
4.7. Tissue establishments with authorisation pending	Musculo-skeletal tissue establishments
approval at 01/01/2011 (more than 1 answer possible):	Cardiovascular tissue establishments
4.7.2. How many musculo-skeletal tissue	1
establishments?	
4.7.4. How many cardiovascular tissue establishments?	1
	1 Cardiovascular tissue establishments

ommoved by 21/12/2011 (massed by 1	
approval by 31/12/2011 (more than 1 answer possible):	1
4.8.4. How many cardiovascular tissue establishments?	1 *
4.9. Tissue establishments first time authorised	Musculo-skeletal tissue establishments
between 01/01/2011 and 31/12/2011 (more than 1	
answer possible):	
4.9.2. How many musculo-skeletal tissue	1
establishments?	
4.10. All tissue establishments authorised by	Musculo-skeletal tissue establishments
31/12/2011 (more than 1 answer possible):	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.10.2.1. How many public musculo-skeletal tissue	1
establishments?	
4.10.2.2. How many private musculo-skeletal tissue	2
establishments?	
4.10.5.1. How many public HSC tissue establishments?	2
4.10.5.2. How many private HSC tissue	none
establishments?	
4.10.6.1. How many public cord blood tissue	none
establishments?	
4.10.6.2. How many private cord blood tissue	1
establishments?	-
4.10.7.1. How many public ART tissue establishments?	none
4.10.7.2. How many private ART tissue	9
establishments?	
4.10.8.1. How many public multi-tissue	3
establishments?	3
4.10.8.2. How many private multi-tissue	1
establishments?	
	N.
4.11. How many tissues and cells were distributed	None
under the direct agreement of the Competent Authority	
according to Art. 6(5) during 2011? Please provide	
number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national	Yes
provisions pursuant to the Directive been defined	
(Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on	
accreditation, authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and	Yes
control measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the	The compliance department of the Irish Medicines Board are in charge of
CA in charge of inspections.	inspections.
5.1.2. If yes, please specify staffing (how many	1 Blood, Tissues and Organs Manager, 2 Blood, Tissues and Organs Inspectors, 1
5.1.2. If yes, please specify staffing (how many inspectors)	1 Blood, Tissues and Organs Manager, 2 Blood, Tissues and Organs Inspectors, 1 Blood, Tissues and Organs Scientific Officer
inspectors).	Blood, Tissues and Organs Scientific Officer.
inspectors).  5.2. Does the inspection scheme interact or overlap	
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for	Blood, Tissues and Organs Scientific Officer.
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same	Blood, Tissues and Organs Scientific Officer.
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common	Blood, Tissues and Organs Scientific Officer.
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	Blood, Tissues and Organs Scientific Officer. Yes
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer	Blood, Tissues and Organs Scientific Officer.  Yes  Blood
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	Blood, Tissues and Organs Scientific Officer.  Yes  Blood Organs
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)	Blood, Tissues and Organs Scientific Officer.  Yes  Blood Organs Advanced therapies
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue	Blood, Tissues and Organs Scientific Officer.  Yes  Blood Organs
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were	Blood, Tissues and Organs Scientific Officer.  Yes  Blood Organs Advanced therapies
inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue	Blood, Tissues and Organs Scientific Officer.  Yes  Blood Organs Advanced therapies

for non-reproductive tissues/cells were conducted in	
2011 (from 1/1/2011 to 31/12/2011) following serious	
adverse events or reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues	none
establishments for non-reproductive tissues/cells were	
conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g.	
due to a whistle-blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-	none
reproductive tissues/cells conducted in 2011	
(01/01/2011  to  31/12/2011): What was the number of	
inspections carried out where no shortcomings were	
observed?	
5.3.4. Outcome of inspections of TEs for non-	5
reproductive tissues/cells conducted in 2011	
(01/01/2011  to  31/12/2011): What was the number of	
inspections carried out where minor shortcomings were	
noted?	
5.3.5. Outcome of inspections of TEs for non-	5
reproductive tissues/cells conducted in 2011	
(01/01/2011  to  31/12/2011): What was the number of	
inspections carried out where major shortcomings were	
noted?	
5.3.6. Outcome of inspections of TEs for non-	none
reproductive tissues/cells conducted in 2011	
(01/01/2011 to 31/12/2011): What was the number of	
inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-	none
reproductive tissues/cells conducted in 2011	
(01/01/2011  to  31/12/2011): What was the number of	
inspections carried out that were followed by closure?	
5.3.8. Outcome of inspections of TEs for non-	none
reproductive tissues/cells conducted in 2011	
(01/01/2011  to  31/12/2011): What was the number of	
other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in	4
ART establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	none
establishments following serious adverse events or	
reactions, or suspicion thereof (from 1/1/2011 to	
31/12/2011)?	
5.4.2. How many other type of inspections were	There were three (3) inspections performed which reviewed applications to vary
conducted on ART establishments (from 1/1/2011 to	the existing Tissue Establishment Authorisations of two ART clinics.
31/12/2011) (e.g. due to a whistle-blower)? Please	The first state of the first sta
1 1 -	
specify.	mana .
5.4.3. Outcome of inspections of ART tissue	none
establishments carried out in 2011 (01/01/2011 to	
31/12/2011): What was the number of inspections	
carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out	6
in ART establishments where minor shortcomings were	
noted?	
5.4.5. What was the number of inspections carried out	1
in ART establishments where major shortcomings were	·
noted?	
5.4.6. What was the number of inspections carried out	none
in ART establishments followed by suspension of	
authorisation?	
5.4.7. What was the number of inspections carried out	none
in ART establishments followed by closure of	
1	I .
respective establishements?	

5.4.8. What was the number of other inspections of	3 - There were three (3) inspections performed which reviewed applications to
ART establishments? Please specify.	vary the existing Tissue Establishment Authorisations of two (2) ART clinics.
5.5. Which type of routine inspections do you conduct?	General system-oriented inspections
(more than 1 answer possible) 5.6. How do you decide which type of routine	All routine TE inspections comprise of a detailed on-site review of the quality
inspection to conduct?	system and processes along with a review of any issues or serious adverse events reactions (SAE/R's) that may have occured since the last inspection. Routine inspections are performed on-site no less than once every two years as per Directive.
5.7. Until 2011, did you implement the requirement	Yes
concerning the time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?	19
5.9. Did you perform/conduct inspections of	No
procurement sites outside tissue establishments?	
5.9.2. If no, why not?	Where procurement occurs in Ireland, the activity is inspected and the site requires a tissue establishment authorisation. If the procurement occurs outside of Ireland, inspection of the relevant documentation occurs onsite at the irish tissue establishment
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	Performing external auditing is mandatory to all TEs and is reviewed as part of the routine IMB inspection
5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	Yes
5.12. Did you send any of your inspectors to the	Yes
training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	5
5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	No
5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	No
5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	No
5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	No
5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as	Yes
inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	The NCA would encourage the development of joint inspections, however, a controlled approach to their development is needed, specifically, with respect to the joint inspection of sites outside of the EEA.
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue	No

immort/overest of tiggues and called from/to third	T
import/export of tissues and celles from/to third countries?	
6.2. Please specify the number of tissue establishments	7
authorised to import tissues and cells from third	
countries (recorded by 31/12/2011).	
6.3. Please specify the number of tissue establishments	7
authorised to export tissues and cells from third	
countries (recorded by 31/12/2011).	
6.4. Please specify which procedures you have in place	The importation of skin is not performed in Ireland.
for verifying the equivalent standards of quality and safety for importation of skin from third countries.	
6.5. Please specify which procedures you have in place	TE's that wish to import Tissues and Cells on a routine basis from a site outside
for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.	the EEA are required to list this activity on their TE authorisation. In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the
	IMB of their intent to import using IMB documentation and will document this
	import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on
	their TE authorisation. In authorising this non - routine import, the IMB performs
	a detailed review of the documentation supplied by the tissue establishment
	including the national and international accreditation status of the third country
	site and the service level agreement (SLA) between both parties. A follow up
	review this non routine import is perfomed onsite as part of the routine Irish TE
( ( Dlane marife mile) manadama and harring in alam	inspection.
6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and	TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation. In authorising
safety for importation of ophtalmic (cornea, sclera, etc)	this routine import, the IMB performs a detailed review of the documentation
tissues from third countries.	supplied by the tissue establishment including the national accreditation status of
	the third country site and the service level agreement (SLA) between both parties.
	TE's that wish to import tissues and cells on a non routine basis, must notify the
	IMB of their intent to import using IMB documentation and will document this
	import as a planned deviation. TE's that wish to import Tissues and Cells on a
	routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs
	a detailed review of the documentation supplied by the tissue establishment
	including the national and international accreditation status of the third country
	site and the service level agreement (SLA) between both parties. A follow up review this non routine import is performed onsite as part of the routine Irish TE
	inspection.
6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from	TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation. In authorising this routine import, the IMB performs a detailed review of the documentation
third countries.	supplied by the tissue establishment including the national accreditation status of
	the third country site and the service level agreement (SLA) between both parties.  TE's that wish to import tissues and cells on a non routine basis, must notify the
	IMB of their intent to import using IMB documentation and will document this
	import as a planned deviation. TE's that wish to import Tissues and Cells on a
	routine basis from a site outside the EEA are required to list the exporting site on
	their TE authorisation. In authorising this non - routine import, the IMB performs
	a detailed review of the documentation supplied by the tissue establishment
	including the national and international accreditation status of the third country
	site and the service level agreement (SLA) between both parties. A follow up
	review this non routine import is performed onsite as part of the routine Irish TE
6.8. Please specify which procedures you have in place	inspection.  TE's that wish to import Tissues and Cells on a routine basis from a site outside
for verifying the equivalent standards of quality and	the EEA are required to list this activity on their TE authorisation. In authorising
safety for importation of haematopoietic stem cells	this routine import, the IMB performs a detailed review of the documentation
(HSC) (other than cord blood) from third countries.	supplied by the tissue establishment including the national accreditation status of
	the third country site and the service level agreement (SLA) between both parties.

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6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries.  6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries.	TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection.  TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation. In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection.  TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on the IMB of their intent to
	including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is performed onsite as part of the routine Irish TE inspection.
6.11. Did you import tissues/cells from 3rd countries	Yes
during 2011 (01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.	7 TE's inported tissues and cells in 2011. 4 non ART establishments and 3 ART establishments. 2 PBSC's 1 Donor Lymphocyte 4 Cord Blood 34 Bone 11 Pericardium 20 Amnion 14 Sclera 168 Corneas 2040 imports of gametes and embryos from 3 ART clinics.
6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination.	export of 734 units to a country outside the EEA.
6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?	No
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)	D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled  E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells
6.14.1. If A or D were selected, please explain how you quantify local/national needs.	Tissues and Cells are imported to Irish Tissue Establishments in cases where Ireland does not provide the resources for patients (e.g procurement of post

	mortem bone, patient specific bone marrow)
6.15. Did you authorise direct imports of tissues/cells	No
to hospitals/clinics in your country?	
6.16. Do you have any additional comments on	The development of guidance by the European working group for import/ export
import/export?	of Tissues and Cells is required and the IMB is participating in this working goup.
7. Distribution/intra community exchanges (Article 23	
7.1. Do you have intra-community exchanges of tissues	No
and cells?	
7.2. How do you ensure that tissues establishments	It is the responsibility of the TE to perform distribution of tissues and cells in
fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells	compliance with the requirements of the Directive.
during distribution? Please specify.	
7.3. Do you allow direct distribution to hospitals/clinics	Yes, no restrictions apply
in your MS from TEs in another MS? (only 1 answer	- 10, no tourname appropri
possible).	
7.4. Have you authorised direct distribution to the	No
recipient of specific tissues and cells (Art. 6, Directive	
2006/17/EC)?	
7.5. Do you collect data regarding the cross-border	Yes
exchange of tissue/cells between your country and	
other EU MS?	
7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units	Allogenic Peripheral Blood Stem Cells - 4 units distributed within the EEA
distributed) concerning distribution to other MS in	
2011 (01/01/2011-31/12/2011).	
7.5.2. Please provide us with data (country of origin,	Bone Marrow Allogenic - 9 Accepted from within EEA Peripheral Blood Stem
type of tissue/cell and number of units distributed)	Cells Allogenic - 14 Accepted from within EEA Bone - 21 Accepted from within
concerning distribution to other MS in 2011	EEA Sclera - 4 Accepted from within EEA Amniotic Membrane - 3 Accepted
(01/01/2011-31/12/2011)	from within EEA Heart Valves - 13 Accepted from within EEA Donor
	Lymphocyte - 1 Accepted from within EEA Tendons - 5 Accepted from within
	EEA Corneas - 5 Accepted from within EEA
7.6. Are you aware of any significant changes in 2012	No
which may invalidate the 2011 data on cross-border	
exchanges of tissues/cells between your country and other EU MS?	
7.7. Do you allow brokerage companies for either	No
distribution in EU and/or import/export of tissues/cells?	NO
In this context, a brokerage company means a body that	
arranges transactions between a supplier (tissue	
establishment/company selling tissues or cells) and a	
buyer (a tissue establishment/a hospital or clinic/an	
individual) without undertaking activities of	
processing, preservation or storage.	
7.8. Are brokers actively supplying health	Yes
professionals/establishments in your country?	Another country
7.8.1. Where are the brokers located? 7.8.2. If the broker is located in another country, how	Another country  There are no Irish brokers actively supplying healthcare professionals /
easy/difficult is it to ensure that safety and quality	establishments in Ireland. However, as no restrictions apply to the distribution of
requirements are met?	tissues and cells to Ireland from brokers within the EU, it is difficult to control the
	quality and safety requirements, specifically with respect to the reporting of
	SAE/R's traceability and recall notification.
7.9. Do you have any additional comments on	The development of guidance in the control of distribution across the EU and
distribution?	directly to health care professionals and recipietns is required.
8. Register of tissue establishments and reporting obli	gations (Article 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on	Yes
the activities of tissue establishments in your Member	
State? (Article 10(1)). If yes, please upload the	
template.	1000/ (-11)
8.2. How many tissue establishments submitted annual	100% (all)
reports of their activities during 2011. Please provide	

an estimation. (1 answer possible)	
8.3. Are these reports publicly available? (Article	No
10(1))	
8.4. Do you publish a national annual report of the	No
consolidated activities of all tissue establishments in	
your country?	
8.4.2. If no, why not?	This is currently being progressed. Our stakeholders will be consulted in this
	regard as any annual activity data may be sensitive particularly in the ART field.
8.5. Is there a publicly accessible register of authorised	Yes
tissue establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the	http://www.imb.ie/EN/Blood-TissuesCells/BloodTissue-Establishments-
register's web site.	.aspx?page=1&name=&orderby=name&orderascending=True&type=3&sitestatus
	=1&withdrawdate=
8.6. Do you provide data regarding tissues and cells	No
activities to the EUROCET registry (non-mandatory	
reporting)?	
8.6.2. If no, why not?	The IMB are not legally required to submit data regarding tissues and cells
	activity to the EUROCET registry. It is felt that the submission of data requires resources not currently available to the IMB. In addition, the IMB have not
	established agreements with their TE's to submit their data to a publicly accessible
	registry.
8.7. Do you have any additional comments on	registry.
reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and I	Directive 2006/86/FC)
9.1. Was the donor identification system (Art. 8(2))	Yes
implemented in your country?	103
9.2. Who assigns the unique code for each donation?	Tissue establishment
(only 1 answer possible)	1155uc establishment
9.3. How is the data storage for traceability purposes	Both paper records and electronic forms
organised in your tissue establishements (Art 8(4))?	Som paper records and electronic forms
(only 1 answer possible)	
9.4. How do you ensure that the 30 years data storage	This area is reviewed as part of the inspection process.
requirement is respected (Directive 2006/89/EC, Art.	
9)? Please specify.	
9.5. Do you have any additional comments on	
traceability?	
10. Notification of serious adverse events and reaction	s (Article 11 Directive 2004/23, Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in place	Yes
(for the reporting of serious adverse events and	
reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	Irish Medicines Board - Tissue & Cell Vigilance
10.1.2. If yes, please provide a short description of its	Blood Tissues and Organs Vigilance Officer is responsible for the receipt and
organisation.	analysis of SAE/Rs and provides information to BTO inspectors for follow up
	during inspections of TEs.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC).	Yes
Do you use the SAR/E (to the CA (2006/76 art 6.4))	
templates developed to the Annual reporting of the EC	
also at national level?	V
10.3. Do you use the Common Approach Document	Yes
developed for the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in	Yes
charge of collecting SAR/E from all TEs?	1 40
10.5. How many tissue establishments provided in	100%
2011 the SAR/SAE data as requested (please provide	10070
the % from the total number of TEs authorised in your	
country).	
10.6. Do you have a mandatory procedure for the	Yes
transplantation centres when reporting SAR/SAE to the	
TEs which distributed the tissues/cells (Art 11.2)?	
1 L5 WINCH distributed the dissues/cells (Alt 11.2)!	

to Reporting Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) associated with Human Tissues and Cells together with the IMB Adreaction / Event Report Form – Human tissues and Cells . These documents be dowloaded and posted into the IMB or submitted via an on-line form avaing on the IMB website  10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?  10.7.1. Please specify.  10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?  10.8.1. Please specify.  10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	e the inich on, s
SAR/SAE recorded at national level?  10.7.1. Please specify.  An annual report of all SAE/Rs reported is issued to all Tissue Establishmen  10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?  10.8.1. Please specify.  Information on SAR/SAEs recorded at EU level are provided if they directly impact TE's in Ireland and for learning purposes.  10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	may
10.7.1. Please specify.  An annual report of all SAE/Rs reported is issued to all Tissue Establishmen  10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?  10.8.1. Please specify.  Information on SAR/SAEs recorded at EU level are provided if they directly impact TE's in Ireland and for learning purposes.  10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?  10.8.1. Please specify.  Information on SAR/SAEs recorded at EU level are provided if they directly impact TE's in Ireland and for learning purposes.  10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011?  Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	
SAR/SAE recorded at EU level?  10.8.1. Please specify.  Information on SAR/SAEs recorded at EU level are provided if they directly impact TE's in Ireland and for learning purposes.  10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011?  Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	·.
impact TE's in Ireland and for learning purposes.  10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011?  Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	
10.9. Do you require your TEs to have a recall procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011?  Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	
procedure?  10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011?  Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	
of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects	
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?  Yes	
10.11.1. If yes, please give a short description of the  The IMB provide national rapid alert information to all affected sites through	
system/procedure. email notification and issue guidance on the required management procedure 10.12. Do you have in place a system/procedure to Yes	3.
notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	
10.12.1. If yes, please give a short description of the  The IMB provide rapid alert information to all affected sites through email	
system/procedure. notification and issue guidance on the required management procedures.	
10.13. Do you provide data regarding SAR/SAE to the No	
EUROCET registry (non-mandatory reporting)?  10.13.2. If no, please specify why not.  This is primarily a resource issue. This information is already provided on an annual basis to the EC and would be a doubling of offert.	
annual basis to the EC and would be a doubling of effort.  10.14. Do you notify alerts communicated via these  Yes	
tissues and cells national vigilance system also to other	
national vigilance/alert systems?	
10.14.1. If yes, please specify which of the following Haemovigilance	
systems are usually contacted. (more than 1 answer possible)  Pharmacovilance Medical devices	
possible) Medical devices Other	
Please specify 'other'. organ vigilance system (also managed by IMB)	
10.15. Did you send a vigilance officer/contact point to Yes	
the trainings organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1	

(insufficient) - 2 (sufficient) 3 (good) - 4 (very good)	
to 5 (essential)?	
10.16. Do you have any additional comments on SARE	
reporting?	
11. Consent and personal data protection (Article 13 a	and 14, Directive 2004/23/EC)
11.1. What consent system for living tissue/cell	Explicit consent (opt-in)
donation do you have in place within your Member	
State?	
11.1.1. Please specify your choice of consent system	Consent to be revised as part of the development of a national Human Tissues
for living tissue/cell donation.	Act. Until its completion - Explicit consent (opt in)
11.2. What consent system for deceased tissue/cell	Explicit consent (opt-in)
donation do you have in place within your Member	
State?	
11.3. According to your national legislation, in case of	First degree relatives (including spouse)
deceased donations, please specify who is giving the	
authorisation for the tissue donation? (more than 1	
answer possible)	V
11.4. Is the consent system for deceased tissue donation	Yes
the same as for organs?  11.5. How is this consent verified during inspections?	Analysis of documentation
(more than 1 answer possible)	Amarysis of documentation
11.6. What measures are in place to ensure that	Other
donors/relatives/authorising persons on behalf of	
donors are provided with the appropriate information,	
as requested by Art. 13(2)? (more than 1 answer	
possible)	
Please specify 'other'.	Inspection of donor file, health and lifestyle questionnaires, information provided
•	to donors and their families and practice (as per S.I 158 of 2006 - Schedule 1 - 6).
11.7. What measures are in place to ensure that both	All TEs are required to comply with Data Protection Legislation here in Ireland.
donors and recipients remain unidentifiable when	A unique identification number is given to both donors and recipients and applied
access is given to third parties (Art. 14(1)). Please	to all documentation relating to the transplantation procedure.
specify.	
11.8. Please specify what measures are in place to	All TEs are required to comply with Data Protection Legislation here in Ireland.
ensure that the identity of the receipient is not disclosed	A unique donor code is appied at donation and is used within the TE at all times.
to the donor and vice versa.	
11.9. Does your national legislation allows disclosure	No
of donor data in case of gametes donation?	
11.9.1. If no, please specify the circumstances and	There is no legislation in Ireland in this area. No donor sperm is procured here in
measures in place.	Ireland. All donor sperm is obtained from another EU Member state. The donor
11.10. Do you have any additional comments on	disclosure rules in that MS would have to be applied to these donors.
consent and data protection?	
1	Divertive 2004/22: Approved I IV/ Divertive 2004/17)
12. Selection, evaluation and procurement (Article 15	·
12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except	Inspections of TEs and procurement sites Audit of documentation
donors of reproductive cells) are respected in your	Addit of documentation
country (Art. 15(1), Annex I Directive 2006/17/EC)?	
(more than 1 answer possible)	
12.2. How do you ensure that all requirements related	Inspections of ART centres
to the evaluation and selection of donors of	Audit documentation
reproductive cells are respected in your country (Art 15	
(1), Annex III of Directive 2006/17/EC)? (more than 1	
answer possible)	
12.3. Do you have more stringent criteria for donor	No
selection than those listed in Annex I of the Directive	
2006/17/EC?	
12.4. What sources are required in your MS for the	· · · · · · · · · · · · · · · · · · ·
	Interview with the donor's family or a person who knew the donor well
evaluation of a deceased donor of tissues/cells? (more	Interview with the donor's family or a person who knew the donor well Medical records of the donor

of donors of reproductive cells than those listed in	
Annex III of the Directive 2006/17/EC?	
12.6. Do you have more stringent criteria for	No
autologous donation than those listed in Annex I of the	
Directive 2006/17/EC?	
12.7. Do you require more information on the donation	No
of tissues/cells than the mandatory one as laid down in	
the Annex of Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements	Inspection of tissue establishment
regarding tissues and cells' procurement, packaging and	Audit of tissue establishment
transport are complied with by tissue establishments in	Inspection of the centre of human application (e.g. transplantation centre, ART
your country (Art 15(1), Annex IV of Directive	centre)
2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of	
procedures, records, personnel functions, equipment,	
materials, facilities, and/or vendors in order to evaluate	
adherence to the written SOP, standards or	
governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance for	
the Transplantation of Organs, Tissues and Cells,	
2011))	
12.9. Do you have any additional comments on	
selection, evaluation and procurement?	
13. Quality management, responsible person, personn	
13.1. How do you ensure that tissue establishments in	Authorisation requirement
your country have in place a quality system respecting	Inspections
the provisions of the Directive 2004/23/EC Art 16.1?	Internal audits
(more than 1 answer possible). (For this question	External audits
"audit" means a documented review of procedures,	
records, personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate adherence	
to the written SOP, standards or governments laws and	
regulations (from Council of Europe Guide to the	
Safety and Quality Assurance for the Transplantation	
of Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments	Authorisation requirement
have a responsible person fulfilling the requirements of	Inspections
Art. 17(1)? (more than 1 answer possible)	
13.3. How do you ensure an appropriate training for the	Authorisation requirement
personnel directly involved in the activities of tissue	Inspections
establishments? (more than 1 answer possible)	
13.4. Do you have national/regional/local training	Yes
programmes for the personnel of tissue establishments?	
13.4.1. If yes, please specify.	It is the responsibility of the tissue establishments to develop their own internal
	training processes as per Article 18 of Directive. This is reviewed on inspection.
	The TEs define the qualification and training of personnel.
13.5. Any additional comments on quality	
management, responsible person, personnel?	
14. Reception, processing, storage, labelling and packa	aging (Art 19-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in	National regulation/policy for reception of tissues/cells
your country fulfill the requirments of the Art. 19	Inspections of tissue establishments
(Tissue and cell reception) of Directive 2004/23/EC	
and Annex IV of Directive 2006/17/EC? (more than 1	
answer possible)	
14.2. How do you ensure that tissue establishments in	SOPs for all processes affecting quality and safety are mandatory for
your country fulfill the requirements of the Art. 20	authorisation
(Tissue and cell processing) of Directive 2004/23/EC?	Inspections of tissue establishments
(more than 1 answer possible)	-r
14.3. How do you ensure that tissue establishments in	SOPs for procedures associated with storage of tissues and cells are mandatory
your country fulfill the requirements of Art. 21 (tissue	for authorisation
and cell storage conditions) of Directive 2004/23/EC?	Inspections of tissue establishments
	1 · ·

(more than 1 answer possible)	
14.4. How do you ensure that tissue establishments in	SOPs for procedures associated with labelling and packaging are mandatory for
your country fulfill the requirements of Art. 22	authorisation
(labelling, documentation and packaging) of Directive	Inspections of tissue establishments
2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.5. Any additional comments on reception,	
processing, storage, labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23	/EC)
15.1. Are third party agreements foreseen/allowed in	Yes
your national legislation?	
15.1.1. If yes, have tissue establishments in your	Yes
Member State notified third party agreements?	
15.1.1.1. Under which circumstances and for which	The import and export of tissues and cells - For service providers - e.g
responsibilities?	maintenance, testing, suppliers - For sites performing prescribed activities on
	behalf of the Tissue Establishment e.g. donation, procurement, processing etc.
15.1.1.2. How are third party agreements controlled	Agreements must be established in accordance with Article 24 of Directive and
(Art 6.2) by the Competent Auhtority(ies) in your MS?	are reviewed as part of inspection process.
Please specify.	
15.2. Any additional comments on third party	
agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent	No
quality and safety requirements than those requested by	
the EU legislation in this field (e.g. restrictions	
concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any	Distribution provisions
difficulties in implementing the requirements in the EU	Vigilance
Tissues and Cells Directives? Please choose from the	
options below.	
16.2.1. For all selected options in question 16.2., please	Distribution provisions - There is difficulty in controlling the distibution of tissues
provide a short description.	and cells to healthcare professionals / establishments from other EU Meber States.
16.3. In your opinion, in which of the following	No shortcomings
Directives are there shortcomings (if any)? (more than	
1 answer possible)	

## A.1.15. Survey response Italy

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health. However, the National Transplant Centre as a
	technical institution of the Ministry, carries out most of the operational
	activities of the Competent Authority.
1.1.2. Address of NCA 1:	National Transplant Centre Via Giano della Bella, 34 00162 Rome Italy
1.1.3. Telephone (central access point):	+39 06 49904040
1.1.4. E-mail (central access point):	cnt@iss.it
1.1.5. Website:	http://www.trapianti.salute.gov.it
1.1.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Reproductive tissues and cells
	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	Vigilance
	Other
Please specify 'other':	Activity data collection (donation and transplantation); traceability (allocation of donation numbers for tissue donations); training;
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	National Blood Centre
1.2.2. Address of NCA 2:	Via Giano della Bella, 27 00162 Rome Italy
1.2.3. Telephone (central access point):	+39 06 49904953
1.2.4. E-mail (central access point):	direzione.cns@iss.it
1.2.5. Website:	http://www.centronazionalesangue.it
1.2.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Blood and blood components
1.2.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	Vigilance
1.3. National Competent Authority 3?	No
1.5. Please give a short description of the legal status and	CNT is a technical instrument of the Ministry of Health and is organised
organisation of the National Competent Authority(ies) (e.g.	as an independent unit within the Higher Institute of Health (Istituto
departments, staffing, number of senior and junior inspectors,	Superiore di Sanità). It was instituted by a law that provides the legal
staff working on EU affairs and legal matters, vigilance officers,	basis for its activities including the promotion and co-ordination of
budget, independence from government etc.).	organ donation and transplantation. Its annual budget is allocated by the
	government in the context of that law and includes funds for the
	implementation of Law no. 191 which is the Italian transposition of
	Directive 2004/23/EC. The centre includes the following sections
	(departments): Medical (organs); Tissues and Cells; Informatics;
	International Relations; Communications; Administration. A small
	number (3) of senior staff work on EU legislative affairs (including the
	Director) and a similar number support the Ministry in the development
	of Italian legislation. There are 6 inspectors for tissues and cells who
	also manage the vigilance activities. There is also a team of experts
	from the field that are trained by CNT to assist on inspections. The
	Centre leads and participates in many EU -funded projects in the field of
	transplantation and assisted reproduction.
1.6. In case of MS with federal or decentralised systems, please	Accreditation, authorisation, licensing of TEs
indicate the roles/tasks of the Regional Competent	Inspection
Authority(ies). (more than 1 answer possible)	Vigilance
1.7. Could you please describe the competence/mandate of the	The Regional Authorities are responsible for authorising Tissue
Regional Competent Authority(ies) and their relation with the	Establishments and for suspending or revoking that authorisation. They
	do this on the basis of an initial evaluation of regional minimal
National Competent Authority(ies) for tissues and cells:	
National Competent Authority(ies) for tissues and cells:	structural and organisational requirements. Their subsequent activity is
National Competent Authority(ies) for tissues and cells:	structural and organisational requirements. Their subsequent activity is subject to insepction to verify compliance with the national legislation
National Competent Authority(ies) for tissues and cells:	
National Competent Authority(ies) for tissues and cells:	subject to insepction to verify compliance with the national legislation
National Competent Authority(ies) for tissues and cells:	subject to insepction to verify compliance with the national legislation that transposes the EU Directives. For tissues and HPCs, these
National Competent Authority(ies) for tissues and cells:	subject to insepction to verify compliance with the national legislation that transposes the EU Directives. For tissues and HPCs, these inspections are carried out by CNT/CNS on a national basis and the
National Competent Authority(ies) for tissues and cells:	subject to insepction to verify compliance with the national legislation that transposes the EU Directives. For tissues and HPCs, these inspections are carried out by CNT/CNS on a national basis and the results are submitted to the regional authorities. In 2010, the Ministry

2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"?	By inspecting some procurement centres
(more than 1 answer possible)	By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	In general, authorisation for procurement is integrated into the tissue establishment inspection scheme and is not granted separately.
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	372 centres
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	63 procurement centres of bone marrow; 83 procurement centres for PBSC, 279 procurement centres for cord blood
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	195 (excluding centres that carry out only intra-uterine insemination (IUI)
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	13 authorised ATMP manufacturers (clinical trials) with procurement at their own hospitals. Some may have procurement in other hospitals for whom they manufacture but the numbers of these procurement centres are not available.
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)	Inspections of the site/centre Analysis of the mandatory documentation
2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	No
2.4.2. Which National Authority is in charge of this activity?	Testing laboratories operate within the national healthcare system and are authorised for their activities by the Regional Health Authorities
2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible)	Analysis of the mandatory documentation requested from the tissue establishment Other
Please specify 'other':	Reliance on the system in place for diagnostic laboratory authorisation.
2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.).	Not possible to provide. See 2.4
2.7. Do you have any additional comments on procurement?	No
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC	
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum
3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).	NAT testing for HIV, HCV and HBV is mandatory for donors of HPCs (bone marrow, PBSC, cord blood) in line with the national blood legislation. It is not mandatory for tissues or gamete donor, except for living tissue donors where the serology test is not repeated at 180 days). It is, nonetheless, routinely carried out by tissue banks. There are no plans to make it mandatory. HTLV testing is carried out only on donors

	with identified risk as specified in Directive 2006/17/EC. Chlamydia is
24.2	a required test for gamete donors but it is not performed by NAT.
3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?	Yes
3.4.1. Please specify why:	Many centres use kits that are not certified for use with cadaveric samples.
3.5. Are any other laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	Depending on the type of donor, the type of tissues/cells or the donor
	history, testing may be required for CMV, toxoplasma, West Nile Virus,
	Chikungunya etc. Obviously, blood grouping and HLA typing are
	required for certain donors and bacteriology testing of tissues/cells is a
	requirement for all types of donations.
3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	No
3.7. Do you request/use international accreditation systems for	Yes
testing laboratories?	165
3.7.1. Please specify.	For HLA testing laboratories: EFI or ASHI accreditation
3.8. Do you have any additional comments on testing?	No
4. Accreditation, designation, authorisation or licensing of tissu	a establishments (Article 6 Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments	165
under your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	Tissues: 13; HPC: 3 inspections at TEs for bone marrow and PBSC
authorising/accrediting/licensing/designating TEs?	and 11 inspections at cord blood banks; ART: 11
	Please note: many centres are given a preliminary
	authorisation/accrediation etc. before inspection on the basis of a
	documentary review.
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	During inspections organised for this purpose
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many authorisations/accreditation/licenses	
were suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	
	0
2004/23/EC), how many authorisations/accreditation/licenses	0
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?	
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a	Yes
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?	Yes
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s)	Yes  Mandatory for authorisation
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s)	Yes  Mandatory for authorisation
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation.
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)  Please specify 'other':	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation.
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)  Please specify 'other':	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation.
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)  Please specify 'other':  4bis. Overview of tissue/cells establishments authorised by the 4.7. Tissue establishments with authorisation pending approval at	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation.  NCA  Musculo-skeletal tissue establishments
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)  Please specify 'other':  4bis. Overview of tissue/cells establishments authorised by the 4.7. Tissue establishments with authorisation pending approval at	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation.  NCA  Musculo-skeletal tissue establishments Cardiovascular tissue establishments Cardiovascular tissue establishments Cord blood tissue establishments Cord blood tissue establishments
2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible)  Please specify 'other':  4bis. Overview of tissue/cells establishments authorised by the 4.7. Tissue establishments with authorisation pending approval at	Yes  Mandatory for authorisation Inspections are conducted jointly by the CAs and independent certifying body No relation Other  Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation.  NCA  Musculo-skeletal tissue establishments Cardiovascular tissue establishments HSC tissue establishments

	Other tissue establishments
4.7.2. How many musculo-skeletal tissue establishments?	
4.7.4. How many cardiovascular tissue establishments?	1
4.7.5. How many HSC tissue establishments?	69
4.7.6. How many cord blood tissue establishments?	16
4.7.7. How many ART tissue establishments?	195
4.7.8. How many multi-tissue establishments?	1
4.7.9. Please specify the type of tissues/cells and how many.	We assume this refers to the 'other' category Pancreatic islets: 1
4.8. Tissue establishments with authorisations pending approval	Musculo-skeletal tissue establishments
by 31/12/2011 (more than 1 answer possible):	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
4.8.2. How many musculo-skeletal tissue establishments?	1
4.8.4. How many cardiovascular tissue establishments?	1
4.8.5. How many HSC tissue establishments?	66
4.8.6. How many cord blood tissue establishments?	9
4.8.7. How many ART tissue establishments?	188
4.8.8. How many multi-tissue establishments?	1
4.9. Tissue establishments first time authorised between	HSC tissue establishments
01/01/2011 and 31/12/2011 (more than 1 answer possible):	Cord blood tissue establishments
	ART tissue establishments
40.5 W WOOd: 418.1 4.0	Other tissue establishments
4.9.5. How many HSC tissue establishments?	3
4.9.6. How many cord blood tissue establishments?	1
4.9.7. How many ART tissue establishments?	7
4.9.9. Please specify the type of tissues/cells and how many.	We assume this refers to the 'other' category Pancreatic islets: 1  Skin tissue establishments
4.10. All tissue establishments authorised by 31/12/2011 (more	Musculo-skeletal tissue establishments
than 1 answer possible):	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.1.1. How many public skin tissue establishments?	5
4.10.1.2. How many private skin tissue establishments?	0
4.10.2.1. How many public musculo-skeletal tissue	4
establishments?	
4.10.2.2. How many private musculo-skeletal tissue	0 (although there is 1 private musculo-skeletal processing facility that is
establishments?	inspected and authorised to process tissue as a third party for public
	banks.
4.10.3.1. How many public ocular tissue establishments?	7
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue establishments?	3
4.10.4.2. How many private cardiovascular tissue	0
establishments?	
4.10.5.1. How many public HSC tissue establishments?	11
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	3
4.10.6.2. How many private cord blood tissue establishments?	0
4.10.7.1. How many public ART tissue establishments?	6
4.10.7.2. How many private ART tissue establishments?	1
4.10.8.1. How many public multi-tissue establishments?	8
4.10.8.2. How many private multi-tissue establishments?	
4.10.9.1. Please specify the type of 'other' public tissues/cells	Pancreatic islets: 2 Amniotic membrane: 1
establishements and how many.	N. P. H.
4.10.9.2. Please specify the type of 'other' private tissues/cells	Not applicable

establishements and how many.	
4.11. How many tissues and cells were distributed under the	0
direct agreement of the Competent Authority according to Art.	·
6(5) during 2011? Please provide number(s) per type	
tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	No
authorisation, designation and licensing?	110
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	105
5.1.1. If yes, please specify the CA/Department of the CA in	Tissue and Cell section of CNT. For HPC and cord blood banks, these
charge of inspections.	inspections are carried out in collaboration with CNS
5.1.2. If yes, please specify staffing (how many inspectors).	6 inspections are carried out in conaboration with CNS  6 inspectors although all of these individuals also have other
3.1.2. If yes, piease specify starting (now many inspectors).	responsibilities. There is also a team of tissue bank expert inspectors, a
	team of HPC centre expert inspectors and 2 teams of ART centre
	inspectors (one regional team and one national team) who work in this
	field or in related fields and have been trained by CNT to assist in
	inspections on an ad-hoc basis.
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	103
pharmaceuticals, etc. (e.g. same inspector team, common	
training, common documentation, etc.)? (more than 1 answer	
possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Accreditation organisations (e.g. JACIE)
5.3. How many routine inspections of tissue establishments for	CB:10; HPC: 3;Tissues:13
non-reproductive tissues/cells were conducted in 2011 (from	,
1/1/2011 to 31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) following serious adverse events or	
reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues	1 cord blood bank inspection to verify traceability and new activity. 1
establishments for non-reproductive tissues/cells were conducted	tissue bank inspection to verify corrective actions following a previous
in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	inspection 1 third party processor to review plans for a new preparation
blower)? Please specify.	process.
5.3.3. Outcome of inspections of TEs for non-reproductive	Tissues: 2;HPC: 0;CB: 2
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where no	
shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	Tissues: 2;HPC: 3;CB: 9
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	Tissues: 9; HPC: 3; CB:9 We have understood this to mean those
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	where 'major' and/or 'critical' non-compliances were noted, according to
What was the number of inspections carried out where major	the EC Operational Manual.
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out that were	
followed by suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out that were	
followed by closure?	

Γ	
5.3.8. Outcome of inspections of TEs for non-reproductive	See question 5.3.2
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of other inspections carried out? Please	
specify.	
5.4. How many routine inspections were conducted in ART	11
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	0
	U
establishments following serious adverse events or reactions, or	
suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on	0
ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a	
whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments	0
carried out in 2011 (01/01/2011 to 31/12/2011): What was the	
number of inspections carried out where no shortcomings were	
observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	11
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective	
establishments?	
	0.540.1
5.4.8. What was the number of other inspections of ART	See 5.4.2 above
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more	General system-oriented inspections
than 1 answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine inspection to	General system-oriented inspections are the normal type of inspection
conduct?	conducted. They are carried out for the first certification of the centre
	and normally for subsequent routine inspections also. On rare occasions
	thematic inspections are carried out, either when the centre has already
	I =
	had a number of general system-oriented inspections and it is decided
	that it will be more fruitful to choose a specific topic on which to focus
	or when a particular issue has arisen in relation to e.g. importation, a
	change in processing or a vigilance incident in the period prior to the
	routine inspection. Desk-based reviews are carried out when there is a
	large number of centres to be inspected for the first time. They are used
	to help prioritise the order of inspections and to allow preliminary
	certification until a site inspection can be conducted.
5.7. Until 2011, did you implement the requirement concerning	
the time interval between two inspections (Art. 7.3.)?	1 INO
and time interval between two inspections (Art. 1.3.):	No
1 , , ,	
5.7.1. Why not?	This was achieved, plus or minus a few months, for tissue banks where
1 , , ,	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC
1 , , ,	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the
1 , , ,	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number
1 , , ,	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of
1 , , ,	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number
1 , , ,	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of
5.7.1. Why not?	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain.
5.7.2. How do you prioritise tissue establishments to be	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain.  Using desk-based review of questionnaires, by the size of the banks and,
5.7.1. Why not?	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain.  Using desk-based review of questionnaires, by the size of the banks and, for HPCs, depending on the timing of JACIE inspections as the CA
5.7.1. Why not?  5.7.2. How do you prioritise tissue establishments to be inspected?	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain.  Using desk-based review of questionnaires, by the size of the banks and, for HPCs, depending on the timing of JACIE inspections as the CA inspection is carried out jointly with JACIE.
5.7.2. How do you prioritise tissue establishments to be inspected?  5.8. How many TEs were inspected at least twice between 2008-	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain.  Using desk-based review of questionnaires, by the size of the banks and, for HPCs, depending on the timing of JACIE inspections as the CA inspection is carried out jointly with JACIE.  Tissues: 20. HPC: 0 but a system of interim documentary
5.7.1. Why not?  5.7.2. How do you prioritise tissue establishments to be inspected?	This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain.  Using desk-based review of questionnaires, by the size of the banks and, for HPCs, depending on the timing of JACIE inspections as the CA inspection is carried out jointly with JACIE.  Tissues: 20. HPC: 0 but a system of interim documentary review was implemented at two years following release of certification
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5.10.1. If yes, how many?	in 2011: 1
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell	
procurement and tissue establishments - Guidelines for	
inspections (Commission Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 ( $1 = \text{not important}$ , 2	
= sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in	140
that MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	140
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	NO
cells were imported in your country (as recorded by	
31/12/2011)?	No.
5.16. Have you asked another MS, or have you been requested	No
by any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections?	Yes
Joint inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	No
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments	No
that are explicitly authorised to perform import/export of tissues	
and celles from/to third countries?	
6.2. Please specify the number of tissue establishments	At this time, any tissue establishment that is certified by CNT as being
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries	compliant with the safety and quality requirements is also allowed to
6.2. Please specify the number of tissue establishments	compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries	compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on Import/export. A specific authorisation will be implemented to allow
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6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments	compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on Import/export. A specific authorisation will be implemented to allow maintenance of the EU TE compendium.
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries	compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on Import/export. A specific authorisation will be implemented to allow maintenance of the EU TE compendium.
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6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).  6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.  6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.  6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries.  6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.	compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on Import/export. A specific authorisation will be implemented to allow maintenance of the EU TE compendium.  to third countries? as 6.2  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation.  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation.  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importation.  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importation.  Inspectors review the compliance of protocols adopted for HSC importation by national (IBMDR, Italian Bone Marrow Transplantation)
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).  6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.  6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.  6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries.  6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6.8. Please specify which procedures you have in place for	compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on Import/export. A specific authorisation will be implemented to allow maintenance of the EU TE compendium.  to third countries? as 6.2  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation.  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation.  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation.  Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation.  Inspectors review the compliance of protocols adopted for HSC

	reviewed by the importing Italian TE and any other documents
6.9. Please specify which procedures you have in place for	associated with the importation.  Inspectors review the compliance of protocols adopted for HSC
verifying the equivalent standards of quality and safety for importation of cord blood from third countries.	importation by national (IBMDR, Italian Bone Marrow Transplantation) and international (WMDA, World Marrow Donor Association)
•	standards .They also review a selection of donor records that have been
	reviewed by the importing Italian TE and any other documents associated with the importation.
6.10. Please specify which procedures you have in place for	Inspectors review the agreements that the art centers have with the third
verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third	country art centers. They also review documents associated with the importation.
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of	Tissues: Not collected centrally though could be obtained from the importing banks HPC:Australia 1 PBSC and 5 CB, Canada 2 BM, 6
origin.	PBSC, China/Hong Kong 1 BM, Israel 4 BM and 15 PBSC, 1 BM and 1 PBSC, Taiwan 1 CB, USA 55 BM, 63 PBSC and 26 CB, Switzerland 1
	BM, 1 PBSC and 1 CB. ART: not known but only imported by couples
	for their own use (the law prohibits non-partner gamete donation and use).
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)? 6.12.1. If yes, please provide the data concerning the	We assume this intends to mean that we export to third countries.
number/volume of exported tissues and cells by country of	Tissues: 357 corneas (at this time we do not record centrally the country
destination.	of destination so this includes both EU and non-EU countries. ART: CNT has had responsibility for import/export of gametes and embryos
	only since January 2013 so we have no data for 2011. HPC: 64;
	Australia 1 CB, Croatia 1 PBSC and 1 CB; Israel 4 BM and 15 PBSC
	and 1 CB, Canada 1 PBSC and 1CB, Chile 1 CB, Russia 1 PBSC, South Africa 2 CB, Switzerland 2 PBSC and 2 CB, Turkey 1 CB, USA 4 BM,
	6 PBSC and 20 CB.
6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells	No
between your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)	A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.
cens and sen-sufficiency: (more than 1 answer possible)	C. Export of tissues/cells is authorised irrespective of national needs
	D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled
	F. Other
Please specify 'other':	Other - import of tissues/cells is allowed only when the same time of
	product is not available within the country from another bank. For HPC import/export depends on the HLA compatibility between donor and
	recipient, characteristics of the donor and of the cellular product (for
6.14.1. If A or D were selected, please explain how you quantify	cord blood units).  For A, tissue banks are asked to check with the other banks for that type
local/national needs.	of tissue (usually by email or fax) to know if there are unmet requests
	for that type of tissue or cell product before it is exported. For D, there needs to be a specific request from a clinical user who confirms that the
	product needs to be imported.
6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	No
6.16. Do you have any additional comments on import/export?	Tissues and cells coming from other EU Member States are managed in a manner equivalent to those coming from third countries. We have a
	recently adopted Decree on Import/Export. Additionally, for HPC
	import/export an authorisation from the Ministry of Health must be obtained.
7. Distribution/intra community exchanges (Article 23 Directiv	
7.1. Do you have intra-community exchanges of tissues and	Yes
cells?	

7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify.	Our decree requires that imports, even from EU MS, enter via an authorised Italian TE which must verify quality and safety. Any additional requirements need to be stipulated in the quality agreement between the tissue establishment in Italy and that in the other MS.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	Yes
7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.	See 7.1.1 For HPC it is necessary to carry out the NAT test for HIV, HBV and HCV.
7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	Through the control of the documentation relating to the donor and the product.
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Yes, but only via an authorised TE in my MS
7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No
7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	Yes
7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).	We understand this question to refer to distribution from Italy to other EU MS. For tissues, 357 corneas were sent out of Italy. At this time we do not record centrally the countries of destination so this will include EU and non-EU countries. For HPCs: Total 84: Austria 1 BM, 2 PBSC, Belgium 3 CB, Czech Republic 1 BM, Denmark 1 BM and 3 CB, France 7 BM, 6 PBSC and 16 CB, Germany 3 BM, 10 PBSC and 5 CB, Greece 1 PBSC and 2 CB, Netherlands 3 CB, Poland 1 PBSC, Portugal 1 CB, Slovakia 1 CB, Slovenia 1 CB, Spain 2 BM, 2 PBSC and 3 CB, Sweden 1 PBSC, UK 1 BM, 4 PBSC and 4 CB.
7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011)	We understand this to mean distribution from EU MS into Italy. The numbers are not centrally available at this time for tissues. For HPC, Total: 429: Austria 2 CB, Belgium 2 CB, Cyprus 3 PBSC, Denmark 1 PBSC, France 6 BM, 6 PBSC and 9 CB, Germany 106 BM, 240 PBSC and 7 CB, Greece 1 CB, Ireland 1 PBSC, Netherlands 1 CB, Poland 2 BM, 7 PBSC, Portugal 3 BM, 12 PBSC, Spain 10 CB, Sweden 1 CB, UK 6 BM, 3 PBSC.
7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS?	No
7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage.	Yes
7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection.	For tissues, such companies are only allowed to operate under a third party agreement with an authorised tissue establishment (which must be public sector). This happening currently only for processed bone products. They can organise the importation on behalf of the TE and can also store and transport on behalf of the TE. The TE must take responsibility for ensuring equivalent quality and safety and for taking orders from clinical users and allocating products to them for distribution. The TE must also take responsibility for traceability and vigilance.
7.8. Are brokers actively supplying health professionals/establishments in your country?	Yes
7.8.1. Where are the brokers located?	Another country
7.8.2. If the broker is located in another country, how easy/difficult is it to ensure that safety and quality requirements are met?	See 7.7.1 above for the limitations that are put on their activities. They are actively supplying only in this context. Any activities outside of an agreement with a TE are not legal. Please note: having selected 'Another country' above, it was not possible to also select 'Your country'. Some of these distributors also operate in Italy.

7.9. Do you have any additional comments on distribution?	No
8. Register of tissue establishments and reporting obligations (A	Article 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the	Yes
activities of tissue establishments in your Member State? (Article	
10(1)). If yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1	
answer possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	They are available on the Eurocet Registry website at www.eurocet.org
o.s.r. if yes, preuse insert the limit(s) to the report(s).	and on the CNT website.
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	110
8.4.2. If no, why not?	The data are published on the Eurocet platform and the CNT website
6.4.2. 11 no, why not:	and presented at conferences, congresses etc.
8.5. Is there a publicly accessible register of authorised tissue	Yes
	168
establishements in place? (Article 10(2))	144 // 4 · · · · · · · · · · · · · · · ·
8.5.1. If yes, please provide us with the link to the register's web	http://www.trapianti.salute.gov.it/cnt/cntHomeSezione.jsp?id=10&area
site.	=cnt-tessuti&menu=menuPrincipale
8.6. Do you provide data regarding tissues and cells activities to	Yes
the EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please	CA details TE detaila Activity data
specify.	
8.7. Do you have any additional comments on reporting?	Regarding 8.1, our reply referred only to tissue banking procurement,
	processing and distribution activity. The following is information
	regarding tissue donation, and HPC activity reporting. Tissues: For
	donation, each donation is entered electronically on the national
	computer software (SIT) managed by CNT. These data are available on
	the system in real time and it generates the annual donation data. Every
	3 months each tissue bank completes a standard form with activity data
	and each Regional Tranpsplant Centre provides data on tissue
	transplants. The form completed by the banks is attached. HPC: For
	HPCs data on transplants are inserted in EBMT's informatic software
	(Promise). This system sends a quarterly report to GITMO (the Italian
	Bone Marrow Transplant Group) who forwards it to CNT. For donation
	activity of cord blood, each cord blood bank reports on a quarterly basis
	to CNT and CNS (the Excel form used is attached). ART: the ART
	centres enter their activity data directly into an informatic system
	managed by the National ART Registry. An annual report is produced
	by the Registry.
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2	2006/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented	Yes
in your country?	
9.2. Who assigns the unique code for each donation? (only 1	Other
answer possible)	
Please specify 'other'.	For tissues: National CA; For HPC: IBMDR (Italian Bone Marrow
	Donor Registry) for unrelated donors; for autologous and related
	donors, codes are allocated by TEs. For ART: allocated by TEs.
9.3. How is the data storage for traceability purposes organised	Both paper records and electronic forms
in your tissue establishements (Art 8(4))? (only 1 answer	p-p records and creations rotting
possible)	
9.4. How do you ensure that the 30 years data storage	Varified during inspection
	Verified during inspection
requirement is respected (Directive 2006/89/EC, Art. 9)? Please	
specify.	
9.5. Do you have any additional comments on traceability?	No
10. Notification of serious adverse events and reactions (Article	11 Directive 2004/23, Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	CNT for tissues and ART. CNT in collaboration with CNS for HPC
1	and cord blood.
	and cord blood.

10.1.2. If yes, please provide a short description of its	There are three slightly different systems in place for Tissues, HPC and
organisation.	ART. In each case the centres are informed regarding how they should notify using forms that are based on those in the annexes of Directive 2006/86/EC. The TEs are responsible for informing clinical users, procurement centres and third parties on how to notify SARE and what to notify. Their procedures for doing this are reviewed during routine inspections.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	No
10.2.1. If no, what template do you use? You are welcome to upload the template if you wish.	We use the templates in the annexes to Directive 2006/86/EC.
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	No
10.4.1. Why not?	The role is shared by the inspector team although one inspector takes the lead for tissues and ART and one for HPC.
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	No
10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs?	By ensuring that TEs when distributing tissues and cells provide full instructions for reporting.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	At this time we do not produce an annual SARE report but we do provide summaries during training courses for TE professionals and at professional society meetings.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	No
10.8.2. Please specify why not.	Until now, there has not been an EC Annual Report to share with the TEs. Once available (2013), it will be shared.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	0
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	No
10.11.2. If no, please specify why not.	Up to now, we communicate by email on a case-by-case basis. This has not yet been formalised in a written procedure.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	No
10.12.2. If no, please specify why not.	Up to now, we communicate by email on a case-by-case basis. This has not yet been formalised in a written procedure.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	No
10.13.2. If no, please specify why not. 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	this data is not requested or reported by Eurocet.  No
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	4

Tions Design	T
10.16. Do you have any additional comments on SARE	Regarding question 10.5, we entered 100% in order to be able to
reporting?	continue compiling the questionnaire. However, the TEs are not
	required to provide an annual SARE report. They report SARE as they
	occur and the CA compiles the annual report. The TEs must provide
	detailed information to transplant centres on how and when to report
	SARE. They manage the interaction with the transplant centres. The
	way they do this is reviewed during routine inspection. See 10.1.2
11. Consent and personal data protection (Article 13 and 14, Di	
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Living donor must sign a consent form.
11.2. What consent system for deceased tissue/cell donation do	Presumed (opt-out) and explicit (opt-in) consent
you have in place within your Member State?	F1:-i+ f
11.2.1. If you have chosen both consent systems for deceased	Explicit for cornea; presumed for other tissues. However, normal
tissue/cell dontation, please specify.	practice is always to consult the family to establish a 'lack of objection'.
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Non-marital partners
tissue donation? (more than 1 answer possible)	V.
11.4. Is the consent system for deceased tissue donation the same	Yes
as for organs?	
11.5. How is this consent verified during inspections? (more than	Analysis of documentation
1 answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	For tissues and HPC, an anonymous donation number must be used. The
recipients remain unidentifiable when access is given to third	requirements for maintenance of anonymity are defined in national
parties (Art. 14(1)). Please specify.	guidelines against which inspectors inspect. For ART, no non-partner
	donation is allowed by law.
11.8. Please specify what measures are in place to ensure that the	See 11.7
identity of the receipient is not disclosed to the donor and vice	
versa.	
11.9. Does your national legislation allows disclosure of donor	No
data in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures in	No non-partner donation of gametes is allowed by the national
place.	legislation (Law No. 40).
11.10. Do you have any additional comments on consent and	No
data protection?	
12. Selection, evaluation and procurement (Article 15 Directive	2004/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of	Inspections of TEs and procurement sites
reproductive cells) are respected in your country (Art. 15(1),	Audit of documentation
Annex I Directive 2006/17/EC)? (more than 1 answer possible)	Other
Please specify 'other'.	For tissues and HPC, detailed requirements are specified in national
	guidelines.
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection	Yes
than those listed in Annex I of the Directive 2006/17/EC?	
12.3.1. If yes, please specify.	NAT testing for HPC donors for HIV, HBV and HCV is required
•	toxoplasma IgM for amniotic membrane (in case of positivity the tissue
	cannot be used for transplant); - CMV IgM for hear valves and vessels
	and amniotic membrane, in case of positivity CMV DNA must be
	performed, if negative the donor is suitable CMV for skin: if positive
	the result must be communicated to the centre that has requested the
	tissue for clinical use CMV,toxoplasma and EBV testing for HPC
	<u> </u>

	unrelated donors Serum archive for all donors Chlamydia testing for
10 4 WIL.	gamete donors
12.4. What sources are required in your MS for the evaluation of	Interview with the donor's family or a person who knew the donor well
a deceased donor of tissues/cells? (more than 1 answer possible)	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors	Yes
of reproductive cells than those listed in Annex III of the	
Directive 2006/17/EC?	
12.5.1. Please specify.	Only partner donation is permitted
12.6. Do you have more stringent criteria for autologous	No
donation than those listed in Annex I of the Directive	
2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues	Inspection of tissue establishment
and cells' procurement, packaging and transport are complied	Audit of tissue establishment
with by tissue establishments in your country (Art 15(1), Annex	Other
IV of Directive 2006/17/EC? (more than 1 answer possible)(For	
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities,	
and/or vendors in order to evaluate adherence to the written SOP,	
standards or governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.8.1. Please specify.	Audits are included in the sense that the CA inspection verifies that
1 7	internal audits are performed as part of the quality management of the
	TE. Other: for tissues, national guidelines define the requirements in
	more detail, including for specific tissues.
12.9. Do you have any additional comments on selection,	No
evaluation and procurement?	
13. Quality management, responsible person, personnel (Articl	o 16, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your	Authorisation requirement
country have in place a quality system respecting the provisions	Inspections
of the Directive 2004/23/EC Art 16.1? (more than 1 answer	Internal audits
possible). (For this question "audit" means a documented review	External audits
of procedures, records, personnel functions, equipment,	Other
materials, facilities, and/or vendors in order to evaluate	Other
adherence to the written SOP, standards or governments laws	
and regulations (from Council of Europe Guide to the Safety and	
•	
Quality Assurance for the Transplantation of Organs, Tissues and	
Cells, 2011)).	Diagon note that the external audite refer only to the field of LIDC-
Please specify 'other'.	Please note that the external audits refer only to the field of HPCs.  Internal audits are a requirement of the quality system and are verified
1	
	during inspection. The authorisation is performed by the Regional
	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues,
	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific
	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection. For tissues, national guidelines are issued that include requirements for specific tissues.
13.2. How do you ensure that tissue establishments have a	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific
responsible person fulfilling the requirements of Art. 17(1)?	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection. For tissues, national guidelines are issued that include requirements for specific tissues.
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections  Inspections
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections Other
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections  Inspections
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections Other
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection. For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections Other  Non-mandatory training
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.  13.4. Do you have national/regional/local training programmes	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection. For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections Other  Non-mandatory training
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?	during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues.  Inspections  Other  Non-mandatory training  Yes

	participates in national and regional courses for professionals in the
	field; the courses are organised by the professional societies.
13.5. Any additional comments on quality management, responsible person, personnel?	No
14. Reception, processing, storage, labelling and packaging (Ar	t 19-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)	Inspections of tissue establishments Internal audits of tissue establishments
14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer	SOPs for all processes affecting quality and safety are mandatory for authorisation Inspections of tissue establishments
possible)  14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage	Internal audits of tissue establishments  SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation
conditions) of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer	SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments
possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?	No No
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national legislation?	Yes
15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?	Yes
15.1.1.1. Under which circumstances and for which responsibilities?	- for processing of tissues - for storage of tissues, HPC, gametes or embryos - for gamma sterilisation of tissues - for tissue or cell transportation - for monitoring and management of liquid nitrogen facilities
15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify.	Reviewed during routine inspections
15.2. Any additional comments on third party agreements?	Third parties that carry our critical steps such as processing or storage of tissues or cells on behalf of TEs must have a direct authorisation from the Ministry of Health. These authorisations are issued on the basis of an inspection by CNT.
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)?	Yes
16.1.1. Please specify.	More stringent requirements for receiving tissues/cells from EU  Member States. Some more stringent requirements for testing and serum archiving as mentioned above.
16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below.	Procurement provisions Testing provisions Inspections
16.2.1. For all selected options in question 16.2., please provide a short description.	Procurement: where tissues/cells - notably cord blood for autologous/family use - is procured but then sent to another EU country (as banking is not allowed in Italy) the CA does not verify the compliance of the conditions of procurement as there is no TE in Italy where this could be performed - we rely on the CA of the receiving MS to confirm this through document review at the receiving TE. Testing: the tissue and cell CA is not competent to inspect and verify the compliance of testing laboratories with the requirements. Inspections: with the high number of centres - particularly HPC and ART centres - and the number of inspectors trained and available to conduct

	inspections, it has not been possible to conduct site inspections at every
	centre and at an interval of every two years.
16.3. In your opinion, in which of the following Directives are	Directive 2004/23/EC
there shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC
	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive	See comments sent on June 2nd 2013 in reply to request from Sanco on
2004/23/EC?	potential shorcomings in the current tissues and cells directives and
	resubmitted now in an email to Ioana Siska.
16.3.2. How would you suggest to solve these issues in Directive	We would have comments on this directive but they would depend on
2006/17/EC?	which comments are accepted for the mother directive.
16.3.3. How would you suggest to solve these issues in Directive	We would have comments on this directive but they would depend on
2006/86/EC?	which comments are accepted for the mother directive.

## A.1.16. Survey response Latvia

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	State Agency of Medicines of the Republic of Latvia
1.1.2. Address of NCA 1:	15 Jersikas Street, Riga, LV-1003
1.1.3. Telephone (central access point):	+371 67078424
1.1.4. E-mail (central access point):	info@zva.gov.lv
1.1.5. Website:	www.zva.gov.lv
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
1 ,	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
	Medical devices
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	State Agency of Medicines is the state institution under
organisation of the National Competent Authority(ies) (e.g.	supervision of the Ministry of Health of the Republic of Latvia, that
departments, staffing, number of senior and junior inspectors, staff	carries out evaluation, marketing authorisation, monitoring, control
working on EU affairs and legal matters, vigilance officers, budget,	and regulation of distribution of medicines and medical devices in
independence from government etc.).	Latvia. It is a state agency not financed from the state budget
	(agency's budget is formed from service fees). There are 13
	departments and 144 employees (www.zva.gov.lv). 2 senior
	inspectors for blood, tissues, cells, and organs, including vigilance in
	the Agency. Legal department consists of 4 employees. EU matters
	- no dedicated staff.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	No regional authority
1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the	No regional authority.
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting the documentation associated with procurement that is
than 1 answer possible)	available in the tissue establishment working with procurement
than I answer possible)	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	0
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	0
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	0
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	0
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	0
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	·
conditions accredited, designated, authorised, licensed)? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	No

authorisation or licensing of laboratories performing donor testing?	
2.4.2. Which National Authority is in charge of this activity?	Latvian National Accreditation Bureau
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	6, information available on www.latak.lv
authorised or licensed in your country (e.g. number, year of	
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
3.2. Please specify laboratory tests required for donors of	Treponema Pallidum
a.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 1 Anti-HIV 2
answer possible)	HBs AG
allswei possiole)	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	In practice NAT HBV, NAT HCV, NAT HIV1 are being performed
please indicate whether you intend to make it mandatory or to	routinely.
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	Yes
reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	On certain circumstances tests for HTLV-1; RhD; HLA; malaria;
	CMV; toxoplasma; EBV; Trypanosoma cruzi should be considered.
3.6. Are any other laboratory tests required for donors of	Yes
reproductive tissues and cells in your Member State?	On certain circumstances tests for HTLV-1; RhD; malaria; CMV;
3.6.1. Please specify.	
3.7. Do you request/use international accreditation systems for	Trypanosoma cruzi should be considered. Yes
testing laboratories?	163
3.7.1. Please specify.	Most testing laboratories are accredited according to EN ISO 15189
	and /or EN ISO 17025 standards.
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing of tissue es	stablishments (Article 6, Directive 2004/23/FC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	0
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	

2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC	Δ
4.7. Tissue establishments with authorisation pending approval at	Cord blood tissue establishments
01/01/2011 (more than 1 answer possible):	Cord blood tissue establishments
4.7.6. How many cord blood tissue establishments?	1
4.8. Tissue establishments with authorisations pending approval by	Other tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.9. Please specify the type of tissues/cells and how many.	"1 (mononuclear stem cells)
4.9. Tissue establishments first time authorised between 01/01/2011	ART tissue establishments
and 31/12/2011 (more than 1 answer possible):	1
4.9.7. How many ART tissue establishments?	1
4.10. All tissue establishments authorised by 31/12/2011 (more than	Musculo-skeletal tissue establishments
1 answer possible):	Cord blood tissue establishments ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?	1
4.10.2.2. How many private musculo-skeletal tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	
4.10.6.2. How many private cord blood tissue establishments?	1
4.10.7.1. How many public ART tissue establishments?	0
4.10.7.2. How many private ART tissue establishments?	1
4.10.8.1. How many public multi-tissue establishments?	1
4.10.8.2. How many private multi-tissue establishments?	0
4.10.9.1. Please specify the type of 'other' public tissues/cells	
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	Placental tissues
establishements and how many.	
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	Penalties: - The Criminal law:Section 139. Illegal Removal of
authorisation, designation and licensing?	Tissue and Organs from a Human Being (1) For a person who
	commits illegal removal of tissue or organs from a deceased human
	being in order to use such for medical purposes, where commission
	thereof is by a medical practitioner, the applicable punishment is
	deprivation of liberty for a term not exceeding four years or
	temporary deprivation of liberty, or community service, or a fine,
	with deprivation of the right to engage in the practice of medical
	treatment for a term not exceeding five years. (2) For a person who
	commits illegal removal of tissue or organs from a living human
	being in order to use such for medical purposes, where commission
	thereof is by a medical practitioner, the applicable punishment is
	deprivation of liberty for a term not exceeding seven years, with
	deprivation of the right to engage in the practice of medical
	treatment for a term not exceeding five years State Agency of
	Medicines has powers to suspend or revoke authorization issued to
	tissue establishment if it no longer fullfils requirements of implementing national provisions.
5. Inspections (Article 7, Directive 2004/23/EC)	imprementing national provisions.
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
measures of district establishments:	1
5.1.1. If yes, please specify the CA/Department of the CA in charge	State Agency of Medicines Pharmaceutical activities compliance
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	State Agency of Medicines. Pharmaceutical activities compliance evaluation department is responsible for inspections.

5.1.2. If yes, please specify staffing (how many inspectors).	2 inspectors (senior experts).
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Organs
	Pharmaceuticals
	Advanced therapies
5.3. How many routine inspections of tissue establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	O O
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	"1 inspection related to establishment authorization
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	-
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	V
5.4.7. What was the number of inspections carried out in ART	0

	T
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	C
5.5. Which type of routine inspections do you conduct? (more than 1 answer possible)	General system-oriented inspections Thematic inspections
5.6. How do you decide which type of routine inspection to conduct?	Type for routine Inspections is selected depending on the particular
	situation and information available to NCA.
5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?	Yes
5.8. How many TEs were inspected at least twice between 2008-	0
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	
5.9.2. If no, why not?	Currently there are no procurement sites outside tissue establishments.
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	None of authorized tissues establisments declared contracts with
	3rd parties (except laboratories, please also see answer to 2.4).
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	NO
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	140
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	No
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by 31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	0
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	None, because not relevant so far. If Agency would be receiving
the equivalent standards of quality and safety for importation of skin	such request for imports equivalency of standards will be evaluated
from third countries.	on case by case basis.
6.5. Please specify which procedures you have in place for verifying	None, because not relevant so far. If Agency would be receiving
the equivalent standards of quality and safety for importation of	such request for imports equivalency of standards will be evaluated

musculo-skeletal (bone, tendons, fascia etc.) tissues from third	on case by case basis.
countries.	
6.6. Please specify which procedures you have in place for verifying	None, because not relevant so far. If Agency would be receiving
the equivalent standards of quality and safety for importation of	such request for imports equivalency of standards will be evaluated
ophtalmic (cornea, sclera, etc) tissues from third countries.	on case by case basis.
6.7. Please specify which procedures you have in place for verifying	None, because not relevant so far. If Agency would be receiving
the equivalent standards of quality and safety for importation of	such request for imports equivalency of standards will be evaluated
cardio vascular tissues from third countries.	on case by case basis.
6.8. Please specify which procedures you have in place for verifying	None, because not relevant so far. If Agency would be receiving
the equivalent standards of quality and safety for importation of	such request for imports equivalency of standards will be evaluated
haematopoietic stem cells (HSC) (other than cord blood) from third	on case by case basis.
countries.	
6.9. Please specify which procedures you have in place for verifying	None, because not relevant so far. If Agency would be receiving
the equivalent standards of quality and safety for importation of cord	such request for imports equivalency of standards will be evaluated
blood from third countries.	on case by case basis.
6.10. Please specify which procedures you have in place for	None, because not relevant so far. If Agency would be receiving
verifying the equivalent standards of quality and safety for	such request for imports equivalency of standards will be evaluated
importation of reproductive cells (sperm, egg cells) from third	on case by case basis.
countries.	on case by case basis.
6.11. Did you import tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	140
· · · · · · · · · · · · · · · · · · ·	N.
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	NY.
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	B. Export of tissues/cells is authorised based on estimations
and self-sufficiency? (more than 1 answer possible)	performed on an annual basis
	F. Other
Please specify 'other':	No special conditions regarding sufficiency for authorization of
	imports
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 20	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.2. How do you ensure that tissues establishments fulfil the	By inspecting the SOPs and records regarding distribution,
requirements of Art. 23 of Directive 2004/23/EC regarding quality	labelling.
of tissues and cells during distribution? Please specify.	mooning.
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Other
from TEs in another MS? (only 1 answer possible).	Ollici
Please specify 'other'.	No provisions regarding distribution from TE in another MS to
ricase specify officer.	Latvian hospitals
7.4. Have you authorized direct distribution to the recipient of	1
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	N N
7.5. Do you collect data regarding the cross-border exchange of	No
tissue/cells between your country and other EU MS?	N.
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Arti	ielo 10. Directivo 2004/23/EC)
	1018 111 11118CHVP /HH4// 3/E4 1

8.1. Do you have an annual report model/template on the activities	No
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.1.1. If no, why not?	EUROCET template is being used.
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
	No
8.4. Do you publish a national annual report of the consolidated	NO
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	It is still under implementation
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	http://www.zva.gov.lv/doc_upl/audu-sunu-20130726.pdf
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please specify.	ART data activity Tissues data activity
8.7. Do you have any additional comments on reporting?	THE data don't by 1155do5 data don't by
	(In CITI CI
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	,
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Tissue establishment
possible)	
9.3. How is the data storage for traceability purposes organised in	Only paper records
your tissue establishements (Art 8(4))? (only 1 answer possible)	711
9.4. How do you ensure that the 30 years data storage requirement is	Procedures ( SOP) are in place in tissue establishments, checked
respected (Directive 2006/89/EC, Art. 9)? Please specify.	during inspection.
9.5. Do you have any additional comments on traceability?	daring inspection.
	Di di Anni di
10. Notification of serious adverse events and reactions (Article 11	*
10.1. Do you have a national vigilance system in place (for the	Yes
	1 65
reporting of serious adverse events and reactions (Article 11(1))?	
reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	State Agency of Medicines
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reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	State Agency of Medicines  Senior expert of Pharmaceutical Activities Compliance Evaluation Department is responsible of data collection, documentation, analysis, corrective and preventive actions. Also for issue of RATC (if necessary) at a national level or communication to EU RATC platform, coordination of actions to be taken if RATC issued by
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at national level?	
10.7.2. Please specify why not.	No SAR/SAE was reported so far
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	No
10.8.2. Please specify why not.	Still under implementation. If Latvia is affected by alert issued at EU level then TEs are contacted. Please also see answer to 10.1.2.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	0
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes
10.11.1. If yes, please give a short description of the system/procedure.	According to SOP if the rapid alert is issued then all tissue establishments potentially affected are identified and contacted by phone and in writing. Depending on the information feedback the follow up measures are decided.
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	
10.12.1. If yes, please give a short description of the system/procedure.	According to SOP if the rapid alert is issued via EU RATC platform then all tissue establishments potentially affected are identified and contacted by phone and in writing. Depending on the information feedback the follow up measures are decided.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	No
10.13.2. If no, please specify why not.	Still under implementation.
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	No
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	4
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direction)	
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	According to national provisions in this case the explicit consent( opt-in) is mandatory
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed (opt-out) and explicit (opt-in) consent
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.	For deceased donors consent is checked in the Citizens Register where any person during life can provide information whether he/she allows or prohibits donation of tissues/cells after death.  According to national provisions if there is no information in the Citizens Register (neither authorization, nor prohibition) then it is to be considered as presumed consent but in this case first degree relatives have option to inform in writing the medical establishment regarding the deceased persons will on donation expressed during his/her life.
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	First degree relatives (including spouse)
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Interviews with personnel

11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art.	Only trained personnel is allowed to provide such information
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	Law on protection of personal data contains provisions for handling personal data, incl. obligation to get authoriztion for handling of such data. Systems and Pprocedures must are in place that ensure that information provided to third parties is in coded/anonymized form. If personal information has to be provided to third party then provisions of the Law applies
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	Law on protection of personal data contains provisions for handling personal data, incl. obligation to get authoriztion for handling such data. Procedures are in place that ensure that information is in coded/anonymized form. In the Regulations there are provisions prohibiting disclosure of such data therefore tissue establishments are obliged to implement appropriate systems and procedures.
11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	No
11.9.1. If no, please specify the circumstances and measures in place.	Law on sexual and reproductive health paragraph 14 provisions ensures that donor data should not be dislosed: 14. Secrecy of Medical Impregnation (1) It is prohibited to disclose any data on potential parents to a gamete donor. (2) Potential parents may only obtain information regarding a gamete donors genetic and anthropometric data.
11.10. Do you have any additional comments on consent and data protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23: Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible)	Regular evaluation of medical personnel
12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC?	No
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
	Medical records of the donor
	Interview with the general practitioner
	Interview with the general practitioner Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC?	No
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	

12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
13. Quality management, responsible person, personnel (Article 16	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	inspections
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	Each tissue establishment has local training programmes for their
	personnel.
13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
142 17 1 1 1 1 1 1 1 1 1	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions)	SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
of Directive 2004/25/EC: (more than 1 answer possible)	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	<u> </u>
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	Donor testing
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	Tissue establishments provide copies of agreements with third
Competent Auhtority(ies) in your MS? Please specify.	parties at the request of the competent authority for evaluation.
	During inspections agreements are reviewed and practices checked
15.2 Any additional comments on third next	against their requirements.
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	No
16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field	No
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
	ı

16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Testing provisions
Directives? Please choose from the options below.	Distribution provisions
	Import-export
	Vigilance
	Traceability
16.2.1. For all selected options in question 16.2., please provide a	ART provisions - very specific area therefore we think it should
short description.	be regulated separately from other types or general tissues and cells
	Testing provisions - in small countries it is not always possible to
	perform testing for rare diseases Distribution provisions - if many
	entities are involved in procurement, transportation and other
	activities it is very difficult to delineate responsibilities of each
	involved party. Also provisions for direct distribution could be
	elaborated in more detail. Import-export - provisions could be
	elaborated in more detail. Vigilance - low awareness at
	tissue establishments level Traceability - if many entities
	(located in different countries) are involved in different activities
	with tissues/cells (e.g., procurement, testing, processing, banking) it
	is very difficult to evaluate the integrity of traceability when
	inspecting only local entity. Other (direct distribution,
	authorization for direct application) - criteria and conditions could
	be elaborated
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC
16.3.1. How would you suggest to solve these issues in Directive	Explain and define requirements for brokers, import/export. Also
2004/23/EC?	harmonize with provisions of organ directive 2010/53/EU where
	possible
16.3.2. How would you suggest to solve these issues in Directive	Elaborate detailed provisions regarding criteria for direct use/direct
2006/17/EC?	distribution

## A.1.17. Survey response Liechtenstein

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Amt für Gesundheit
1.1.2. Address of NCA 1:	Aculestrasse 51 9490 Vaduz Liechtenstein
1.1.2. Address of NCA 1.  1.1.3. Telephone (central access point):	00423 236 73 25
1.1.4. E-mail (central access point):	pharminfo@llv.li
1.1.5. Website:	N 1 2 2 1 11
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Pharmaceuticals
	Medical devices
Di Cold I	Other
Please specify 'other':	reimbursement of pharmaceuticals and medical devices, public
115 77	medical office, health prevention and promotion
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	The office of Public Health is a part of the Liechtenstein
organisation of the National Competent Authority(ies) (e.g.	Administration which is dependent of the government. It consists of
departments, staffing, number of senior and junior inspectors, staff	6 departments and secretariat and legal support. The staff consists of
working on EU affairs and legal matters, vigilance officers, budget,	18 persons. For the issues of pharmaceuticals, medical devices,
independence from government etc.).	human tissues and cells and blood including vigilance two persons
	are in charge. More information can be found at the
	http://www.llv.li/amtsstellen/llv-ag-home.htm.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	not applicable
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	
2.1.2. How many such authorisations were granted in 2011 (01/01-	1
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	0
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	1
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	2
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	0
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed) ? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	
2.4.1. Please provide the number of the laboratories performing	1

donor testing.	
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	Labor Risch, authorisation for microbiolog., serolog. diagnostic for
authorised or licensed in your country (e.g. number, year of	blood, blood products or tissues and cells, by Swissmedic, valid till
accreditation/authorisation/license, which donor tests are performed	02.11.2014
etc.).	V2.11.2011
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
3.3. If NAT testing is not mandatory in your country, could you	NAT testing is not mandatory due to the requirements of dir.
please indicate whether you intend to make it mandatory or to	2006/17/EU, annex II and III
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing of tissue es	stablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	2
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC.	A
4.7. Tissue establishments with authorisation pending approval at	ART tissue establishments
01/01/2011 (more than 1 answer possible):	
4.7.7. How many ART tissue establishments?	2
4.8. Tissue establishments with authorisations pending approval by	Cord blood tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.6. How many cord blood tissue establishments?	1
	1

4.9. Tissue establishments first time authorised between 01/01/2011	ART tissue establishments
and 31/12/2011 (more than 1 answer possible):	
4.9.7. How many ART tissue establishments?	2
4.10. All tissue establishments authorised by 31/12/2011 (more than	Cord blood tissue establishments
1 answer possible):	ART tissue establishments
4.10.6.1. How many public cord blood tissue establishments?	1
4.10.6.2. How many private cord blood tissue establishments?	0
4.10.7.1. How many public ART tissue establishments?	0
4.10.7.2. How many private ART tissue establishments?	2
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
	Yes
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	N
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Arzneimittelkontrolle, for coordination and the Swissmedic
of inspections.	inspectorate by agreement
5.1.2. If yes, please specify staffing (how many inspectors).	3 Swissmedic inspectors
5.2. Does the inspection scheme interact or overlap with the	No
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.3. How many routine inspections of tissue establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	O .
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	none
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	none
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	none
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	none
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	none
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	none

tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	2
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	none
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	2
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	none
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	n/a
establishments? Please specify.  5.5. Which type of routine inspections do you conduct? (more than 1	Convert existent exicuted instructions
* * * * * * * * * * * * * * * * * * * *	General system-oriented inspections
answer possible)  5.6. How do you decide which type of routine inspection to conduct?	based on inspection results
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	Tes
5.8. How many TEs were inspected at least twice between 2008-	n/a
2011 (01/01/2008-31/12/2011)?	11/4
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	1
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	n/a
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	N.
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	INU
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	No
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	

5.17.1. Could you please explaint why not?  5.18 Do you have a register of authorised issue establishments that are explicitly authorised to private p	Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections? 6.1. Importeeport (Article 9 Directive 2004/23/EC) 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import espons of issues and cells from third countries? 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). 6.3. Please specify the number of tissue establishments authorised to export issues and cells from third countries (recorded by 31/12/2011). 6.4. Please specify the number of tissue establishments authorised to export issues and cells from third countries (recorded by 31/12/2011). 6.4. Please specify which procedures you have in place for verifying he equivalent standards of quality and safety for importation of skin from third countries. 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of sunsaciou-skeletal flowe, tendons, fascia etc.) Issues from third countries. 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophthalinic corners, selera, tell tissues from third countries. 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of curilo vascular tissues from third countries. 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of curilo vascular tissues from third countries. 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. 6.10. Please specify which procedures with a please for verifying the equivalent		no ressources
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and self-sufficiency? (more than 1 answer possible)  Please specify 'other':  6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?  6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)  7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?		
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6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? 6.16. Do you have any additional comments on import/export?  7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC) 7.1. Do you have intra-community exchanges of tissues and cells? No 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?		
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7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)  7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the n/a requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?		
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from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?		No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?		
	-	No
7.5. Do you collect data regarding the cross-horder exchange of No		
The Bolycu contest unit regarding the cross contest should be	7.5. Do you collect data regarding the cross-border exchange of	No

	T
tissue/cells between your country and other EU MS?	l N
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	Yes
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.7.1. Please describe the legal requirements and your role (if any) as	The legal requirements are based on the standards of dir
a Competent Authority, in their authorisation/monitoring or	2004/23/EG
inspection.	N.
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Arti	
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	<50%
their activities during 2011. Please provide an estimation. (1 answer	
possible)	l N
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	Due to data protection legislation it is not possible to publish
	activities of only 2 ART tissue establishments, in a tiny country the
	anonymity would not be given; no annual report is requested for the
	establishment with blood cord activities.
8.5. Is there a publicly accessible register of authorised tissue	No
establishements in place? (Article 10(2))	
8.5.2. If no, why not?	no legal basis
8.6. Do you provide data regarding tissues and cells activities to the	No
EUROCET registry (non-mandatory reporting)?	
8.6.2. If no, why not?  8.7. Do you have any additional comments on reporting?	no contact
	(IOCIDIC)
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	
9.1. Was the donor identification system (Art. 8(2)) implemented in	No
your country?	
9.1.1. If no, why not?	we are waiting for the new European code for tissues and cells
9.2. Who assigns the unique code for each donation? (only 1 answer	Other
possible)	0.1.1
Please specify 'other'.	see 9.1.1.
9.3. How is the data storage for traceability purposes organised in	Only paper records
your tissue establishements (Art 8(4))? (only 1 answer possible)	
9.4. How do you ensure that the 30 years data storage requirement is	legal requirement, ensured by inspections
respected (Directive 2006/89/EC, Art. 9)? Please specify.	
9.5. Do you have any additional comments on traceability?	
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	Amt für Gesundheit
10.1.2. If yes, please provide a short description of its organisation.	one person resposnible for vigilance
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	Yes
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	Yes

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collecting SAR/E from all TEs?  10.5. How many tissue establishments provided in 2011 the	<50%
SAR/SAE data as requested (please provide the % from the total	30%
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
	Yes
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	by legislation
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at national level?	
10.7.2. Please specify why not.	Should we?
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	No
at EU level?	
10.8.2. Please specify why not.	Should we?
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	by fax and Phone
system/procedure.	
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	163
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	if necessary by fax and phone
system/procedure.	if necessary by fax and phone
	No.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	no contact
10.14. Do you notify alerts communicated via these tissues and cells	No
national vigilance system also to other national vigilance/alert	
systems?	
10.15. Did you send a vigilance officer/contact point to the trainings	No
organised by the EU-funded project SOHO V&S?	
10.15.2. If no, please specify why not.	lack of time
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Presumed consent (opt-out)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	not regulated
tissue/cell donation.	
11.2. What consent system for deceased tissue/cell donation do you	Presumed consent (opt-out)
have in place within your Member State?	×1 "7
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other
tissue donation? (more than 1 answer possible)	
Please specify 'other'.	see art. 88 f-90 of Gesundheitsverordnung, LR 811.011,
ricuse specify outer.	www.gesetze.li
11.4. Is the consent system for deceased tissue donation the same as	Yes
	165
for organs?	Analysis of documentation
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	ID numbers are generated

recipients remain unidentifiable when access is given to third parties	
(Art. 14(1)). Please specify.	gag 11.7
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	see 11.7
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?	140
11.9.1. If no, please specify the circumstances and measures in	not allowed
place.	not anowed
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 200	04/23: Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	inspections of 125 and productions side
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Other
deceased donor of tissues/cells? (more than 1 answer possible)	
Please specify 'other'.	there are only living donors, for cord blood cells
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	N-
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?  12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	INO
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Inspection of tissue commission.
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	
and procurement?	
13. Quality management, responsible person, personnel (Article 16	
13.1. How do you ensure that tissue establishments in your country	Inspections
have in place a quality system respecting the provisions of the	
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Inspections
responsible person fulfilling the requirements of Art. 17(1)? (more	_ *
than 1 answer possible)	
13.3. How do you ensure an appropriate training for the personnel	Inspections
directly involved in the activities of tissue establishments? (more	
than 1 answer possible)	

13.4. Do you have national/regional/local training programmes for	No
the personnel of tissue establishments?	
13.4.2. If no, in which country(ies) is your personnel trained?	EU countries
13.4.2.1. Please specify EU-countries.	The Swissmedic inspectors have their own training programm. They
	participated in the EUSTITE training and PIC/s quality circles.
13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	
Directive 2004/23/EC? (more than 1 answer possible)	
14.3. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	
of Directive 2004/23/EC? (more than 1 answer possible)	
14.4. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 22 (labelling, documentation and	
packaging) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	No
notified third party agreements?	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	Other
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	many activities are not applicable in Liechtenstein.
short description.	
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC
	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive	I do not know if there are shortcomings as already mentioned many
2004/23/EC?	activities do not take place in Liechtenstein.
16.3.2. How would you suggest to solve these issues in Directive	
2006/17/EC?	
16.3.3. How would you suggest to solve these issues in Directive	
2006/86/EC?	

## A.1.18. Survey response Lithuania

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	National Transplants Bureau under the Ministry of Health of the Republic of
	Lithuania
1.1.2. Address of NCA 1:	2, Santariskiu street LT 08661 Vilnius Lithuania
1.1.3. Telephone (central access point):	+ 370 52 79 6096
1.1.4. E-mail (central access point):	info@transplantacija.lt
1.1.5. Website:	www.transplantacija.lt
1.1.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1	Inspection
answer possible)	Vigilance
unon el possiole)	Other
Please specify 'other':	Coordination of all national activities in the field of donation and transplantation of human organs, tissues and cells; responsibility for crafting all necessary legislating acts regulating the field of HOTC donation and transplantation; maintenance of the National Register of Donors and Recipients for HOTC
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Ministry of Health of the Republic of Lithuania
1.2.2. Address of NCA 2:	Ministry of Health of the Republic of Lithuania Vilnius str. 33, LT-01506
	Vilnius, Lithuania Tel. (+370 5) 268 5110 Fax. (+370 5) 2661402
1.2.3. Telephone (central access point):	+37052685110
1.2.4. E-mail (central access point):	ministerija@sam.lt
1.2.5. Website:	www.sam.lt
1.2.6. The NCA is responsible for? (more than 1 answer	Reproductive tissues and cells
possible)	
1.2.7. What are the role/tasks of the NCA? (more than 1	Other
answer possible)	
Please specify 'other':	_
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	State Health Care Accreditation Agency under the Ministry of Health
1.3.2. Address of NCA 3:	Jeruzalės str. 21, LT-08420 Vilnius Tel. (+370) 5 261 51 77, Fax. (+370) 5
	212 73 10
1.3.3. Telephone (central access point):	(+370) 5 261 51 77
1.3.4. E-mail (central access point):	vaspvt@vaspvt.gov.lt
1.3.5. Website:	http://www.vaspvt.gov.lt/en
1.3.6. The NCA is responsible for? (more than 1 answer	Medical devices
possible)	Other
Please specify 'other':	-
1.3.7. What are the role/tasks of the NCA? (more than 1	Accreditation, authorisation, licensing of TEs
answer possible)	recreation, audiorisation, needsing of 125
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and	National Transplant Bureau(NTB) is a National Competent Authority in
organisation of the National Competent Authority(ies) (e.g.	charge of the implementation of quality and safety standards related to
departments, staffing, number of senior and junior	donation, procurement, testing, processing, preservation, storage,
inspectors, staff working on EU affairs and legal matters,	distribution and transplantation of human tissues, cells and organs. It is also
vigilance officers, budget, independence from government	engaged in inspection procedures for tissue banks and in supervising
etc.).	procedures for tissues, cells and organs procurement, transportation and
	transplantation. NTB is a State budgetary institution with staff of 25:
	administration 5 persons (director, deputy director, administrator, chief
	accountant, accountant); Transplants Coordination Division with 10
	specialists (1 senior specialist for organs, 1 senior specialist for tissues and
	cells also acting as a vigilance officer, and the rest transplant coordinators);
	Legal and Supervisory Division with Head of division and 4 specialists (2 of
	them inspectors); Public Communications Division with Head and 4
	specialists. Budget for the year 2013 is 283 thousand EUR; of which 204,5
	thousand euros will be spent on salaries. 2. Family health division of the
	Ministry of Health is responsible for the preparation of the bill on artificial
	rannony of frontin is responsible for the preparation of the offi off artificial

	Learner to the second of the s
	fertilization and transposition of EU Directives. 3. State Health Care Accreditation Agency under the Ministry of Health is responsible for the accreditation, licencing and supervision of comformity to licencing
	conditions.
1.6. In case of MS with federal or decentralised systems,	Not applicable
please indicate the roles/tasks of the Regional Competent	
Authority(ies). (more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of	Not applicable
the Regional Competent Authority(ies) and their relation	
with the National Competent Authority(ies) for tissues and	
cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of	By inspecting the documentation associated with procurement that is
procurement"? (more than 1 answer possible)	available in the tissue establishment working with procurement centres
2.1.2. How many such authorisations were granted in 2011	1
(01/01-31/12/2011)?	
2.2.1 Please provide the number of procurement centres in	3
which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic	
membrane, pancreatic islet, hepatocytes, adipose tissue etc.)	
were carried out in 2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in	2
which procurement of haematopoietic stem cells (bone	
marrow, PBSC, cord blood etc.) were carried out in 2011	
(01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in	0
which procurement of gametes, embryos and other	
reproductive tissues were carried out in 2011 (01/01-	
31/12/2011).	
2.2.4. Please provide the number of procurement centers in	0
which procurement of tissues/cells for ATMP manufacturing	
were carried out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply	Analysis of the mandatory documentation
with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC	
(e.g. trained personnel, conditions accredited, designated,	
authorised, licensed)? (more than 1 answer possible)	
2.4. Are you also responsible for the accreditation,	No
designation, authorisation or licensing of laboratories	110
performing donor testing?	
2.4.2. Which National Authority is in charge of this activity?	State Health Care Accreditation Agency under the Ministry of Health
,	(VASPVT) www.vaspvt.gov.lt
2.5. How do you ensure, as CA for T&C, that tests	Inspections of the laboratories
required for donors are carried out only by qualified	Analysis of the mandatory documentation requested from the tissue
laboratories accredited, designated, authorised or licensed	establishment
Art. 5(2))? (more than 1 answer possible)	
2.6. Please provide data on qualified laboratories accredited,	There are 4 licensed laboratories, which perform donor tests: 1) laboratory
authorised or licensed in your country (e.g. number, year of	of the Vilnius University Hospital Santariskiu Klinikos, licensed in 1999; 2)
accreditation/authorisation/license, which donor tests are	laboratory of the Hospital of Lithuanian University of Health Sciences
performed etc.).	Kauno klinikos, licensed in 2000; 3) laboratory of Klaipda University
	Hospital, licensed in 1990; 4) National Public Health Surveillance
2.7. Do you have any additional comments on procurement?	Laboratory, licensed in 2005.
	7/EC)
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/1'	
3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State.	Anti-HIV 1 Anti-HIV 2
(more than 1 answer possible)	Ag HIV
(more than 1 unswer possible)	HBs AG
	Anti HBc
	_ · · · · ·

	<del>,</del>
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	Treponema Pallidum
	HTLV-2
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more	Anti-HIV 2
than 1 answer possible)	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could	NAT testing is mandatory for HCV, HBV. It is not mandatory for HTLV as
you please indicate whether you intend to make it mandatory	Lithuania is not high prevalence area. NAT HIV could be mandatory to
or to encourage its use? Please specify why or why not (e.g.	avoid "window period mistakes as it could shorten it from 15 to 10-12
number of additional cases detected, cost-benefit etc.).	days. But it will prolong the time of donor testing from 6 to 7.5 hrs that
	means in some cases (when we have multiorgan donor) organs could be
	lost. AntiHIV-1,2 and Ag HIV is enough to prove the negative results. From
	Lithuania's long practice in testin of the donated blood by NAT method there
	were no one case positive with HIV.
3.4. Do you have concerns on accuracy of the available tests	No No
and test procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of	Yes
non-reproductive tissues and cells in your Member State?	
3.5.1. Please specify.	Syphilis RPR, CMV IgM, CMV IgG, EBV IgG, Toxo IgG, Anti HTLV-1
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems	Yes
for testing laboratories?	
3.7.1. Please specify.	ISO
3.8. Do you have any additional comments on testing?	
4. Accreditation, designation, authorisation or licensing of	tissue establishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue	
establishments under your responsability?	
4.2. Is inspection a prerequisite for the designation,	Yes
authorisation, accreditation or licensing of tissue	
establishments?	
4.2.1. How many inspections were performed in 2011 for	1
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer	By review of a submitted application with supporting documentation
possible)	J
4.4. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many	
authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	0
	·
2004/23/EC), how many	
77	
authorisations/accreditation/licenses were revoked in 2011?	No
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity	No
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?	
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by	the NCA
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending	
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):	the NCA  Multi-tissue establishments
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?	the NCA  Multi-tissue establishments
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending	the NCA  Multi-tissue establishments
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):	the NCA  Multi-tissue establishments  1  Multi-tissue establishments
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?	the NCA  Multi-tissue establishments  1  Multi-tissue establishments  0
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.9. Tissue establishments first time authorised between	the NCA  Multi-tissue establishments  1  Multi-tissue establishments
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	the NCA  Multi-tissue establishments  1  Multi-tissue establishments  0  Multi-tissue establishments
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.8. How many multi-tissue establishments?	the NCA  Multi-tissue establishments  1  Multi-tissue establishments  0  Multi-tissue establishments  1
authorisations/accreditation/licenses were revoked in 2011?  4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?  4bis. Overview of tissue/cells establishments authorised by  4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.8. How many multi-tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	the NCA  Multi-tissue establishments  1  Multi-tissue establishments  0  Multi-tissue establishments

4.10.6.1. How many public cord blood tissue	0
establishments?	
4.10.6.2. How many private cord blood tissue	1
establishments?	
4.10.8.1. How many public multi-tissue establishments?	1
4.10.8.2. How many private multi-tissue establishments?	0
4.11. How many tissues and cells were distributed under the	All together - 36 (35 units of PBSC (every time 500 ml) and 1 unit of
direct agreement of the Competent Authority according to	m/sceletal tissue)
Art. 6(5) during 2011? Please provide number(s) per type	
tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national	No
provisions pursuant to the Directive been defined (Article	
27)?	
4.17. Do you have any additional comments on	
accreditation, authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	l v
5.1. Is a system in place for organising inspections and	Yes
control measures of tissue establishments?	T 1 10 1 Division 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
5.1.1. If yes, please specify the CA/Department of the CA in	Legal and Supervisory Division of the National Transplant Bureau under the
charge of inspections.	Ministry of Health of Lithuania in charge of inspections of non-reproductive
	tissues and cells
5.1.2. If yes, please specify staffing (how many inspectors).	1 (2)
5.2. Does the inspection scheme interact or overlap with the	No
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common	
training, common documentation, etc.)? (more than 1 answer	
possible)	
5.3. How many routine inspections of tissue establishments	1
for non-reproductive tissues/cells were conducted in 2011	
(from 1/1/2011 to 31/12/2011)?	
5.3.1. How many inspections of tissues establishments for	0
non-reproductive tissues/cells were conducted in 2011	
(from 1/1/2011 to 31/12/2011) following serious adverse	
events or reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues	0
establishments for non-reproductive tissues/cells were	
conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due	
to a whistle-blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	1
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where no	
shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where major	
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out that were	
followed by suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	V
What was the number of inspections carried out that were	
followed by closure?	1 ivet deals beard impropries before TF
5.3.8. Outcome of inspections of TEs for non-reproductive	1, just desk based inspection before TE getting licensed

(* / 11 1 4 1 2011 (01/01/2011 4 21/12/2011)	
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of other inspections carried out?	
Please specify.	
5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	0
establishments following serious adverse events or reactions,	
or suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted	0
on ART establishments (from 1/1/2011 to 31/12/2011) (e.g.	
due to a whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments	0
	U
carried out in 2011 (01/01/2011 to 31/12/2011): What was	
the number of inspections carried out where no	
shortcomings were observed?	
5.4.4. What was the number of inspections carried out in	0
ART establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in	0
ART establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in	0
ART establishments followed by suspension of	
authorisation?	
5.4.7. What was the number of inspections carried out in	0
ART establishments followed by closure of respective	
establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct?	Desk based reviews
(more than 1 answer possible)	
5.6. How do you decide which type of routine inspection to	We are entitled to conduct only desk based reviews
conduct?	·
5.7. Until 2011, did you implement the requirement	Yes
concerning the time interval between two inspections (Art.	
7.3.)?	
5.8. How many TEs were inspected at least twice between	1
2008-2011 (01/01/2008-31/12/2011)?	
	N .
5.9. Did you perform/conduct inspections of procurement	No
sites outside tissue establishments?	
5.9.2. If no, why not?	We were not entitled to perform such inspections between 2008-2011
5.10 Did	· · · · · · · · · · · · · · · · · · ·
5.10. Did you carry out inspections of third parties?	No
5.10. Did you carry out inspections of third parties? 5.10.2. If no, why not?	
	No
5.10.2. If no, why not? 5.11. Do you use at national level the Operational Manual	No We were not entitled to perform such inspections between 2008-2011
5.10.2. If no, why not? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell	No We were not entitled to perform such inspections between 2008-2011
5.10.2. If no, why not? 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for	No We were not entitled to perform such inspections between 2008-2011
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	No We were not entitled to perform such inspections between 2008-2011 No
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No We were not entitled to perform such inspections between 2008-2011 No  1. For routine inspections: Law on public administration of the Republic of
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	No We were not entitled to perform such inspections between 2008-2011 No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus audinis, Istelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus audinis, Istelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo,
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus audinis, Istelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus audinis, Istelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus audinis, Istelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros/staigs, teikian is ~mogaus audinis, Istelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: ,,Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"  1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=123381; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=432986&p_query
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"  1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=123381; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=432986&p_query =&p_tr2=2
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: ,,Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"  1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=123381; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=432986&p_query
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE,	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"  1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=123381; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=432986&p_query =&p_tr2=2
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"  1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=123381; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=432986&p_query =&p_tr2=2  Yes
5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.11.1. If no, which guidelines/regulations are used for inspections at national level?  5.11.2. If no, please provide a hyperlink to these guidelines/inspections.  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE,	No  We were not entitled to perform such inspections between 2008-2011  No  1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations: "Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir Istelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls"  1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=123381; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_1?p_id=432986&p_query =&p_tr2=2

not important, 2 = sufficient, 3 = good, 4 = very good, 5 =	
essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA	
in that MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS	
in collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement	No
centres or tissue establishments in third countries from	
which tissues and/or cells were imported in your country (as	
recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been	No
requested by any other MS, on the results and control	
measures of your inspections, as part of an	
enquiry/investigation?	
5.17. Would you be interested in developing joint	Yes
inspections? Joint inspections should be understood as	
inspections of tissue establishments conducted jointly by two	
or more Member States' Competent Authorities on their	
territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue	No
establishments that are explicitly authorised to perform	
import/export of tissues and celles from/to third countries?	
6.2. Please specify the number of tissue establishments	0
authorised to import tissues and cells from third countries	
(recorded by 31/12/2011).	
6.3. Please specify the number of tissue establishments	0
authorised to export tissues and cells from third countries	
(recorded by 31/12/2011).	
6.4. Please specify which procedures you have in place for	No procedures yet as Lithuania doesn't import skin from third countries. If in
verifying the equivalent standards of quality and safety for	the future TEs will perform import of skin, they should follow requirements
importation of skin from third countries.	of Health Care Minister Order No V-397; (21 May 2007); No V-188 (13
	March 2009); No V-463 (22 June 2004); No V-401 (22 May 2007); No V-
	364 (14 May 2004)
6.5. Please specify which procedures you have in place for	The Health Care minister Order No V-463 (22 June 2004) and other orders
verifying the equivalent standards of quality and safety for	(see above)
importation of musculo-skeletal (bone, tendons, fascia etc.)	
tissues from third countries.	
6.6. Please specify which procedures you have in place for	The Health Care minister Order No V-463 (22 June 2004) and other orders
verifying the equivalent standards of quality and safety for	(see above)
importation of ophtalmic (cornea, sclera, etc) tissues from	(
third countries.	
6.7. Please specify which procedures you have in place for	The Health Care minister Order No V-463 (22 June 2004) and other orders
verifying the equivalent standards of quality and safety for	(see above)
importation of cardio vascular tissues from third countries.	(3-1-2-3-4)
6.8. Please specify which procedures you have in place for	The Health Care minister Order No V-463 (22 June 2004)
verifying the equivalent standards of quality and safety for	110 110 million order 110 1 105 (22 Julie 2001)
importation of haematopoietic stem cells (HSC) (other than	
cord blood) from third countries.	
6.9. Please specify which procedures you have in place for	Same procedures as for other tissues and cells (see above)
verifying the equivalent standards of quality and safety for	same procedures as for other tissues and cens (see above)
importation of cord blood from third countries.	
6.10. Please specify which procedures you have in place for	no (importation is not allowed)
verifying the equivalent standards of quality and safety for	no (importation is not allowed)
importation of reproductive cells (sperm, egg cells) from	
third countries.	
	Yes
6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	1 05
2011 (01/01/2011-31/12/2011)!	

6.11.1. If yes, please provide the data concerning the	4x500 ml PBSC from USA
number/volume of imported tissues and cells by country of	
origin.	
6.12. Did you export tissues/cells from 3rd countries during	No
2011 (01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012	No
which may invalidate the 2011 data on imports/exports of	
tissues/cells between your country and other third countries?	
6.14. What is the relation between import/export of tissues	C. Export of tissues/cells is authorised irrespective of national needs
and cells and self-sufficiency? (more than 1 answer possible)	E. Import of tissues/cells is authorised based on estimations showing that
	there is chronic deficiency of those tissues/cells
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	
6.15.1. If yes, please specify the number of cases and for	PBSC, 32 cases (including cases from EU countries) or only 4 cases from
which type of tissues/cells.	third country (USA)
6.16. Do you have any additional comments on	ama county (corr)
import/export?	
7. Distribution/intra community exchanges (Article 23 Dire	ective 2004/23/EC)
7.1. Do you have intra-community exchanges of tissues and	Yes
cells?	
7.1.1. If yes, how do you address the possible more stringent	Quality and safety measures should be the same. If we do not perform the
quality and safety measures established by other Member	test required in another MS, we should do it before export.
States? Please specify.	test required in another two, we should do it before export.
7.1.2. If yes, do you have more stringent quality and safety	Yes
	Yes
measures than in other Member States?	
7.1.2.1. How do you address this difference for tissues and	Quality and safety measures should be the same. If no, there is upon the
cells coming from a MS with minimum quality	specialists who decide if they will transplant such tissues/cells or not.
requirements? Please specify.	
7.2. How do you ensure that tissues establishments fulfil the	Health Care Minister's Order No V-1010 Chapter X (about distribution of
requirements of Art. 23 of Directive 2004/23/EC regarding	T&C): X. AUDINIr, LSTELIr PASKIRSTYMAS 57. Apdoroti audiniai ir
quality of tissues and cells during distribution? Please	lstels neturi bkti paskirstomos, kol neatitinka viss aio Apraao nustatyts
specify.	reikalavims. 58. Paskirstymas atlikus audinis, Istelis /sigijim: 58.1.
specify.	
	Kiekvienam audinis, lstelis gabenimui turi bkti skirtas lydraatis, kuriame
	pateikiama ai informacija: 58.1.1. donorysts data (ir laikas, jeigu galima);
	58.1.2. perspjimas apie pavojs; 58.1.3. bet kokie priedai (jeigu tokie
	naudojami); 58.1.4. autologins donorysts atveju nurodant, kad audiniai,
	lstels skirti tik autologiniam naudojimui; 58.1.5. tikslins donorysts atveju
	nurodomas recipientas. 58.2. Jei audinius, Isteles gabena tarpininkas,
	kiekvienas gabenamas konteineris turi bkti pa~enklintas pateikiant toki
	informacij: 58.2.1. nuorod, kad konteineryje gabenami audiniai, lstels; u~raa
	Elgtis atsargiai; 58.2.2. /staigos, ia kurios gabenamas konteineris, pavadinim
	(adres, telefono numer/) ir asmen/, / kur/ galima kreiptis kilus problemoms;
	58.2.3. /staigos, / kuri gabenamas konteineris, pavadinim (adres, telefono
	numer/) ir asmen/, / kur/ galima kreiptis, kad jis paimts konteiner/; 58.2.4.
	gabenimo prad~ios dat ir laik; 58.2.5. gabenimo slygs techninius
	reikalavimus, svarbius audinis, lstelis kokybei ir saugai; 58.2.6. audinis,
	Istelis produkts atveju pridti /raa Neavitinti; 58.2.7. jei ~inoma, jog audiniai,
	lstels teigiamai reaguoja / atitinkam u~kre iamos ligos ~ymen/, pridti u~raa
	Biologinis pavojus; 58.2.8. autologinis donors atveju pridti u~raa Tik
	autologiniam naudojimui; 58.2.9. laikymo slygs techninius reikalavimus
	(tokius kaip Neaaldyti). 59. Paskirstymas recipientui arba sveikatos
	prie~ikros /staigai: 59.1. Galutinis paskirstoms audinis, lstelis ~enklinimas:
	59.1.1. Ant pirmins audinis, Istelis talpos bktina nurodyti ai informacij:
	59.1.1.1. audinis, lstelis tip; 59.1.1.2. audinis, lstelis identifikavimo numer/
	(prireikus, siuntos arba partijos numer/); 59.1.1.3. Audinis banko
	identifikavimo duomenis; 59.1.1.4. galiojimo dat; 59.1.1.5. autologins
	donorysts atveju reikia u~raayti nuorod (Tik autologiniam naudojimui) ir
	nurodyti donoro / recipiento tapatyb; 59.1.1.6. tikslins donorysts atveju
	etiketje reikia nurodyti numatom recipient; 59.1.1.7. kai ~inoma, kad
	audiniai, lstels teigiamai reaguoja / atitinkam u~kre iamos ligos ~ymen/,
	bktina pridti u~raa BIOLOGINIS PAVOJUS. 59.1.2. Jeigu / pirmins talpos

	<del>,</del>
	etiket negalima /raayti jokios 51.1 punkte nurodytos informacijos, j reikia
	pateikti atskirame lape, pridedamame prie pirmins talpos. `is lapas
	pridedamas prie pirmins talpos taip, kad bkts u~tikrinta, jog jie liks kartu.
	59.1.3. Etiketje arba lydraa iuose turi bkti nurodyta ai informacija: 59.1.3.1.
	audinis, Istelis apraaymas (apibr~tis) ir, jei taikoma, matmenys; 59.1.3.2. jei
	taikoma, morfologiniai ir funkciniai duomenys; 59.1.3.3. audinis, lstelis
	paskirstymo data; 59.1.3.4. su donoru atlikti biologiniai tyrimai ir js
	rezultatai; 59.1.3.5. laikymo rekomendacijos; 59.1.3.6. talpos, pakuots
	atidarymo taisykls ir kita reikiama informacija, susijusi su manipuliavimu;
	59.1.3.7. galiojimo datos po atidarymo / manipuliavimo; 59.1.3.8. praneaimo
	apie nepageidaujamas reakcijas ir (arba) reiakinius taisykls; 59.1.3.9.
	cheminis med~iags liku is, kurie gali bkti kenksmingi (pvz., antibiotiks,
	etilinoksido ir kt.), buvimas. 59.2. Gabenimo konteinerio iaors ~enklinimas:
	59.2.1. Gabenant pirmin talpa turi bkti pakrauta / gabenimo konteiner/, kur/
	bktina ~enklinti, nurodant bent jau ai informacij: 59.2.1.1. Audinis banko, ia
	kurio gabenama, identifikavimo duomenis, /skaitant adres ir telefono
	numer/; 59.2.1.2. u~ audinis, lstelis naudojim ~monms atsakingos /staigos
	(ar organizacijos), kuriai gabenama, identifikavimo duomenis, /skaitant
	adres ir telefono numer/; 59.2.1.3. nuorod, kad pakuotje yra ~mogaus
	audiniai, Istels, bei u~raa ELGTIS ATSARGIAI; 59.2.1.4. kai reikia
	persodinti Isteles, pavyzd~iui, kamienines Isteles, turi bkti u~raaas
	NE'VITINTI; 59.2.1.5. rekomenduojamos gabenimo slygos (pvz., laikyti
	aaltai, neapversti ir kt.); 59.2.1.6. saugos taisykles ir (arba) aaldymo bkd (kai
	taikoma). 59.3. Siekiant ialaikyti reikiamas audinis, Istelis savybes turi bkti
	nurodytos svarbios gabenimo slygos, pavyzd~iui, temperatkra ir trukm. 59.4.
	Talpa ir (arba) pakuot turi bkti saugi ir u~tikrinti, kad nustatytomis slygomis
	audiniai, Istels ialaikys reikiamas tolesniam naudojimui savybes.
7.3. Do you allow direct distribution to hospitals/clinics in	Yes, but only via an authorised TE in my MS
your MS from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient	Yes
of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.4.1. If yes, how many authorisations were given in 2011	32
(01/01/2011 to 31/12/2011)?	
7.4.2. If yes, for which tissues/cells?	PBSC, musculo/sceletal
7.5. Do you collect data regarding the cross-border exchange	Yes
of tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination,	From Lithuania to Irland PBSC - 1x500ml;
type of tissue/cell and number of units distributed)	
concerning distribution to other MS in 2011 (01/01/2011-	
31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	From Germany to Lithuania PBSC 28x500ml; from UK to Lithuania PBSC
tissue/cell and number of units distributed) concerning	2x500ml; from Poland to Lithuania m/s -1 unit
distribution to other MS in 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which	No
may invalidate the 2011 data on cross-border exchanges of	
tissues/cells between your country and other EU MS?	
7.7. Do you allow brokerage companies for either	No
distribution in EU and/or import/export of tissues/cells? In	
this context, a brokerage company means a body that	
arranges transactions between a supplier (tissue	
establishment/company selling tissues or cells) and a buyer	
(a tissue establishment/a hospital or clinic/an individual)	
without undertaking activities of processing, preservation or	
storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligation	ns (Article 10. Directive 2004/22/EC)
8.1. Do you have an annual report model/template on the	Yes
activities of tissue establishments in your Member State?	103
(Article 10(1)). If yes, please upload the template.	
(Article 10(1)). If yes, piease apload the template.	

8.2. How many tissue establishments submitted annual reports of the activation. (1 answer possible) 8.3. Are these reprist publicly available? (Article 10(1)) 8.4. Do you publish a national annual report of the consolidated extirution of all the activation of the consolidated extirution of all tissue establishments in put country?  8.4. Please insert the link to the published national annual report of the consolidated extirution of all tissue establishments in place? (Article 10(2)) 8.5. Is five, she provide dust regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6. It fiyes, been provide to the tregistry (non-mandatory reporting)?  8.7. Do you have any additional comments on reporting?  8.7. Do you have any additional comments on reporting?  9. Trecability (Article 8. Directive 2006/89/EC, and Directive 2006/86/EC)  9. Who is assigned in your tissue establishments (Art 8(4)) (only 1 answer possible)  9. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)?  Please specify,  9. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have any additional comments on tracebility?  10. Do you have a national vigitation system in place (or you have a national layer)  10. Do you have a nati		
estimation (1 answer possible)  8.3 Acr these reports publicly available? (Article 10(1))  8.4 De you publish a national annual report of the consolidated earlivities of all tissue establishments in your country?  8.4 I. Please insert the link to the published national annual report of the consolidated earlivities of all tissue establishments in place? (Article 10(2))  8.5 I. If yes, please provide us with the link to the register's web site.  8.6 Do you provide data regarding rissues and cells estivities to the EUROCET registery (non-mandatory reporting)?  8.6 Droy you provide data regarding rissues and cells estivities to the EUROCET registery (non-mandatory reporting)?  8.7 Do you have any additional comments on reporting?  9.7 Traceability (Article 8.) Eirrective 2004/32/EC and Directive 2006/86/ECC)  9.8 The across respective of traceability purposes.  9.9 Who assigns the unique code for each donation? (only 1 answer possible)  9.3 How is the data storage for traceability purposes.  9.4 How do you ensure that the 30 years data storage requirement is respected (Directive 2006/88/PEC, Art. 97)  Please specify.  9.5 Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11) Directive 2004/32, Article 6 Directive 2006/76)  9.5 Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11) Directive 2004/32, Article 6 Directive 2006/76)  10. 1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11) Directive 2004/32, Article 6 Directive 2006/76)  10. 1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11) Directive 2004/32, Article 6 Directive 2006/76)  10. 1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11) Directive 2004/32, Article 6 Directive 2006/76)  10. 1. Do you have a dedicated v	8.2. How many tissue establishments submitted annual	60-99%
8.3. Ab Do you publish a national amount report of the consolidated activities of all tissue establishments in your country?  8.4.1. Please insert the link to the published national annual report of the consolidated activities of all tissue establishments in your country?  8.4.1. Please insert the link to the published national annual report of the consolidated activities of all tissue establishments in place? (Article 10/2).  Yes  8.5.1. If yes, please provide us white link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?  8.6. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  8.7. Traceability (Article 8.) Directive 2004/25/EC; and Directive 2006/86/EC)  Yes  1. Traceability (Article 8.) Directive 2004/25/EC; and Directive 2006/86/EC)  Yes  1. Traceability (Article 8.) Directive 2004/25/EC; and Directive 2006/86/EC)  Yes  1. Traceability (Article 8.) Directive 2004/25/EC; and Directive 2006/86/EC)  Yes  2. Traceability (Article 8.) Directive 2004/25/EC; and Directive 2006/86/EC)  Yes  3. How she data storage for traceability purposes organised in your tissue establishments (Art 8(4))? (only 1 answer possible)  3. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)?  Please specify.  1. Do you have any additional comments on traceability?  1. Do you have a national vigilance system in place (for the reporting of Serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  Nes  National Transplant Bureau under the Ministry of Health Care ministro 2007 m. gegu-5 21 d. /sakymas Nr. V-307 '7Di ministro 2007 m. gegu-5 22 d. /sakymas Nr. V-307 '7Di ministro 2007 m. gegu-5 21 d. /sakymas Nr. V-307 '7Di ministro 2007 m. gegu-5 21 d. /sakymas Nr. V-307 '7Di ministro 2007 m. gegu-5 21 d. /sakymas Nr. V-307 '7Di ministro 2007 m. gegu-5 22 d. /sakymas Nr. V-307 '7Di ministro	reports of their activities during 2011. Please provide an	
8.4. Decoving the control annual report of the concombidated earlies of all tissue establishments in your country?  8.5. Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))  8.5. It. If yes, please provide to the published national annual report.  8.6. Do you provide data regarding tissues and cells activities to the IUROCET registry (non-mandatory reporting)?  8.6. It. If yes, what data are provided to EUROCET? Please specify.  8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)  9. Iwas the donor identification system (Art. 8(2)) implemented in your country?  9. Wes  15	estimation. (1 answer possible)	
comodidated activities of all tissue establishments in your country?  8.4.1 Please insert the link to the published national annual export.  8.5.1 Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))  8.5.1 Is yes, please provide as with the link to the register's web site.  8.6 Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting?)  8.6.1 It yes, please provide as with the link to the register's web site.  8.7 Do you have any additional comments on reporting?  9.8 Traceability, (Article 8. Directive 2004/238/EC) and Directive 2006/86/EC)  9.1 Was the donor identification system (Art. 8(2)) mplemented in your country?  9.2 Who assigns the unique code for each donation? (only 1 answer possible)  9.3 How is the data storage for traceability purposes organised in your tissue establishments (Art 8(4))? (only 1 answer possible)  9.4 How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)?  Please specify.  9.5 Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)  10.1. Byes, which CA/institution is responsible?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/6 at 6.4)) templates developed to the Annual reporting to the EC also at national level?  10.3. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TES?  10.5. How many issue establishments provided in 2011 the	8.3. Are these reports publicly available? (Article 10(1))	No
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10.5. How many tissue establishments provided in 2011 the 70-99%		Yes
SAR/SAE data as requested (please provide the % from the		70-99%
	SAR/SAE data as requested (please provide the % from the	

total number of TEs authorised in your country).	Yes
10.6. Do you have a mandatory procedure for the	1 es
transplantation centres when reporting SAR/SAE to the TEs	
which distributed the tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	The Health Care Minister's Order No V-401 (2007 m. gegu~s 22 d. /sakymas Nr. V-401 "Dl praneaims apie nepageidaujamas reakcijas ir (ar) reiakinius, susijusius su audinis ir lstelis /sigijimu, iatyrimu, apdorojimu, laikymu, paskirstymu ir transplantacija, tvarkos apraao patvirtinimo" (} in., 2007, Nr.58-2253; 2010, Nr. 138- 081)), article 4.3, which says exactly, that institution should report about SARE to TE which distributed T&C: 4.
	Praneaan ioji /staiga privalo taikyti SVP, skirtas informacijai apie /sigytus ir transplantuotus audinius ir lsteles iasaugoti, irnedelsdama praneati apie visas nepageidaujamas reakcijas aioms /staigoms: 4.1. Nacionaliniam organs transplantacijos biurui; 4.2. /staigai, gavusiai audinius, lsteles ir organus, susijusius su nepageidaujama reakcija, skirtus transplantacijai, jeigu juos paskirst praneaan ioji /staiga; 4.3. /staigai, paskirs iusiai audinius, lsteles ir organus, susijusius su nepageidaujama reakcija, jeigu juos paskirst kita /staiga.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	We communicate with all TEs in case of SARE reported at national level and give them feedback according to the same Health Care Minister's Order No V-401 (see above) and according to the Order of the Director of National Transplant Bureau T1-44, 11 October 2010 ,,Dl keitimosi informacija apie pavojingus nepageidaujamus reiskinius ir reakcijas
	~mogaus audinis ir lastelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo srityje tvarkos apraao"
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	We inform our TEs in cases of SARE recorded at EU level if these cases could be relevant to them according to both Orders mentioned above.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	0
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes
10.11.1. If yes, please give a short description of the system/procedure.	The Order of the Director of National Transplant Bureau No T1-44, 11 October 2010 "Dl keitimosi informacija apie pavojingus nepageidaujamus reiskinius ir reakcijas ~mogaus audinis ir lastelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo srityje tvarkos apraao", which stays that information about national rapid alert should be communicated to all TEs, POs, Transplant centers, Health Care Ministry and other related Competent Authorities
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes
10.12.1. If yes, please give a short description of the system/procedure.	The Order of the Director of National Transplant Bureau No T1-44, 11 October 2010 "Dl keitimosi informacija apie pavojingus nepageidaujamus reiskinius ir reakcijas ~mogaus audinis ir lastelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo srityje tvarkos apraao" Article 2(2), which stays that information from RATC should be communicated to all TEs, POs, Transplant centers, Health Care Ministry and other related Competent Authorities.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	No
10.13.2. If no, please specify why not.	it was not requested from EUROCET yet
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national	Yes

::1	
vigilance/alert systems?  10.14.1. If yes, please specify which of the following	Haemovigilance
systems are usually contacted. (more than 1 answer possible)	Medical devices
10.15. Did you send a vigilance officer/contact point to the	Yes
· · · · · · · · · · · · · · · · · · ·	Yes
trainings organised by the EU-funded project SOHO	
V&S?	
10.15.1. If yes, how would you rate the usefulness and	4
efficacy of these trainings on a scale from 1 (insufficient) - 2	
(sufficient) 3 (good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE	
reporting?	
11. Consent and personal data protection (Article 13 and 1	
11.1. What consent system for living tissue/cell donation do	Explicit consent (opt-in)
you have in place within your Member State?	
11.1.1. Please specify your choice of consent system for	The Transplant Law, Article 10(2) specifies that consent for living donation
living tissue/cell donation.	should be given by person him/herself in written form: 10 straipsnis.
	Transplantavimo ia gyvo donoro tvarka 1. Transplantacijai audiniai, Istels ir
	organai gali bkti imami ia gyvo asmens tik recipientui gydyti ir kai nra
	mirusio asmens tinkams audinis, lstelis ar organo bei kits efektyvis gydymo
	alternatyvs. 2. Imti audinius, lsteles bei organus ia gyvo veiksnaus donoro
	leid~iama tik gavus jo raatiak sutikim. Donoras turi teis ataaukti savo
	sutikim.
11.2. What consent system for deceased tissue/cell donation	Explicit consent (opt-in)
do you have in place within your Member State?	
11.3. According to your national legislation, in case of	First degree relatives (including spouse)
deceased donations, please specify who is giving the	
authorisation for the tissue donation? (more than 1 answer	
possible)	
11.4. Is the consent system for deceased tissue donation the	Yes
same as for organs?	
11.5. How is this consent verified during inspections? (more	Analysis of documentation
than 1 answer possible)	
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	Information for donors are standardised at national/regional level
provided with the appropriate information, as requested by	
Art. 13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors	These rules are described in 3 Acts: I. The Order of Health Care Minister No
and recipients remain unidentifiable when access is given to	V-1010 (7 December 2007), Art 9(6): 9.6. Visi duomenys, /skaitant bendrj
third parties (Art. 14(1)). Please specify.	informacij, sulyginami su Apraao taikymo sritimi, kuriais gali naudotis tre
uma parates (i.iv. 1.i(1)). Trease specify.	iosios aalys, turi bkti anoniminiai, kad nei donorai, nei recipientai nebkts
	identifikuoti. `iam tikslui Audinis bankas turi u~tikrinti, kad: 9.6.1. bkts
	pritaikytos duomens apsaugos priemons ir apsaugos /renginiai, neleid~iantys
	papildyti, iatrinti arba pakeisti duomens donors bylose arba /raauose apie
	donorysts sustabdym bei perkelti informacij; 9.6.2. bkts nustatyta tvarka,
	padedanti panaikinti duomens neatitikimus; 9.6.3. nebkts informacijos
	atskleidimo be leidimo atvejs, tuo pa iu metu garantuojant transplantants
	siet/. II.Government Decree on Registry (Dl }mogaus audinis, Istelis ir
	organs donors bei recipients registro /steigimo ir jo nuostats patvirtinimo
	(}in., 2000, Nr. 72-2230, 2012, Nr. 115-5834), chapter VI article 38 and 39:
	38. Registro duomenys vieaai neskelbiami, iaskyrus nurodytuosius 39
	punkte. 39. Vieaai gali bkti pateikiami tik apibendrinti, suvestiniai registro
	duomenys. III. in Transplant Law Art 3(4): 3 straipsnis. }mogaus audinis,
	Istelis ir organs donors bei recipients registras 1. Transplantacijos atvejai ir
	duomenys apie donorus ir recipientus atskirais sraaais turi bkti /raaomi /
	mogaus audinis, Istelis ir organs donors bei recipients registr. 2. mogaus
	audinis, Istelis ir organs donors bei recipients registr steigia ir jo nuostatus
	tvirtina Lietuvos Respublikos Vyriausyb. 3. Kad bkts iasaugotas donors bei
	recipients konfidencialumas, naudojimosi }mogaus audinis, lstelis ir organs
	donors bei recipients registro duomenimis tvark nustato Sveikatos apsaugos
	ministerija. 4. U~ }mogaus audinis, lstelis ir organs donors bei recipients
	registro duomens konfidencialum atsako visi fiziniai ir juridiniai asmenys,

	kurie naudojasi aio registro duomenimis.
11.8. Please specify what measures are in place to ensure	Transplant Law Art 3 (3,4) and Art 5: 3. Kad bkts iasaugotas donors bei
that the identity of the receipient is not disclosed to the	recipients konfidencialumas, naudojimosi }mogaus audinis, lstelis ir organs
donor and vice versa.	donors bei recipients registro duomenimis tvark nustato Sveikatos apsaugos
	ministerija. 4. U~ }mogaus audinis, lstelis ir organs donors bei recipients
	registro duomens konfidencialum atsako visi fiziniai ir juridiniai asmenys,
	kurie naudojasi aio registro duomenimis. 5 straipsnis. Donoro, recipiento
	duomens konfidencialumas Informacija apie donoro ir recipiento sveikatos
	bkkl, taip pat visa kita asmeninio pobkd~io informacija, tarp js ir duomenys
	apie asmens tapatyb, yra konfidenciali ir suteikiama tik Pacients teisis ir
	~alos sveikatai atlyginimo /statymo ir kits teiss akts nustatyta tvarka. Also
	see above (question 11.7)
11.9. Does your national legislation allows disclosure of	No
donor data in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures	0 (gametes donation is not allowed)
in place.	
11.10. Do you have any additional comments on consent and	
data protection?	1 A00 (100 )
12. Selection, evaluation and procurement (Article 15 Direction 12.1. How do you ensure that all requirements related to the	Audit of documentation
evaluation and selection of donors (except donors of	Addit of documentation
reproductive cells) are respected in your country (Art. 15(1),	
Annex I Directive 2006/17/EC)? (more than 1 answer	
possible)	
12.2. How do you ensure that all requirements related to the	Audit documentation
evaluation and selection of donors of reproductive cells are	Other
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
Please specify 'other'.	Reproductive cells donation is not allowed
12.3. Do you have more stringent criteria for donor selection	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the	Interview with the donor's family or a person who knew the donor well
evaluation of a deceased donor of tissues/cells? (more than 1	Medical records of the donor
answer possible)	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
12.5. Do you have more stringent criteria for selection of	No
donors of reproductive cells than those listed in Annex III of	
the Directive 2006/17/EC?	
12.6. Do you have more stringent criteria for autologous	No
donation than those listed in Annex I of the Directive	
2006/17/EC?  12.7. Do you require more information on the donation of	No.
· ·	No
tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding	Audit of tissue establishment
tissues and cells' procurement, packaging and transport are	Addit of tissue establishment
complied with by tissue establishments in your country (Art	
15(1), Annex IV of Directive 2006/17/EC? (more than 1	
answer possible)(For this question "audit" means a	
documented review of procedures, records, personnel	
functions, equipment, materials, facilities, and/or vendors in	
order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe	
Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	
evaluation and procurement?	
13. Quality management, responsible person, personnel (A	
13.1. How do you ensure that tissue establishments in your	Authorisation requirement
country have in place a quality system respecting the	Inspections

provisions of the Directive 2004/23/EC Art 16.1? (more than	Internal audits
1 answer possible). (For this question "audit" means a	External audits
documented review of procedures, records, personnel	
functions, equipment, materials, facilities, and/or vendors in	
order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe	
Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)?	<u> </u>
	Inspections
(more than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.3. How do you ensure an appropriate training for the	Authorisation requirement
personnel directly involved in the activities of tissue	Inspections
establishments? (more than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.4. Do you have national/regional/local training	No
programmes for the personnel of tissue establishments?	
13.4.2. If no, in which country(ies) is your personnel	EU countries
trained?	
13.4.2.1. Please specify EU-countries.	Czech Republic, Spain
	Czech Kepublic, Spani
13.5. Any additional comments on quality management,	
responsible person, personnel?	
14. Reception, processing, storage, labelling and packaging	
14.1. How do you ensure that tissue establishments in your	National regulation/policy for reception of tissues/cells
country fulfill the requirments of the Art. 19 (Tissue and cell	Inspections of tissue establishments
reception) of Directive 2004/23/EC and Annex IV of	Internal audits of tissue establishments
Directive 2006/17/EC? (more than 1 answer possible)	internal addits of dissac establishments
	CODe for all processes offseting quality and sefety are mandatory for
14.2. How do you ensure that tissue establishments in your	SOPs for all processes affecting quality and safety are mandatory for
country fulfill the requirements of the Art. 20 (Tissue and	authorisation
cell processing) of Directive 2004/23/EC? (more than 1	Inspections of tissue establishments
answer possible)	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your	SOPs for procedures associated with storage of tissues and cells are
country fulfill the requirements of Art. 21 (tissue and cell	mandatory for authorisation
storage conditions) of Directive 2004/23/EC? (more than 1	Inspections of tissue establishments
answer possible)	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your	SOPs for procedures associated with labelling and packaging are mandatory
1 14 4 Flow do you ensure that fissue establishments in Vollt	1 501 5 for procedures associated with labelling and packaging are mandatory
country fulfill the requirements of Art. 22 (labelling,	for authorisation
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and	for authorisation Inspections of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer	for authorisation
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and	for authorisation Inspections of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer	for authorisation Inspections of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)	for authorisation Inspections of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?	for authorisation Inspections of tissue establishments Internal audits of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)	for authorisation Inspections of tissue establishments Internal audits of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your	for authorisation Inspections of tissue establishments Internal audits of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member	for authorisation Inspections of tissue establishments Internal audits of tissue establishments
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes
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country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis,
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis:
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, lstelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, lstelis apdorojimo etaps tre
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos prie~ikros /staigai, kuri neturi licencijos Audinis banko veiklai; 5.10.4. kai
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos prie~ikros /staigai, kuri neturi licencijos Audinis banko veiklai; 5.10.4. kai
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos prie~ikros /staigai, kuri neturi licencijos Audinis banko veiklai; 5.10.4. kai Audinis bankas paskirsto tre isjs aalis apdorotus audinius, Isteles. 5.11. Audinis bankas vertina ir atrenka tre isias aalis, remdamasis js galimybmis
country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which	for authorisation Inspections of tissue establishments Internal audits of tissue establishments  Yes  According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, Istelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, Istelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, Istelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos prie~ikros /staigai, kuri neturi licencijos Audinis banko veiklai; 5.10.4. kai Audinis bankas paskirsto tre isjs aalis apdorotus audinius, Isteles. 5.11.

15.1.1.2. How are third party agreements controlled (Art 6.2)	5.14. Nacionalinio transplantacijos biuro praaymu Audinis bankai privalo pateikti susitarims su tre iosiomis aalimis kopijas.  According Health Care Minister's Order No V-1010: 5.14. Nacionalinio
by the Competent Auhtority(ies) in your MS? Please specify.	transplantacijos biuro praaymu Audinis bankai privalo pateikti susitarims su tre iosiomis aalimis kopijas.
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)?	Yes
16.1.1. Please specify.	Mandatory unpaid donation. Commercial donation is forbidden. According Transplant Law Art.11(1): 11 straipsnis. Komercinis sandoris neleistinumas 1. Gyvo ar mirusio ~mogaus audiniai, lstels ir organai negali bkti civilinis komercinis sandoris objektas. Taip pat draud~iama skelbti apie ~mogaus audinis, lstelis ir organs poreik/ arba js prieinamum, siekiant finansins arba panaaios naudos.
16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below.	ART provisions Other
<ul><li>16.2.1. For all selected options in question 16.2., please provide a short description.</li><li>16.3. In your opinion, in which of the following Directives</li></ul>	The Law on ART has not been approved since 2001 due to differences of political parties views  No shortcomings
are there shortcomings (if any)? (more than 1 answer possible)	

## A.1.19. Survey response Luxembourg

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministère de la Santé
1.1. Name of National Competent Authority (NCA) 1.  1.1.2. Address of NCA 1:	Villa Louvigny - allée Marconi L-2120 LUXEMBOURG
1.1.2. Address of NCA 1:  1.1.3. Telephone (central access point):	+352 2478 5505
1.1.4. E-mail (central access point):	Hinistere-Sante@ms.etat.lu
1.1.4. E-mail (central access point): 1.1.5. Website:	http://www.ms.public.lu/fr/
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs Pharmaceuticals
	Medical devices
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	
possible)	Accreditation, authorisation, licensing of TEs Inspection
possible)	Vigilance
1.2. National Competent Authority 2?	No No
1.5. Please give a short description of the legal status and	Ministry of Health with the Directorate of Health - Governmental
organisation of the National Competent Authority(ies) (e.g.	Institution
• • • • • • • • • • • • • • • • • • • •	HISHUUH
departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget,	
independence from government etc.).	
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	του αργιτοαυτο
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	/
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	By inspecting the documentation associated with procurement that is
than I allower possible)	
	available in the tissue establishment working with procurement centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	available in the tissue establishment working with procurement
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	available in the tissue establishment working with procurement centres
31/12/2011)?	available in the tissue establishment working with procurement centres
	available in the tissue establishment working with procurement centres none
31/12/2011)? 2.2.1 Please provide the number of procurement centres in which	available in the tissue establishment working with procurement centres none
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues,	available in the tissue establishment working with procurement centres none
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane,	available in the tissue establishment working with procurement centres none
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	available in the tissue establishment working with procurement centres none
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	available in the tissue establishment working with procurement centres  none  5
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which	available in the tissue establishment working with procurement centres  none  5
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC,	available in the tissue establishment working with procurement centres  none  5
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	available in the tissue establishment working with procurement centres  none  5
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which	available in the tissue establishment working with procurement centres  none  5
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues	available in the tissue establishment working with procurement centres  none  5
3/1/2/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried	available in the tissue establishment working with procurement centres  none  5
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	available in the tissue establishment working with procurement centres  none  5  0  1
3/1/2/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its	available in the tissue establishment working with procurement centres  none  5  0  1
3/1/2/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel,	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre
3/1/2/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre
3/1/2/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre Analysis of the mandatory documentation
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation,	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre
3.1/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre Analysis of the mandatory documentation  Yes
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre Analysis of the mandatory documentation
31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre Analysis of the mandatory documentation  Yes  3
3.1/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	available in the tissue establishment working with procurement centres  none  5  0  Inspections of the site/centre Analysis of the mandatory documentation  Yes

	<del>,</del>
donors are carried out only by qualified laboratories accredited,	Analysis of the mandatory documentation requested from the tissue
designated, authorised or licensed Art. 5(2))? (more than 1 answer	establishment
possible)	
2.6. Please provide data on qualified laboratories accredited,	laboratories accreditated according our general legislation on
authorised or licensed in your country (e.g. number, year of	laboratories; all donor tests as foreseen in the directives
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	/
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	<u> </u>
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
unswer possible)	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
2.2 Ni	Anti-HIV 1
3.2. Please specify laboratory tests required for donors of	
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	HTLV-2
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	/
please indicate whether you intend to make it mandatory or to	
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	/
4. Accreditation, designation, authorisation or licensing of tissue e	stablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	0
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	No
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
	V
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC	A
4.7. Tissue establishments with authorisation pending approval at	Musculo-skeletal tissue establishments
01/01/2011 (more than 1 answer possible):	
4.7.2. How many musculo-skeletal tissue establishments?	0
4.8. Tissue establishments with authorisations pending approval by	Musculo-skeletal tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.2. How many musculo-skeletal tissue establishments?	0
-	
4.9. Tissue establishments first time authorised between 01/01/2011	Other tissue establishments

and 31/12/2011 (more than 1 answer possible):	
4.9.9. Please specify the type of tissues/cells and how many.	/
4.10. All tissue establishments authorised by 31/12/2011 (more than	Musculo-skeletal tissue establishments
1 answer possible):	ART tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?	0
4.10.2.2. How many private musculo-skeletal tissue establishments?	1
4.10.7.1. How many public ART tissue establishments?	0
4.10.7.2. How many private ART tissue establishments?	1
4.11. How many tissues and cells were distributed under the direct	/
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Division de la médecine curative
of inspections.	Division de la medeeme curative
5.1.2. If yes, please specify staffing (how many inspectors).	2
5.2. Does the inspection scheme interact or overlap with the	No No
inspection scheme of other activities, for example blood,	110
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.3. How many routine inspections of tissue establishments for non-	1
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
· · · · · · · · · · · · · · · · · · ·	

was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	1
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	V
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	V
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	· ·
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	O .
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	/ Desk based reviews
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	Yes
5.8. How many TEs were inspected at least twice between 2008-	1
2011 (01/01/2008-31/12/2011)?	V
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	. 1
5.9.1. If yes, how many?	>1
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	not appropriate
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	N.
5.12. Did you send any of your inspectors to the training courses	No
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	. 71
5.12.2. Why not?	not possible
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	N <sub>2</sub>
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	N-
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	N
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	N
5.17. Would you be interested in developing joint inspections? Joint	No
inspections should be understood as inspections of tissue	
inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States'	
inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries.	
inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States'	no time

6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	No
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	0
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	/
the equivalent standards of quality and safety for importation of skin	
from third countries.	
6.5. Please specify which procedures you have in place for verifying	/
the equivalent standards of quality and safety for importation of	
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	/
the equivalent standards of quality and safety for importation of	
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	/
the equivalent standards of quality and safety for importation of	
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	/
the equivalent standards of quality and safety for importation of	
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	/
the equivalent standards of quality and safety for importation of cord	
blood from third countries.	
6.10. Please specify which procedures you have in place for	/
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	F. Other
and self-sufficiency? (more than 1 answer possible)	
Please specify 'other':	no import/export
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 20	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.2. How do you ensure that tissues establishments fulfil the	audit
requirements of Art. 23 of Directive 2004/23/EC regarding quality	
of tissues and cells during distribution? Please specify.	
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, no restrictions apply
from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.5. Do you collect data regarding the cross-border exchange of	No
tissue/cells between your country and other EU MS?	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
5	1

The state of the s	T
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Arti	icle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	No
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.1.1. If no, why not?	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	10070 (411)
possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
* *	INU
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	/
8.5. Is there a publicly accessible register of authorised tissue	No
establishements in place? (Article 10(2))	
8.5.2. If no, why not?	information given on demand
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please specify.	ART
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Tissue establishment
possible)	
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	
9.4. How do you ensure that the 30 years data storage requirement is	/
9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	
respected (Directive 2006/89/EC, Art. 9)? Please specify.	
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?	
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11)	Directive 2004/23, Article 6 Directive 2006/76)
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the	
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	Directive 2004/23, Article 6 Directive 2006/76) Yes
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?	Directive 2004/23, Article 6 Directive 2006/76)
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé /
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	Directive 2004/23, Article 6 Directive 2006/76) Yes
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé /
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level?	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level?  10.3. Do you use the Common Approach Document developed for	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé /
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes
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respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes  Yes  No
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  /  Yes  Yes  No  not enough personnal
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes  Yes  No
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  /  Yes  Yes  No  not enough personnal
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes  Yes  No  not enough personnal  100%
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respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).  10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes  Yes  No  not enough personnal  100%
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).  10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes  Yes  No not enough personnal 100%
respected (Directive 2006/89/EC, Art. 9)? Please specify.  9.5. Do you have any additional comments on traceability?  10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?  10.1.1. If yes, which CA/institution is responsible?  10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level?  10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?  10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).  10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the	Directive 2004/23, Article 6 Directive 2006/76)  Yes  Direction de la Santé  / Yes  Yes  No  not enough personnal  100%

10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at national level?	
10.7.1. Please specify.	case by case
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?	
10.8.1. Please specify.	case by case
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	email - fax - telephone
system/procedure.	onun iun telephone
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	163
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	email - fax - telephone
system/procedure.	Cinan - iax - telephone
* *	V
10.13. Do you provide data regarding SAR/SAE to the EUROCET	Yes
registry (non-mandatory reporting)?	ind appr
10.13.1. If yes, please specify what data.	if then ART
10.14. Do you notify alerts communicated via these tissues and cells	No
national vigilance system also to other national vigilance/alert	
systems?	
10.15. Did you send a vigilance officer/contact point to the trainings	No
organised by the EU-funded project SOHO V&S?	
10.15.2. If no, please specify why not.	no time
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
	Explicit consent (opt-in) the person must give his or hers authorization
have in place within your Member State?	
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.	the person must give his or hers authorization
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you	
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	the person must give his or hers authorization  Explicit consent (opt-in)
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased	the person must give his or hers authorization
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the	the person must give his or hers authorization  Explicit consent (opt-in)
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	the person must give his or hers authorization  Explicit consent (opt-in)  First degree relatives (including spouse)
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as	the person must give his or hers authorization  Explicit consent (opt-in)
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as for organs?	the person must give his or hers authorization  Explicit consent (opt-in)  First degree relatives (including spouse)  No
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as for organs?  11.4.1. If no, please describe the difference.	the person must give his or hers authorization  Explicit consent (opt-in)  First degree relatives (including spouse)  No  organs = opt out system
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as for organs?  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1	the person must give his or hers authorization  Explicit consent (opt-in)  First degree relatives (including spouse)  No
have in place within your Member State?  11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as for organs?  11.4.1. If no, please describe the difference.  11.5. How is this consent verified during inspections? (more than 1 answer possible)	the person must give his or hers authorization  Explicit consent (opt-in)  First degree relatives (including spouse)  No  organs = opt out system  Analysis of documentation
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12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
	Medical records of the donor
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
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governments laws and regulations (from Council of Europe Guide to	
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12.9. Do you have any additional comments on selection, evaluation and procurement?  13. Quality management, responsible person, personnel (Article 16) 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.2. If no, in which country(ies) is your personnel trained?  13.4.2.1. Please specify EU-countries.  13.5. Any additional comments on quality management, responsible	Authorisation requirement Inspections  Authorisation requirement Inspections  Authorisation requirement Inspections  No
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12.9. Do you have any additional comments on selection, evaluation and procurement?  13. Quality management, responsible person, personnel (Article 16) 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.2. If no, in which country(ies) is your personnel trained?  13.4.2.1. Please specify EU-countries.  13.5. Any additional comments on quality management, responsible	Authorisation requirement Inspections  Authorisation requirement Inspections  Authorisation requirement Inspections  No  EU countries /
12.9. Do you have any additional comments on selection, evaluation and procurement?  13. Quality management, responsible person, personnel (Article 16) 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.2. If no, in which country(ies) is your personnel trained?  13.5. Any additional comments on quality management, responsible person, personnel?	Authorisation requirement Inspections  Authorisation requirement Inspections  Authorisation requirement Inspections  No  EU countries /
12.9. Do you have any additional comments on selection, evaluation and procurement?  13. Quality management, responsible person, personnel (Article 16) 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.2. If no, in which country(ies) is your personnel trained?  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country	Authorisation requirement Inspections  Authorisation requirement Inspections  Authorisation requirement Inspections  No EU countries /
12.9. Do you have any additional comments on selection, evaluation and procurement?  13. Quality management, responsible person, personnel (Article 16) 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.2. If no, in which country(ies) is your personnel trained?  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Authorisation requirement Inspections  Authorisation requirement Inspections  Authorisation requirement Inspections  No  EU countries /  -22 Directive 2004/23/EC) Inspections of tissue establishments
12.9. Do you have any additional comments on selection, evaluation and procurement?  13. Quality management, responsible person, personnel (Article 16) 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.2. If no, in which country(ies) is your personnel trained?  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country	Authorisation requirement Inspections  Authorisation requirement Inspections  Authorisation requirement Inspections  No  EU countries /  -22 Directive 2004/23/EC) Inspections of tissue establishments

14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	No
legislation?	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	/
short description.	
16.3. In your opinion, in which of the following Directives are there	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	

## A.1.20. Survey response Malta

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Superintendence of Public Health, Ministry for Health, Malta
1.1.2. Address of NCA 1:	SLH-OPD- Level 1 St. Lukes Square, Gwardamangia PTA1010
1.1.3. Telephone (central access point):	(+00356) 25953326/8
1.1.4. E-mail (central access point):	healthstandards.sph@gov.mt
1.1.5. Website:	https://ehealth.gov.mt/HealthPortal/public_health/publichealthregula
	tion/introduction.aspx and
	https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_st
	andards/tissues_cells_organs.aspx
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
	Other
Please specify 'other':	Public Health Regulation, Health Care Standards, Health
	Promotion/Disease Prevention and Environmental Health
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	The National Competent Authority is the Superintendent of Public
organisation of the National Competent Authority(ies) (e.g.	Health. The Superintendence has three directorates under its remit-
departments, staffing, number of senior and junior inspectors, staff	1. The Health Care Standards Directorate which is accountable to the
working on EU affairs and legal matters, vigilance officers, budget,	Superintendent of Public Health in managing issues related to the
independence from government etc.).	regulation of subtances of Human Origin. There is just one person
	responsible for this area, the Director who is a consultant in Public
	Health and is responsible for regulatory matters related to SOHO,
	inspections, authorisations, related EU and legal matters and SOHO
	vigilance. 2. The Health Promotion/Disease Prevention Directorate
	3. The Environmental Health Directorate. The Medicines Authority
	also falls under the Superintendence from the technical point of view
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	N. F. H. W.
1.7. Could you please describe the competence/mandate of the	Not applicable- There are no regional Competent Authorities.
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting all procurement centres
than 1 answer possible)	By inspecting the documentation associated with procurement that is
	available in the tissue establishment working with procurement
	centres
2.1.2. How many such authorisations were granted in 2011 (01/01-	Provisional Authorisations were given to two cord blood companies
31/12/2011)?	in 2011. These have now been fully authorised in 2013 together with
2217	another new cord blood procurement organisation.
2.2.1 Please provide the number of procurement centres in which	0
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	2
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	0
procurement of gametes, embryos and other reproductive tissues	
L word corried out in 2011 (01/01/21/12/2011)	1
were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which	0

procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed)? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	
2.4.1. Please provide the number of the laboratories performing	Cord blood procurement organisations in Malta store cord blood in
donor testing.	tissue/cell establishments abroad and in such cases the testing is
	done by the mother company abroad
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	0
authorised or licensed in your country (e.g. number, year of	
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	Nil
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	There is no intention to make it mandatory. The prevalence of
please indicate whether you intend to make it mandatory or to	HIV/Hep B etc in Malta is low and a cost-benefit analysis does not
encourage its use? Please specify why or why not (e.g. number of	warrant its introduction
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
	I NO
reproductive tissues and cells in your Member State?	NO
reproductive tissues and cells in your Member State?  3.7. Do you request/use international accreditation systems for	
3.7. Do you request/use international accreditation systems for	No
3.7. Do you request/use international accreditation systems for testing laboratories?	
3.7. Do you request/use international accreditation systems for testing laboratories?      3.8. Do you have any additional comments on testing?	No Nil
<ul> <li>3.7. Do you request/use international accreditation systems for testing laboratories?</li> <li>3.8. Do you have any additional comments on testing?</li> <li>4. Accreditation, designation, authorisation or licensing of tissue expression.</li> </ul>	No Nil stablishments (Article 6, Directive 2004/23/EC)
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue ed. 1. Do you have a system of designation, authorisation,	No Nil
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue ed. 1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under	No Nil stablishments (Article 6, Directive 2004/23/EC)
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue e  4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?	No Nil  Stablishments (Article 6, Directive 2004/23/EC) Yes
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue ed. 1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation,	No Nil stablishments (Article 6, Directive 2004/23/EC)
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments under your responsability?	No Nil Stablishments (Article 6, Directive 2004/23/EC) Yes Yes
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4.2.1. How many inspections were performed in 2011 for	No Nil  Stablishments (Article 6, Directive 2004/23/EC) Yes
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?	No Nil Stablishments (Article 6, Directive 2004/23/EC) Yes  Yes 2
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?  4.3. Are preparation processes authorised?	No Nil Stablishments (Article 6, Directive 2004/23/EC) Yes  Yes  2 Yes
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?	No  Nil  Stablishments (Article 6, Directive 2004/23/EC)  Yes  Yes  2  Yes  During routine inspections
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?  4.3. Are preparation processes authorised?	No  Nil  Stablishments (Article 6, Directive 2004/23/EC)  Yes  Yes  2  Yes  During routine inspections During inspections organised for this purpose
3.7. Do you request/use international accreditation systems for testing laboratories?  3.8. Do you have any additional comments on testing?  4. Accreditation, designation, authorisation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments under your responsability?  4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?  4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?  4.3. Are preparation processes authorised?	No Nil Stablishments (Article 6, Directive 2004/23/EC) Yes  Yes  2  Yes  During routine inspections

how many authorisations/accreditation/licenses were suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	Nil
how many authorisations/accreditation/licenses were revoked in	IVII
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC	A
4.7. Tissue establishments with authorisation pending approval at	Cord blood tissue establishments
01/01/2011 (more than 1 answer possible):	
4.7.6. How many cord blood tissue establishments?	2 procurement organisations
4.8. Tissue establishments with authorisations pending approval by	Other tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.9. Please specify the type of tissues/cells and how many.	Two cord blood procurement organisations Other tissue establishments
4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	Other tissue establishments
4.9.9. Please specify the type of tissues/cells and how many.	Two cord blood procurement organisations which have now been
4.7.7.1 lease specify the type of tissues/cens and now many.	authorised.
4.10. All tissue establishments authorised by 31/12/2011 (more than	Other tissue establishments
1 answer possible):	
4.10.9.1. Please specify the type of 'other' public tissues/cells	Nil
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	2 cord blood procurement organisations which were in the process of
establishements and how many.	being authorised and were then authorised in 2012
4.11. How many tissues and cells were distributed under the direct	Nil
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	165
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	Nil
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	The Superintendence of Public Health
of inspections.	-
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).	1 expert on tissues and Cells and two GMP inspectors
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the	-
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood,	1 expert on tissues and Cells and two GMP inspectors
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training,	1 expert on tissues and Cells and two GMP inspectors
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	1 expert on tissues and Cells and two GMP inspectors Yes
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training,	1 expert on tissues and Cells and two GMP inspectors Yes Blood
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	1 expert on tissues and Cells and two GMP inspectors Yes
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)	1 expert on tissues and Cells and two GMP inspectors  Yes  Blood Organs Advanced therapies
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs Advanced therapies Hospitals
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs Advanced therapies Hospitals
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?	1 expert on tissues and Cells and two GMP inspectors Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?  5.3.2. How many other type of inspections of tissues establishments	1 expert on tissues and Cells and two GMP inspectors  Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?	1 expert on tissues and Cells and two GMP inspectors  Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?  5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify.	1 expert on tissues and Cells and two GMP inspectors  Yes  Blood Organs Advanced therapies Hospitals Nil
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?  5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	1 expert on tissues and Cells and two GMP inspectors  Yes  Blood Organs Advanced therapies Hospitals Nil

was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	2 cord blood procurement organisations
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	Nil
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	Nil
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	Not applicable
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	Depending on the nature of the organisation- whetehr it is a
	procurment organisation with storage of tissues/cells in
	establishments in Eu or EEA Member States, the nature of tissues
	and cells collected and the nature of processes.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	0
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	2
5.10. Did you carry out inspections of third parties?	Yes
5.10.1. If yes, how many?	1
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
L	•

5.12. Did you send any of your inspectors to the training courses	V
	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	5
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	110
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
	N.
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	Malta has to rely on the help of other inspectors from EU member
	states to assist the local inspectors during the inspections
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	No
· · · · · · · · · · · · · · · · · · ·	110
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	0
	o a constant of the constant o
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	Notification of the import to the Competent Authority who verifies
the equivalent standards of quality and safety for importation of skin	the equivalence of standards and a requirement of cerification by the
from third countries.	responsible person of the exporting tissue establishment stating the
	equivalence of standards
6.5. Please specify which procedures you have in place for verifying	Notification of the import to the Competent Authority who verifies
the equivalent standards of quality and safety for importation of	the equivalence of standards and a requirement of cerification by the
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	responsible person of the exporting tissue establishment stating the
countries.	equivalence of standards
6.6. Please specify which procedures you have in place for verifying	Notification of the import to the Competent Authority who verifies
the equivalent standards of quality and safety for importation of	the equivalence of standards and a requirement of cerification by the
ophtalmic (cornea, sclera, etc) tissues from third countries.	responsible person of the exporting tissue establishment stating the
opinamine (cornea, serera, etc) ussues from unita countries.	
	equivalence of standards. No such importations have as yet taken
	place.
6.7. Please specify which procedures you have in place for verifying	Notification of the import to the Competent Authority who verifies
the equivalent standards of quality and safety for importation of	the equivalence of standards and a requirement of cerification by the
cardio vascular tissues from third countries.	responsible person of the exporting tissue establishment stating the
	equivalence of standards. No such imporations have as yet taken
	place.
(0 D) (0 1) 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 *
6.8. Please specify which procedures you have in place for verifying	Notification of the import to the Competent Authority who verifies
the equivalent standards of quality and safety for importation of	the equivalence of standards and a requirement cerification of the
haematopoietic stem cells (HSC) (other than cord blood) from third	responsible person of the exporting tissue establishment stating the
countries.	equivalence of standards. No such imporations have as yet taken
	place.
6.9. Please specify which procedures you have in place for verifying	Notification of the import to the Competent Authority who verifies
the equivalent standards of quality and safety for importation of cord	the equivalence of standards and a requirement cerification of the
blood from third countries.	responsible person of the exporting tissue establishment stating the
	equivalence of standards. No such importations have as yet taken

Γ	l wloop
6.10. Please specify which procedures you have in place for	place.  Not applicable. Importation of gametes is not allowed in Malta
verifying the equivalent standards of quality and safety for	Not applicable. Importation of gametes is not anowed in Maria
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	165
6.11.1. If yes, please provide the data concerning the	Skin- from Netherlands
	Skiii- Itolii Netilerialids
number/volume of imported tissues and cells by country of origin.	N.
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	NY
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	F. Other
and self-sufficiency? (more than 1 answer possible)	
Please specify 'other':	Import is considered when the tissues/cells are not available locally at
	all.
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	
6.15.1. If yes, please specify the number of cases and for which type	Demineralised bone matrix
of tissues/cells.	
6.16. Do you have any additional comments on import/export?	Nil
7. Distribution/intra community exchanges (Article 23 Directive 2	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.2. How do you ensure that tissues establishments fulfil the	They have to be certified by the responsible person of the tissue
requirements of Art. 23 of Directive 2004/23/EC regarding quality	establishment distributing them.
of tissues and cells during distribution? Please specify.	establishment distributing them.
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Other
from TEs in another MS? (only 1 answer possible).	Oulci
Please specify 'other'.	Direct distribution to hospitals/clinics through brokers after
ricase specify officer.	
	notification of the Competent Authority who authorises the import if the relevant documentation shows equivalence of standards
7.4. Have you authorised direct distribution to the recipient of	Yes
	i es
specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.4.1. If yes, how many authorisations were given in 2011	0
· · · · · · · · · · · · · · · · · · ·	One
(01/01/2011 to 31/12/2011)?	
7.4.2. If yes, for which tissues/cells?	Demineralised bone martix
7.5. Do you collect data regarding the cross-border exchange of	No
tissue/cells between your country and other EU MS?	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	Yes
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.7.1. Please describe the legal requirements and your role (if any) as	The Competent Authority has to be notified regarding each and
a Competent Authority, in their authorisation/monitoring or	every importation, requests further information, analyses the
inspection.	information provided and only gives authorisation for importaion
	after equivalence of standards is verified
7.8. Are brokers actively supplying health	Yes
professionals/establishments in your country?	
	Vous country
7.8.1. Where are the brokers located?	Your country Nil
7.8.1. Where are the brokers located? 7.9. Do you have any additional comments on distribution?	Nil
<ul><li>7.8.1. Where are the brokers located?</li><li>7.9. Do you have any additional comments on distribution?</li><li>8. Register of tissue establishments and reporting obligations (Art</li></ul>	Nil icle 10, Directive 2004/23/EC)
7.8.1. Where are the brokers located? 7.9. Do you have any additional comments on distribution?	Nil

yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	100/0 (411)
possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	17
	https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_st andards/tissues_cells_organs.aspx
8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?	Yes
8.4.1. Please insert the link to the published national annual report.	https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_st andards/tissues_cells_organs.aspx
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	163
8.5.1. If yes, please provide us with the link to the register's web site.	https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_st andards/tissues_cells_organs.aspx
8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?	Yes
8.6.1. If yes, what data are provided to EUROCET? Please specify.	Data on procurement of cord blood and distribution of any imported tissues (such as imported skin or bone matrix for clinical application in Malta).
8.7. Do you have any additional comments on reporting?	Nil
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in your country?	Yes
9.2. Who assigns the unique code for each donation? (only 1 answer possible)	Procurement centre
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement is	By randomly checking that donations till now can be traced and
respected (Directive 2006/89/EC, Art. 9)? Please specify.	overseeing that procurement organisations have adequate data
Toppoted (Birothyo 2000/05/20, Tit. 7). Thouse speenly.	backup sytems and checking that they also have in place a system
	wherby data can be stored even in case of closure of the
	establishment.
9.5. Do you have any additional comments on traceability?	Nil
10. Notification of serious adverse events and reactions (Article 11	Directive 2004/23, Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	The Superintendence of Public Health
10.1.2. If yes, please provide a short description of its organisation.	The Superintendence of Public Health is made up of three
, , , , , , , , , , , , , , , , , , ,	directorates- (1) The Directorate for Health Care Standards (2) the
	Health Promotion and Disease Surveillnace Directortyae and the
	Environmental Health Directorate. The Vigilance sytem is taken
	care of by the Health Care Standards Directorate. The same
	directorate also takes care of the haemovigilance system and
	vigilance and surveillnce related to organ transplants.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	Yes
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in 2011 the	100%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	Transplantation centres have to report to the Tissue establishments
	which distributed the tissues/cells. The tissue/cell establishments

	then investigate the issue and report to the Competent Authority.
	Transplantation centres are also obliged to inform the Competent
10.7 D	Authority when such SAR/SAEs occur.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	An annual report consolidated report is posted on the website
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?	168
10.8.1. Please specify.	An annual report consolidated report is posted on the website
10.0.1. Heast specify.  10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	Nil
were issued in your country in 2011? Please specify the number and	TVII
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	The same directorate responsible for Vigilance and Surveilance
system/procedure.	system for Tissues/Cell is also responsible for the national rapid alert
	sytem. The system also communicates with rapid alert sytems for
	blood and other substances of human origin. It can also send alerts to
	the Malta Medicines Authority whhich is responsible for
	Pharmacovigilance and to the MCCAA which is the Competent
	Authority responsible for Medical Devices.
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the system/procedure.	The same directorate responsible for Vigilance and Surveilance
system/procedure.	system for Tissues/Cell is the Directorate that receives the alerts through the RATC platform and is also responsible for the national
	rapid alert sytem. The system also communicates with rapid alert
	sytems for blood and other substances of human origin. It can also
	send alerts to the Malta Medicines Authority which is responsible
	for Pharmacovigilance and to the MCCAA which is the Competent
	Authority responsible for Medical Devices. The alert can be also
	cascaded to tissue establishments and procurement sites and also to
	end users like hospitals and transplantation centres.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	Yes
registry (non-mandatory reporting)?	
10.13.1. If yes, please specify what data.	Cord blood procurement data.
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Pharmacovilance
	Medical devices
Di Calata	Other
Please specify 'other'.	End users, transpnt centres including the organ tranplant centre.
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
organised by the EU-funded project SOHO V&S?	5
10.15.1. If yes, how would you rate the usefulness and efficacy of	5
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	Nil
11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell denotion do you	
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living	It is considered that the donor has a right to decide whether to donate
tissue/cell donation.	or not.
11.2. What consent system for deceased tissue/cell donation do you	Explicit consent (opt-in)
11.2. What consent system for deceased dissucted donation do you	Explicit consent (opt-in)

have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other relatives
tissue donation? (more than 1 answer possible)	
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties	The donors and recipients are given a unique identifier number.
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	The identity of the donor is not revealed to the recipient and all
identity of the receipient is not disclosed to the donor and vice versa.	precautions are taken so that any material is given a unique identifier
identity of the receiptent is not discressed to the donor and vice versu.	number that can only be traced back by the procurement
	organisation or tissue establishment as the the traceability
	requrements dictate and in the case of a need for look-back
	procedures in investigations or by the Competent Authority during
	investigations.
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures in	Not applicable as gamete donation is not permitted in Malta.
place.	
11.10. Do you have any additional comments on consent and data	Data Protection is ensured through the Data Protection Act of 2001.
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Audit of documentation
evaluation and selection of donors (except donors of reproductive	
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	A Poli
12.2. How do you ensure that all requirements related to the	Audit documentation
evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	110
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
,	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	Y
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Inspection of the centre of human application (e.g. transplantation
tissue establishments in your country (Art 15(1), Annex IV of	centre, ART centre)
Directive 2006/17/EC? (more than 1 answer possible)(For this	Other
question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
50 Territories 14 We and regulations (from Council of Europe Outde to	

Also Cafety and Oscillate Assumption 6 of T. T. 1 of C. C.	
the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011))	
12.8.1. Please specify.	Related information is also requested in the Tissue Establishment  Dossier that is requested prior to inspections. This dossier and the
	documentation therein is inspected by the Licensing Authority prior to the onsite inspection.
12.9. Do you have any additional comments on selection, evaluation	Nil
and procurement?	
13. Quality management, responsible person, personnel (Article 16	, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	
this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)	Inspections
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Other
Please specify 'other'.	At inspection, the inspectorate team asks for documentation of
	training for the personnel directly involved in the activities of tissue
13.4. Do you have national/regional/local training programmes for	establishments. Yes
the personnel of tissue establishments?	165
13.4.1. If yes, please specify.	The training undergone depends on the type of personnel. The
	Tissue Establishment has to have a Quality Manual that defines the
	job description and the qualifications and training required by the
	personnel. It has to define how the training is to be provided, the proficiency testing of the personnel and the documentation of such
	training/proficiency tests and competencies of the personnel.
13.5. Any additional comments on quality management, responsible	Nil
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and	SOPs for procedures associated with labelling and packaging are mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	Nil
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	Voc
15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?	Yes
15.1.1.1. Under which circumstances and for which responsibilities?	Cord blood procurement organisations have third party agreements
22 Share when encompanions and for which responsibilities:	2012 212 24 provident organizations have time party agreements

	with clinical teams responsible for procurement.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	The procurement organisation/tissue establishment has to have a
Competent Auhtority(ies) in your MS? Please specify.	documented list of third parties with which it has agreements and
	has to have documented copied of the agreement. The agreements
	have to define the responsibilities of both parties with definition of
	SOPs for all the processes and control measures that could affect the
	quality and safety of the tissues and cells.
15.2. Any additional comments on third party agreements?	Nil
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	Not applicable
short description.	
16.3. In your opinion, in which of the following Directives are there	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	

## A.1.21. Survey response Netherlands

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health, Welfare and Sport (Ministerie voor
r (	Volksgezondheid, Welzijn en Sport, VWS)
1.1.2. Address of NCA 1:	P.O. Box 20350 2500 EJ Den Haag The Netherlands
1.1.3. Telephone (central access point):	+ 31 70 340 7911
1.1.4. E-mail (central access point):	-
1.1.5. Website:	www.minvws.nl
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
	Medical devices
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Other
Please specify 'other':	policy making
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ)
1.2.2. Address of NCA 2:	P.O Box 2680 3500 GR Utrecht The Netherlands
1.2.3. Telephone (central access point):	+ 31 (0)88-120 5000
1.2.4. E-mail (central access point):	meldpunt@igz.nl
1.2.5. Website:	www.igz.nl
1.2.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
127 W	Medical devices
1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)	Inspection
1.3. National Competent Authority 3?	Vigilance Yes
1.3.1. Name of National Competent Authority 3:	Dutch Transplantation Foundation (Nederlandse Transplantatie
1.5.1. Name of National Competent Authority 5.	Stichting, NTS)
1.3.2. Address of NCA 3:	P.O.Box 2304 2301 CH Leiden The Netherlands
1.3.3. Telephone (central access point):	+ 31 (0)71 5795 777
1.3.4. E-mail (central access point):	info@transplantatiestichting.nl
1.3.5. Website:	http://www.transplantatiestichting.nl/
1.3.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
1.5.0. The Period responsible for (more than 1 answer possible)	Reproductive tissues and cells
	Human organs
1.3.7. What are the role/tasks of the NCA? (more than 1 answer	Other
possible)	
Please specify 'other':	donor registry, patient waiting list, allocation of organs and tissues.
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and	NCA1 Ministerie van Volksgezondheid, Welzijn en Sport (VWS,
organisation of the National Competent Authority(ies) (e.g.	Ministry of Health, Welfare and Sport); responsible for policy making;
departments, staffing, number of senior and junior inspectors, staff	divisions Public Health, Curative Care, Long-term Care; staffing: total
working on EU affairs and legal matters, vigilance officers,	4200 fte's, 8 dedicated to EU (legal) affairs; budget ca € 18 billion;
budget, independence from government etc.).	NCA2 Inspectie voor de GezondheidsZorg (IGZ, Health Care
	Inspectorate); independent part of ministry of Health, Welfare and
	Sport; departements: Cure, care, pharmaceutical products (including
	organs, tissues, cells, and blood); budget € 60 million; staffing: total
	500, 300 dedicated to inspections, specific tissues and cells; staff for
	international/European inspection and vigilance: 2 senior, 1 junior, 1
	support, 1 legal. NCA3 Nederlandse TransplantatieStichting (NTS,
	Dutch Transplantation Foundation); legally assigned as Organcenter, in
	Labores at damor regulator, mateaut regiting list allocation of argans and
	charge of donor registry, patient waiting list, allocation of organs and tissues; budget € 30 million; staffing: total 65;

1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	N/a
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	V
2.1. Do you authorise the "conditions of procurement"? 2.1.1. How do you authorise the "conditions of procurement"?	Yes  By inspecting the documentation associated with procurement that is
(more than 1 answer possible)	
2.1.2. How many such authorisations were granted in 2011	available in the tissue establishment working with procurement centres  18 TE; Conditions of procurement were inspected and granted at each
(01/01-31/12/2011)?	inspection of TE, except when at inspections for authorisations for
(01/01-51/12/2011):	import and distributions.
2.2.1 Please provide the number of procurement centres in which	38
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out	
in 2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	11
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	80
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	1
procurement of tissues/cells for ATMP manufacturing were	
carried out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed) ? (more	
than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor	Yes
testing?	
2.4.1. Please provide the number of the laboratories performing	51
donor testing.	
2.5. How do you ensure, as CA for T&C, that tests required	Inspections of the laboratories
for donors are carried out only by qualified laboratories	Analysis of the mandatory documentation requested from the tissue
accredited, designated, authorised or licensed Art. 5(2))? (more	establishment
than 1 answer possible)	
2.6. Please provide data on qualified laboratories accredited,	43 donor test labs for 2006/17 tests; 8 donor test labs for 2006/17 tests
authorised or licensed in your country (e.g. number, year of	plus HLA typing. In the Netherlands accreditation of donor test labs
accreditation/authorisation/license, which donor tests are	started in 2011.
performed etc.).	
2.7. Do you have any additional comments on procurement?	no
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum

3.3. If NAT testing is not mandatory in your country, could you	We do not plan to make NAT mandatory; 180 days quarantaine in case
please indicate whether you intend to make it mandatory or to	of living donors is regarded sufficient.
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and	No
test procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	Yes
	168
reproductive tissues and cells in your Member State?	D 10 YYTYYY 1 . I'
3.5.1. Please specify.	Donor is tested for HTLV, depending on the country of origine.
3.6. Are any other laboratory tests required for donors of	Yes
reproductive tissues and cells in your Member State?	
3.6.1. Please specify.	The non-partner donor is tested for HTLV, depending on the country
	of origine.
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	no
4. Accreditation, designation, authorisation or licensing of tissue	e establishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments	
under your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	18
authorising/accrediting/licensing/designating TEs?	
	l v
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	During inspections organised for this purpose
4.4. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many authorisations/accreditation/licenses	
were suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many authorisations/accreditation/licenses	
were revoked in 2011?	
4.6. Do you require TEs to be certified by an external entity to a	Yes
	ies
quality system standard (e.g. ISO, JACIE, FACT)?	
4.6.1. What is the relation between the indpendent certification(s)	Mandatory for authorisation
(e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue	
establishments? (more than 1 answer possible)	
4bis. Overview of tissue/cells establishments authorised by the N	NCA
4.7. Tissue establishments with authorisation pending approval at	Other tissue establishments
01/01/2011 (more than 1 answer possible):	Office disside establishments
	Or no outhorizations nonding approval at 01/01/2011
4.7.9. Please specify the type of tissues/cells and how many.	0; no authorisations pending approval at 01/01/2011.
4.8. Tissue establishments with authorisations pending approval	Other tissue establishments
by 31/12/2011 (more than 1 answer possible):	
4.8.9. Please specify the type of tissues/cells and how many.	0; no authorisations pending approval at 31/12/2011.
4.9. Tissue establishments first time authorised between	Musculo-skeletal tissue establishments
01/01/2011 and 31/12/2011 (more than 1 answer possible):	HSC tissue establishments
	ART tissue establishments
4.9.2. How many musculo-skeletal tissue establishments?	1
4.9.5. How many HSC tissue establishments?	
4.9.7. How many ART tissue establishments?	16
4.10. All tissue establishments authorised by 31/12/2011 (more	Skin tissue establishments
than 1 answer possible):	Musculo-skeletal tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	ART tissue establishments
4.10.1.1 How many public clain tissue establishments?	ART tissue establishments Multi-tissue establishments
4.10.1.1. How many public skin tissue establishments? 4.10.1.2. How many private skin tissue establishments?	ART tissue establishments

4.10.2.1. How many public musculo-skeletal tissue	0
establishments? 4.10.2.2. How many private musculo-skeletal tissue	15
establishments?	15
4.10.4.1. How many public cardiovascular tissue establishments?	0
4.10.4.2. How many private cardiovascular tissue establishments?	1
4.10.5.1. How many public HSC tissue establishments?	0
4.10.5.2. How many private HSC tissue establishments?	11
4.10.6.1. How many public cord blood tissue establishments?	0
4.10.6.2. How many private cord blood tissue establishments?	3
4.10.7.1. How many public ART tissue establishments?	0
4.10.7.2. How many private ART tissue establishments?	79
4.10.8.1. How many public multi-tissue establishments?	0
4.10.8.2. How many private multi-tissue establishments?	5
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5)	
during 2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	l v
4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?	Yes
4.16.1. Have penalties already been imposed?	Yes
4.16.1.1. How many penalties have been imposed in 2011 (from	0
01/01/2011-31/12/2011)?	
4.16.1.2. What were the reasons for imposing the penalties? Please describe.	N/a
4.16.1.3. What kind of penalties were imposed? Please describe	N/a
(e.g. suspension of authorisation, criminal penalty etc.)	1V/d
4.17. Do you have any additional comments on accreditation,	4.6, 4.6.1: JACIE, FACT, only for (HP)stemcells;
authorisation, designation and licensing?	1.0, 1.0.1. 0.1.0.1., 0.1., 1.0. (1.1.)0.0.1.0.1.0,
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
measures of tissue establishments!	
5.1.1. If yes, please specify the CA/Department of the CA in	Health Care Inspectorate
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Health Care Inspectorate
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. 5.1.2. If yes, please specify staffing (how many inspectors).	2 senior inspectors,1 junior inspector, 1 supporting staff member
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the	
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.      5.1.2. If yes, please specify staffing (how many inspectors).      5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood,	2 senior inspectors,1 junior inspector, 1 supporting staff member
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.      5.1.2. If yes, please specify staffing (how many inspectors).      5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training,	2 senior inspectors,1 junior inspector, 1 supporting staff member
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.      5.1.2. If yes, please specify staffing (how many inspectors).      5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	2 senior inspectors, 1 junior inspector, 1 supporting staff member Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.      5.1.2. If yes, please specify staffing (how many inspectors).      5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training,	2 senior inspectors, 1 junior inspector, 1 supporting staff member Yes  Blood
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.      5.1.2. If yes, please specify staffing (how many inspectors).      5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	2 senior inspectors, 1 junior inspector, 1 supporting staff member Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.      5.1.2. If yes, please specify staffing (how many inspectors).      5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	2 senior inspectors, 1 junior inspector, 1 supporting staff member Yes  Blood Organs
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)	2 senior inspectors,1 junior inspector, 1 supporting staff member Yes  Blood Organs Advanced therapies
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?	2 senior inspectors,1 junior inspector, 1 supporting staff member Yes  Blood Organs Advanced therapies
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-	2 senior inspectors,1 junior inspector, 1 supporting staff member Yes  Blood Organs Advanced therapies
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011	2 senior inspectors,1 junior inspector, 1 supporting staff member Yes  Blood Organs Advanced therapies
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or	2 senior inspectors,1 junior inspector, 1 supporting staff member Yes  Blood Organs Advanced therapies
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?	2 senior inspectors,1 junior inspector, 1 supporting staff member Yes  Blood Organs Advanced therapies 11
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shortcomings were noted?	10
5.3.5. Outcome of inspections of TEs for non-reproductive	10
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major	
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	24
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	0
establishments following serious adverse events or reactions, or	
suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on	0
ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a	
whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments	0
carried out in 2011 (01/01/2011 to 31/12/2011): What was the	
number of inspections carried out where no shortcomings were	
observed?	
5.4.4. What was the number of inspections carried out in ART	24
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	20
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more	General system-oriented inspections
than 1 answer possible)	General system offened hispections
5.6. How do you decide which type of routine inspection to	N/a
conduct?	IV/a
5.7. Until 2011, did you implement the requirement concerning	No
	INU
the time interval between two inspections (Art. 7.3.)?	Understaffed
5.7.1. Why not?	Understaffed.
5.7.2. How do you prioritise tissue establishments to be inspected?	Criteria: - external certification; - previous shortcomings (type and
	numer); -notifications (events, reactions, alerts, and field signals); -
60 H	size of TE (numer of tissues distributed or processed); - type of activity
5.8. How many TEs were inspected at least twice between 2008-	33
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	
5.9.2. If no, why not?	This is regarded the responsibility of the TE. See 2.1.1: documentation
	associated with (conditions of) procurement is inspected at the TE
	working with the procurement centres.
5.10. Did you carry out inspections of third parties?	Yes
5.10.1. If yes, how many?	2
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell	
procurement and tissue establishments - Guidelines for	

inspections (Commission Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	165
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	3
these training courses on a scale from 1 to 5 (1 = not important, 2	
= sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	Yes
establishment in another MS in collaboration with the NCA in that	165
MS (Art 7(6))?	
5.13.1. Could you please explain why?	In case of shipment of tissues to the Netherlands.
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	110
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	110
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	Yes
any other MS, on the results and control measures of your	103
inspections, as part of an enquiry/investigation?	
5.16.1. If yes, please specify.	NL requested clarifications of a license issued in another MS.
5.17. Would you be interested in developing joint inspections?	Yes
Joint inspections should be understood as inspections of tissue	100
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	no
	IIO .
6. Import/export (Article 9 Directive 2004/23/EC)	N.
6.1. Do you have a register of authorised tissue establishments that	No
are explicitly authorised to perform import/export of tissues and celles from/to third countries?	
1 ( 2 D)	1 10
6.2. Please specify the number of tissue establishments authorised	12
to import tissues and cells from third countries (recorded by	12
to import tissues and cells from third countries (recorded by 31/12/2011).	
to import tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments authorised	Unknown
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countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	No data.
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.12.1. If yes, please provide the data concerning the	skin 5453, bone 4830, cornea 48, HPSC unrelated 1 (bonemarrow) 14
number/volume of exported tissues and cells by country of	(periphere blood), 4 (cord blood), embryo 8. ART 2011 not available
destination.	yet.
6.13. Are you aware of any significant changes in 2012 which	No
may invalidate the 2011 data on imports/exports of tissues/cells	
between your country and other third countries?	
6.14. What is the relation between import/export of tissues and	F. Other
cells and self-sufficiency? (more than 1 answer possible)	
Please specify 'other':	Export of post-mortal tissues and scarce tissues is restricted.
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	
6.15.1. If yes, please specify the number of cases and for which	One (1) case of direct import of an embryo.
type of tissues/cells.	
6.16. Do you have any additional comments on import/export?	See activities and conclusions of the Working Group Import of Tissues
	and Cells.
7. Distribution/intra community exchanges (Article 23 Directive	2004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent	This is responsibility of the authorised distributor/TE.
quality and safety measures established by other Member States?	
Please specify.	
7.1.2. If yes, do you have more stringent quality and safety	Yes
measures than in other Member States?	
7.1.2.1. How do you address this difference for tissues and cells	For safety reasons more stringent measures are regulated in The
coming from a MS with minimum quality requirements? Please	Netherlands in order to control the distribution of unprocessed tissues
specify.	from other MS.
7.2. How do you ensure that tissues establishments fulfil the	On site inspections of TE's.
requirements of Art. 23 of Directive 2004/23/EC regarding quality	
of tissues and cells during distribution? Please specify.	Other
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Other
` · · · · · · · · · · · · · · · · · · ·	Yes, but FOR UNPROCESSED TISSUES only via an authorised TE
Please specify 'other'.	in our MS.
7.4. Have you authorised direct distribution to the recipient of	No
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	110
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination, type of	Distributed to EU (none NL; no data on country of destination): skin
tissue/cell and number of units distributed) concerning distribution	9830, bone 16821, tendon 99, cornea 182, sclera 15, amnion 10, heart
to other MS in 2011 (01/01/2011-31/12/2011).	valve 27, blood vessel 5, HPSC 4 (bone marow), 15 (periphere blood),
(0.1/01/2011/01/12/11).	7 (cord blood), lymfocyt 1, semen (donor) 156, semen (partner) 963,
	oocyt (autologeous) 745, embryo 8.
7.5.2. Please provide us with data (country of origin, type of	Not available.
tissue/cell and number of units distributed) concerning distribution	
to other MS in 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in	Yes
EU and/or import/export of tissues/cells? In this context, a	
brokerage company means a body that arranges transactions	
between a supplier (tissue establishment/company selling tissues	
or cells) and a buyer (a tissue establishment/a hospital or clinic/an	
individual) without undertaking activities of processing,	

preservation or storage.	
7.7.1. Please describe the legal requirements and your role (if any)	In the Netherlands, a broker is a legal entity, in the field of tissues only
as a Competent Authority, in their authorisation/monitoring or	allowed to make financial and logistic arrangents between seller and
inspection.	buyer without handling the tissues. Handling the tissues is only
	allowed to authorised TE's.
7.8. Are brokers actively supplying health	Yes
professionals/establishments in your country?	
7.8.1. Where are the brokers located?	Another country
7.8.2. If the broker is located in another country, how	Unknown, yet to be determined.
easy/difficult is it to ensure that safety and quality requirements	
are met?	
7.9. Do you have any additional comments on distribution?	no
8. Register of tissue establishments and reporting obligations (A	
8.1. Do you have an annual report model/template on the activities	No
of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template.	
8.1.1. If no, why not?	This is the responsibility of the TE.
8.2. How many tissue establishments submitted annual reports of	1 Into 15 the responsionity of the 1E. <50%
their activities during 2011. Please provide an estimation. (1	5070
answer possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	Following from the Act of Freedom of Information, annual reports
	from TE's are already publicly available.
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web	http://www.farmatec.nl/doc/pdf/Internetoverzicht%20Wvkl-
site.	erkenningen%20en%20-
	vergunningen%20afgegeven%20vanaf%201%20juni%202007_18122.
	pdf
8.6. Do you provide data regarding tissues and cells activities to	No
the EUROCET registry (non-mandatory reporting)?	
8.6.2. If no, why not?	no raw data readily accessible;
8.7. Do you have any additional comments on reporting?	No
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2	
9.1. Was the donor identification system (Art. 8(2)) implemented	Yes
in your country?  9.2. Who assigns the unique code for each donation? (only 1	National Comments Authority
answer possible)	National Competent Authority
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement	On site inspections.
is respected (Directive 2006/89/EC, Art. 9)? Please specify.	on one inspections.
9.5. Do you have any additional comments on traceability?	No
10. Notification of serious adverse events and reactions (Article	11 Directive 2004/23, Article 6 Directive 2006/76)
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	Health Care Inspectorate (IGZ)
10.1.2. If yes, please provide a short description of its	See question 1.5.
organisation.	
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	No
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to	
the Annual reporting of the EC also at national level?	
10.2.1. If no, what template do you use? You are welcome to	For annual SAR/E - report we use descriptive set-up (text, tables and
upload the template if you wish.	figures) instead of a specific template.
10.3. Do you use the Common Approach Document developed for	Yes
	1
the Annual reporting to the EC also at national level?	
the Annual reporting to the EC also at national level?  10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	Yes

10.5. How many tissue establishments provided in 2011 the	70-99%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	No
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.2. If no, how do you ensure that SAR/SAE are reported to the	1. The reporting of SAR/E's are incorporated in the instructions for use
TEs?	of the tissue-product. 2. On-site inspections.
10.7. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at national level?	
10.7.1. Please specify.	Feedback is given for single notifications if necessary, and on a general
	level in the national annual report for SAR/E.
10.8. Do you give feedback to the TEs regarding SAR/SAE	No
recorded at EU level?	
10.8.2. Please specify why not.	Already publicly available on SANCO website.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of	0
tissues/cells were issued in your country in 2011? Please specify	
the number and which tissues were recalled and why (e.g. missing	
consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	Part of specific standard operating procedure of the Health Care
system/procedure.	Inspectorate.
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued	
via the EU RATC platform?	
10.12.1. If yes, please give a short description of the	Part of specific standard operatnig procedure of the Health Care
system/procedure.	Inspectorate.
10.13. Do you provide data regarding SAR/SAE to the	No
EUROCET registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	This is not deemed necessary.
10.14. Do you notify alerts communicated via these tissues and	Yes
cells national vigilance system also to other national	
vigilance/alert systems?	W
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Medical devices
DI CLAL	Other
Please specify 'other'.	Organs, clinical trials.
10.15. Did you send a vigilance officer/contact point to the	Yes
trainings organised by the EU-funded project SOHO V&S?  10.15.1. If yes, how would you rate the usefulness and efficacy of	3
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	3
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	No
	1.75
11. Consent and personal data protection (Article 13 and 14, Din 11.1. What consent system for living tissue/cell donation do you	
have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living	Political decision.
tissue/cell donation.	1 ontotal decision.
11.2. What consent system for deceased tissue/cell donation do	Explicit consent (opt-in)
you have in place within your Member State?	r
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other relatives
tissue donation? (more than 1 answer possible)	Non-marital partners
	Other
Please specify 'other'.	Guardian, in case of child of 12 years of age or older.
11.4. Is the consent system for deceased tissue donation the same	Yes
as for organs?	

11.5. How is this consent verified during inspections? (more than	Analysis of documentation
1 answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	omy dumed personner is anowed to provide such information
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	Legally regulated in Dutch Act on Safety and Quality of SoHO
recipients remain unidentifiable when access is given to third	(WVKL).
parties (Art. 14(1)). Please specify.	(WVKE).
11.8. Please specify what measures are in place to ensure that the	Legally regulated in Dutch Act on Safety and Quality of SoHO
identity of the receipient is not disclosed to the donor and vice	(WVKL).
versa.	(WVRE).
11.9. Does your national legislation allows disclosure of donor	Yes
data in case of gametes donation?	163
11.10. Do you have any additional comments on consent and data	No
protection?	110
12. Selection, evaluation and procurement (Article 15 Directive 2	2004/23. Approved LIV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of reproductive	Inspections of TEs and procurement sites
cells) are respected in your country (Art. 15(1), Annex I Directive	Audit of documentation
2006/17/EC)? (more than 1 answer possible)	Regular evaluation of medical personnel
12.2. How do you ensure that all requirements related to the	Standardised questionnaires at national level
evaluation and selection of donors of reproductive cells are	
	Inspections of ART centres Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	Regular evaluation of medical personnel
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor well
deceased donor of tissues/cells? (more than 1 answer possible)	Medical records of the donor
	Interview with the treating physician
	Interview with the general practitioner
12.5. Do you have more stringent criteria for selection of donors	Autopsy report No
of reproductive cells than those listed in Annex III of the Directive	NO
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	NO
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	NO
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues	Inspection of tissue establishment
and cells' procurement, packaging and transport are complied with	Inspection of the centre of human application (e.g. transplantation
by tissue establishments in your country (Art 15(1), Annex IV of	centre, ART centre)
Directive 2006/17/EC? (more than 1 answer possible)(For this	conte, Act conte)
question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities,	
and/or vendors in order to evaluate adherence to the written SOP,	
standards or governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	No
evaluation and procurement?	
13. Quality management, responsible person, personnel (Article	16. 17. 18 Directive 2004/23/EC\
13.1. How do you ensure that tissue establishments in your	Authorisation requirement
country have in place a quality system respecting the provisions of	Authorisation requirement Inspections
the Directive 2004/23/EC Art 16.1? (more than 1 answer	mapocaona
possible). (For this question "audit" means a documented review	
of procedures, records, personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate adherence to the	
written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for	
Council of Europe Outde to the Safety and Quanty Assurance for	

the Transplantation of Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	
13.4. Do you have national/regional/local training programmes for	No
the personnel of tissue establishments?	
13.4.2. If no, in which country(ies) is your personnel trained?	EU countries
	Non-EU countries
13.4.2.1. Please specify EU-countries.	Unknown; location of training of the personnel of TE's is not notified or registred at the level of national competent authority.
13.4.2.2. Please specify non EU-countries.	Unknown; location of training of the personnel of TE's is not notified
13.4.2.2. Fleuse speetly non-Eo countries.	or registred at the level of national competent authority.
13.5. Any additional comments on quality management,	No
responsible person, personnel?	110
	10.22 D: (12004/22/EC)
14. Reception, processing, storage, labelling and packaging (Art	
14.1. How do you ensure that tissue establishments in your	National regulation/policy for reception of tissues/cells
country fulfill the requirements of the Art. 19 (Tissue and cell	Inspections of tissue establishments
reception) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	I gop a H
14.2. How do you ensure that tissue establishments in your	SOPs for all processes affecting quality and safety are mandatory for
country fulfill the requirements of the Art. 20 (Tissue and cell	authorisation
processing) of Directive 2004/23/EC? (more than 1 answer	Inspections of tissue establishments
possible)	
14.3. How do you ensure that tissue establishments in your	SOPs for procedures associated with storage of tissues and cells are
country fulfill the requirements of Art. 21 (tissue and cell storage	mandatory for authorisation
conditions) of Directive 2004/23/EC? (more than 1 answer	Inspections of tissue establishments
possible)	
14.4. How do you ensure that tissue establishments in your	SOPs for procedures associated with labelling and packaging are
country fulfill the requirements of Art. 22 (labelling,	mandatory for authorisation
documentation and packaging) of Directive 2004/23/EC and	Inspections of tissue establishments
Annex IV of Directive 2006/17/EC? (more than 1 answer	
possible)	
14.5. Any additional comments on reception, processing, storage,	No
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which	One case in 2012 concerning storage.
responsibilities?	
15.1.1.2. How are third party agreements controlled (Art 6.2) by	- agreements between TE and third parties are requirement for
the Competent Auhtority(ies) in your MS? Please specify.	authorisation of TE on-site inspection of TE or third party.
15.2. Any additional comments on third party agreements?	No
16. General comments - implementation	V
16.1. Do you have at national level more stringent quality and	Yes
safety requirements than those requested by the EU legislation in	
this field (e.g. restrictions concerning the donation/use of certain	
tissues/cells, mandatory unpaid donation etc.)?	
16.1.1. Please specify.	Distribution of unprocessed tissue from other MS to the Netherlands.
16.2. Has your Member State encountered any difficulties in	Inspections
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	- inspection interval; selection of sites to be inspected.
short description.	
16.3. In your opinion, in which of the following Directives are	Directive 2004/23/EC
there shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC

	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive	We refer to the outcome and report of the PCAM in Vienna, November
2004/23/EC?	2012.
16.3.2. How would you suggest to solve these issues in Directive	We refer to the outcome and report of the PCAM in Vienna, November
2006/17/EC?	2012.
16.3.3. How would you suggest to solve these issues in Directive	We refer to the outcome and report of the PCAM in Vienna, November
2006/86/EC?	2012.

## A.1.22. Survey response Norway

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Norwegian directorate of health
1.1.2. Address of NCA 1:	Norwegian directorate of health P.b 7000 St.Olavs plass NO-0130
	Oslo Norway
1.1.3. Telephone (central access point):	+47 81020050
1.1.4. E-mail (central access point):	postmottak@helsedir.no
1.1.5. Website:	www.helsedirektoratet.no
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Medical devices
DI CLAIL	Other
Please specify 'other':	Gene modified micro organisms
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs Inspection
possible)	Vigilance
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Norwegian board of health supervision
1.2.2. Address of NCA 2:	Calmeyers gate 1 P.b 8128 NO-0032 Oslo Norway
1.2.3. Telephone (central access point):	+47 21529900
1.2.4. E-mail (central access point):	postmottak@helsetilsynet.no
1.2.5. Website:	www.helsetilsynet.no
1.2.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
1.2.0. The IVEN is responsible for: (more than 1 answer possible)	Reproductive tissues and cells
	Blood and blood components
	Human organs
1.2.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	Norwegian medicines agency
1.3.2. Address of NCA 3:	pb. 63 Kaldbakken NO-0901 Oslo Norway
1.3.3. Telephone (central access point):	+47 22897700
1.3.4. E-mail (central access point):	post@legemiddelverket.no
1.3.5. Website:	www.legemiddelverket.no
1.3.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells Pharmaceuticals
1.3.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and	The national competent authorities are organised under the norwegian
organisation of the National Competent Authority(ies) (e.g.	ministry og health and care services. The inspectors are independent
departments, staffing, number of senior and junior inspectors, staff	from governmental control.
working on EU affairs and legal matters, vigilance officers, budget,	
independence from government etc.).	No. 15 11
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	There are no provinced accountant and the Company
1.7. Could you please describe the competence/mandate of the	There are no regional competent authorities for TE
Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	
* * * * * * * * * * * * * * * * * * * *	
2. Procurement (Article 5 Directive 2004/23/EC)	Voc
2.1. Do you authorise the "conditions of procurement"?	Yes  Projecting the decomposition associated with programment that is
2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	14
	I .

2.2.1 Please provide the number of procurement centres in which	11
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	0
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	10
procurement of gametes, embryos and other reproductive tissues	10
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	1
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed) ? (more	
than 1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	
2.4.1. Please provide the number of the laboratories performing	15
donor testing.	Transations of the Inhamatories
2.5. How do you ensure, as CA for T&C, that tests required	Inspections of the laboratories
for donors are carried out only by qualified laboratories accredited,	Analysis of the mandatory documentation requested from the tissue
designated, authorised or licensed Art. 5(2))? (more than 1 answer	establishment
possible)	
2.6. Please provide data on qualified laboratories accredited,	Number: 15, Year of accreditiation: 2008-2013, tests: HCV, HBV,
authorised or licensed in your country (e.g. number, year of	Tp, HIV, HTLV-1, HTLV-2
accreditation/authorisation/license, which donor tests are performed	
ata)	
etc.).	1
2.7. Do you have any additional comments on procurement?	
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	Apri HTV 1
<ul> <li>2.7. Do you have any additional comments on procurement?</li> <li>3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)</li> <li>3.1. Please specify laboratory tests required for donors of non-</li> </ul>	Anti-HIV 1
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1)	Anti-HIV 2
<ul> <li>2.7. Do you have any additional comments on procurement?</li> <li>3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)</li> <li>3.1. Please specify laboratory tests required for donors of non-</li> </ul>	Anti-HIV 2 HBs AG
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1)	Anti-HIV 2 HBs AG Anti HBc
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HBc Anti HCV-Ab
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum NAT is not mandatory according to cost-benefit analysis and
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum NAT is not mandatory according to cost-benefit analysis and
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3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.4.1. Please specify why:	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum NAT is not mandatory according to cost-benefit analysis and epidemiological situation in Norway.
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2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.4.1. Please specify why:  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum NAT is not mandatory according to cost-benefit analysis and epidemiological situation in Norway.  Yes  Shortcomings of available tests for deseased donors
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2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.4.1. Please specify why:  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum NAT is not mandatory according to cost-benefit analysis and epidemiological situation in Norway.  Yes  Shortcomings of available tests for deseased donors No Yes
2.7. Do you have any additional comments on procurement?  3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)  3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible)  3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?  3.4.1. Please specify why:  3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?  3.6. Are any other laboratory tests required for donors of	Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab Treponema Pallidum HTLV-2 Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab HTLV-2 NAT Chlamydia Treponema Pallidum NAT is not mandatory according to cost-benefit analysis and epidemiological situation in Norway.  Yes  Shortcomings of available tests for deseased donors No

testing laboratories?	
3.8. Do you have any additional comments on testing?	
	11:1 4 (A C I ( D' C 2004/22/EC)
<b>4.</b> Accreditation, designation, authorisation or licensing of tissue 4.1. Do you have a system of designation, authorisation,	
	Yes
accreditation or licensing for all types of tissue establishments	
under your responsability?	No
4.2. Is inspection a prerequisite for the designation, authorisation,	No
accreditation or licensing of tissue establishments?	Yes
4.3. Are preparation processes authorised?	
4.3.1. How are they authorised? (more than 1 answer possible)	By review of a submitted application with supporting documentation 0
4.4. Following inspections/controls (Art. 6.4, Directive	U
2004/23/EC), how many authorisations/accreditation/licenses were	
suspended in 2011? 4.5. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many authorisations/accreditation/licenses were	
revoked in 2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	NO
	24
4bis. Overview of tissue/cells establishments authorised by the NO	
4.7. Tissue establishments with authorisation pending approval at	Other tissue establishments
01/01/2011 (more than 1 answer possible):	A 1 1 1 NY 45 1 1 1 1
4.7.9. Please specify the type of tissues/cells and how many.	Approvals given in Norway are not time limited
4.8. Tissue establishments with authorisations pending approval by	Other tissue establishments
31/12/2011 (more than 1 answer possible):	A 1 ' ' NI
4.8.9. Please specify the type of tissues/cells and how many.	Approvals given in Norway are not time limited
4.9. Tissue establishments first time authorised between 01/01/2011	Other tissue establishments
and 31/12/2011 (more than 1 answer possible):	A 1
4.9.9. Please specify the type of tissues/cells and how many.	Approvals given in Norway are not time limited
4.10. All tissue establishments authorised by 31/12/2011 (more	Other tissue establishments
than 1 answer possible):	A
4.10.9.1. Please specify the type of 'other' public tissues/cells	Approvals given in Norway are not time limited
establishements and how many.  4.10.9.2. Please specify the type of 'other' private tissues/cells	Ammovala givan in Namvay are not time limited
establishements and how many.	Approvals given in Norway are not time limited
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5)	U U
during 2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	V
4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?	Yes
4.16.1. Have penalties already been imposed?	No
1 1	NO
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	Voc
5.1. Is a system in place for organising inspections and control measures of tissue establishments?	Yes
	Nowronian hoard of hoalth aumomission
5.1.1. If yes, please specify the CA/Department of the CA in charge	Nowregian board of health supervision
of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).	2
5.1.2. If yes, please specify starting (now many inspectors).  5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	1 05
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
3.2.1. 11 yes, prease specify. (more main 1 diswer possible)	Pharmaceuticals
	Advanced therapies
	Medical devices
	Accreditation organisations (e.g. JACIE)
5.3. How many routine inspections of tissue establishments for	0
non-reproductive tissues/cells were conducted in 2011 (from	-
Transactive debags, constitution in 2011 (noin	

1/1/2011 to 31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011	
to 31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	· ·
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
· · · =	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major	
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
	U
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	9
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	0
establishments following serious adverse events or reactions, or	
suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a	
whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	2
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	7
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	V
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than	General system-oriented inspections
1 answer possible)	Thematic inspections
5.6. How do you decide which type of routine inspection to	Based on review of documentation, risk assessement and history of
1	deficiencies
conduct?	
5.7. Until 2011, did you implement the requirement concerning the	Yes
5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?	
5.7. Until 2011, did you implement the requirement concerning the	Yes 0

5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	
5.9.2. If no, why not?	Not relevant
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	Not relevant
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	4
these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	NO
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections?	Yes
Joint inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised	5
to import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by	0
31/12/2011).	
6.4. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of skin from third countries.	
6.5. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of musculo-skeletal (bone, tendons, fascia etc.) tissues	
from third countries.	
6.6. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of ophtalmic (cornea, sclera, etc) tissues from third	
countries.	
6.7. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of haematopoietic stem cells (HSC) (other than cord	
blood) from third countries.	

6.9. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of cord blood from third countries.	
6.10. Please specify which procedures you have in place for	National regulation of quality and standards equivalent to EU
verifying the equivalent standards of quality and safety for	standards
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
	105
(01/01/2011-31/12/2011)?	N . 211
6.11.1. If yes, please provide the data concerning the	Not available
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	D. Import of tissues/cells is authorised only after checking that
and self-sufficiency? (more than 1 answer possible)	local/national needs are not fulfilled
and sent sufficiency: (more than 1 answer possible)	E. Import of tissues/cells is authorised based on estimations showing
6141 KA D	that there is chronic deficiency of those tissues/cells
6.14.1. If A or D were selected, please explain how you quantify	National list of patients in need of tissues and cells or transplantation
local/national needs.	
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	
6.15.1. If yes, please specify the number of cases and for which	1, tendonse
type of tissues/cells.	
6.16. Do you have any additional comments on import/export?	
	0004/02/ECD
7. Distribution/intra community exchanges (Article 23 Directive 2	
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
1 7 1 1 If you have do you address the possible many stringent	
7.1.1. If yes, how do you address the possible more stringent	Distribution conditions shall comply with national regulations.
quality and safety measures established by other Member States?	Distribution conditions snall comply with national regulations.
quality and safety measures established by other Member States? Please specify.	Distribution conditions snall comply with national regulations.
quality and safety measures established by other Member States?	Distribution conditions shall comply with national regulations.  Yes
quality and safety measures established by other Member States? Please specify.	
quality and safety measures established by other Member States? Please specify. 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	Yes
quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells	Yes  TE with import license must ensure, and document, comliance with
quality and safety measures established by other Member States?  Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please	Yes
quality and safety measures established by other Member States?  Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.	Yes  TE with import license must ensure, and document, comliance with national regulations.
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quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality	Yes  TE with import license must ensure, and document, comliance with national regulations.
quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	Yes  TE with import license must ensure, and document, comliance with national regulations.  Licensing and inspection
quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes  TE with import license must ensure, and document, comliance with national regulations.
quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Yes  TE with import license must ensure, and document, comliance with national regulations.  Licensing and inspection
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quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS?  7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or	Yes  TE with import license must ensure, and document, comliance with national regulations.  Licensing and inspection  Yes, but only via an authorised TE in my MS  No  No  No
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quality and safety measures established by other Member States? Please specify.  7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?  7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS?  7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage.  7.7.1. Please describe the legal requirements and your role (if any)	Yes  TE with import license must ensure, and document, comliance with national regulations.  Licensing and inspection  Yes, but only via an authorised TE in my MS  No  No  Yes

and foreign to the tribute of the control of the co	T
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Art	
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	50.700/
8.2. How many tissue establishments submitted annual reports of	50-69%
their activities during 2011. Please provide an estimation. (1 answer possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	By contacting Norwegian directorate of health
8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	165
8.4.1. Please insert the link to the published national annual report.	http://www.helsedirektoratet.no/kvalitet-planlegging/bio-
0.4.1. I lease insert the link to the published national annual report.	genteknologi/celler-og-
	vev/Documents/ÅRSRAPPORT%20celler%20og%20vev%202011.p
	df
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web	http://www.helsedirektoratet.no/kvalitet-planlegging/bio-
site.	genteknologi/celler-og-vev/Sider/default.aspx
8.6. Do you provide data regarding tissues and cells activities to the	No
EUROCET registry (non-mandatory reporting)?	
8.6.2. If no, why not?	Lack of accordance with eurocet scheme
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2004/23/EC)	06/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	No
your country?	
9.1.1. If no, why not?	Identification of donor is determined by national unique personal
	number identification system
9.2. Who assigns the unique code for each donation? (only 1	Tissue establishment
answer possible)	
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	
9.4. How do you ensure that the 30 years data storage requirement	License and inspections
is respected (Directive 2006/89/EC, Art. 9)? Please specify.	
9.5. Do you have any additional comments on traceability?	
10. Notification of serious adverse events and reactions (Article 1)	
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	N
10.1.1. If yes, which CA/institution is responsible?	Norwegian directorate of health
10.1.2. If yes, please provide a short description of its organisation.	www.cellerogvev.no
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	No
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	Wo yas ardinaw mail
10.2.1. If no, what template do you use? You are welcome to	We use ordinary mail.
upload the template if you wish.  10.3. Do you use the Common Approach Document developed for	No
the Annual reporting to the EC also at national level?	No
10.3.1. If no, please specify what guidelines you use.	National regulations
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	103
10.5. How many tissue establishments provided in 2011 the	<50%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	Procedures according to national regulations
10.7. Do you give feedback to the TEs regarding SAR/SAE	Yes
	I

recorded at national level?	
10.7.1. Please specify.	Feedback are given to TE who reports.
10.8. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at EU level?	
10.8.1. Please specify.	Feedback are given to relevant TE's
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of	0
tissues/cells were issued in your country in 2011? Please specify	
the number and which tissues were recalled and why (e.g. missing	
consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	Rapid alert information are sendt to relevant TE's
system/procedure.	
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued	
via the EU RATC platform?	
10.12.1. If yes, please give a short description of the	Rapid alert information are sendt to relevant TE's
system/procedure.	
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	Not yet implemented
10.14. Do you notify alerts communicated via these tissues and	No
cells national vigilance system also to other national vigilance/alert	
systems?	
10.15. Did you send a vigilance officer/contact point to the	Yes
trainings organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	4
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Dire	·
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	Written conscent
tissue/cell donation.	
11.2. What consent system for deceased tissue/cell donation do you	Presumed consent (opt-out)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	Other relatives
tissue donation? (more than 1 answer possible)	Non-marital partners
	Friends
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	Analysis of documentation
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	National regulations
11.7. What measures are in place to ensure that both donors and	National regulations
recipients remain unidentifiable when access is given to third	
parties (Art. 14(1)). Please specify.	Darsonal identification is replaced with denor so de
11.8. Please specify what measures are in place to ensure that the	Personal identification is replaced with donor code
identity of the receipient is not disclosed to the donor and vice	
Versa.  11.0 Does your national legislation allows disclosure of donor data	No
11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	INU
	IVE children have right to know identification of denor
11.9.1. If no, please specify the circumstances and measures in	IVF children have right to know identification of donor

place.	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	004/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
	Medical records of the donor
12.5. Do you have more stringent evitoric for collection of denotes of	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive	No
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP,	
standards or governments laws and regulations (from Council of	
Europe Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	
evaluation and procurement?	
13. Quality management, responsible person, personnel (Article 1	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible).	Internal audits
(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials,	
facilities, and/or vendors in order to evaluate adherence to the	
written SOP, standards or governments laws and regulations (from	
Council of Europe Guide to the Safety and Quality Assurance for	
the Transplantation of Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
•	Mandatory trainings
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	Sentralised competence centres
13.5. Any additional comments on quality management,	

responsible person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art	9-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing)	authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage	mandatory for authorisation
conditions) of Directive 2004/23/EC? (more than 1 answer	Inspections of tissue establishments
possible)	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which	Documention of third party agreement
responsibilities?	
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	Licensing and inspection
Competent Auhtority(ies) in your MS? Please specify.	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and	No
safety requirements than those requested by the EU legislation in	
this field (e.g. restrictions concerning the donation/use of certain	
tissues/cells, mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	TE's mainly comply with national regulations
short description.	
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	
16.3.1. How would you suggest to solve these issues in Directive	The required interval between two inspections are to short. We would
2004/23/EC?	prefer intervals of three/four years.

## A.1.23. Survey response Poland

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	National Centre for Tissue and Cell Banking
1.1.2. Address of NCA 1:	ul. Chalubinskiego 5, 02-004 Warsaw, Poland
1.1.3. Telephone (central access point):	+48 22 621 75 43
1.1.4. E-mail (central access point):	sekretariat@kcbtik.pl; artur.kaminski@wum.edu.pl;
1.1.5. Website:	www.kcbtik.pl
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	Vigilance
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Polish Transplant Coordinating Center - Poltransplant
1.2.2. Address of NCA 2:	Al. Jerozolimskie 87, 02-001 Warsaw, Poland
1.2.3. Telephone (central access point):	+ 48 22 622 58 06
1.2.4. E-mail (central access point):	transpl@poltransplant.org.pl
1.2.5. Website:	www.poltransplant.org.pl
1.2.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
1.2.0. The tvert is responsible for. (more than 1 answer possible)	Human organs
1.2.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	Vigilance
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	Department of Mother and Child, Ministry of Health
1.3.2. Address of NCA 3:	ul. Długa 38/40, 00-241 Warsaw, Poland
1.3.3. Telephone (central access point):	+48 22 53 00 383
1.3.4. E-mail (central access point):	dep-md@mz.gov.pl
1.3.5. Website:	www.mz.gov.pl
1.3.6. The NCA is responsible for? (more than 1 answer possible)	Reproductive tissues and cells
1.3.7. What are the role/tasks of the NCA? (more than 1 answer	Vigilance
possible)	Vignance
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and	National Centre for Tissue and Cell Banking (KCBTiK – Krajowe
organisation of the National Competent Authority(ies) (e.g.	Centrum Bankowania Tkanek i Komorek) is a budgetary unit
departments, staffing, number of senior and junior inspectors, staff	submitted to the minister competent to do with health matters. The
working on EU affairs and legal matters, vigilance officers, budget,	tasks of the National Centre for Tissue and Cell Banking include, in
independence from government etc.).	particular: 1) organization of a co-operation between tissue and cell
,	banks; 2) performance of reference and consultative functions; 3)
	supervision and inspection of tissue and cell banks in respect of the
	merits; 4) keeping a register of tissue and cell banks; 5) organizing
	the trainings with regard to recovery, collection, testing, processing,
	sterilization, storage and distribution of cells and tissues; 6) keeping
	the list of persons who completed the trainings with regard to
	recovery, collection, testing, processing, sterilization, storage and
	distribution of cells and tissues; 7) exercising substantive
	supervision over the activity of recovery teams; 8) management of
	SAREs. Polish Transplant Coordinating Center is responsible for: 1)
	procurement and transplant centers of biovital tissues and cells, 2)
	HSC import and export, 3) management of SAREs in the field of
	HSC. Department of Mother and Child has no assigned status of the
	NCA. However it deals with matters related to ART in Poland.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	There are no Regional CAs in Poland.
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	By inspecting some procurement centres
2.1.1. How do you authorise the conditions of procurement? (more	By hispecting some procurement centres

	available in the tissue establishment working with procurement
2.1.2. How many such authorisations were granted in 2011 (01/01-	centres 3
31/12/2011)?	154
2.2.1 Please provide the number of procurement centres in which	154
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	100
2.2.2 Please provide the number of procurement centers in which	120
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	no data
procurement of gametes, embryos and other reproductive tissues	
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	27
procurement of tissues/cells for ATMP manufacturing were carried	
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Inspections of the site/centre
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the mandatory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed) ? (more than	
1 answer possible)	
2.4. Are you also responsible for the accreditation, designation,	No
authorisation or licensing of laboratories performing donor testing?	
2.4.2. Which National Authority is in charge of this activity?	National Chamber of Diagnostic Laboratories
2.5. How do you ensure, as CA for T&C, that tests required for	Analysis of the mandatory documentation requested from the tissue
donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	59
authorised or licensed in your country (e.g. number, year of	
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	In 2012 there were 15 on site inspections of procurement centers.
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	·
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
• ′	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT testing is used for verification of doubtfull serological results
please indicate whether you intend to make it mandatory or to	5
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	Due to the lack of the regulation regarding ART in Poland the panel
5.6. Do you have any additional comments off testing!	Due to the fack of the regulation regarding AKT in rotatio the panel

	of obligatory laboratory tests required for donors of reproductive
	tissues and cells is not formally established.
4. Accreditation, designation, authorisation or licensing of tissue es	
4.1. Do you have a system of designation, authorisation,	No
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.1.1. Why not?	Designation of tissue and cell establishments is done by Minister of
	Health
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes. Review of submitted documentation and on-site inspection is
accreditation or licensing of tissue establishments?	always required.
4.2.1. How many inspections were performed in 2011 for	5
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine on-site inspections and by review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in 2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC.	
4.7. Tissue establishments with authorisation pending approval at	Ocular tissue establishments
01/01/2011 (more than 1 answer possible):	HSC tissue establishments
4.7.3. How many ocular tissue establishments?	1
4.7.5. How many HSC tissue establishments?	4
4.8. Tissue establishments with authorisations pending approval by	HSC tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.5. How many HSC tissue establishments?	1
4.9. Tissue establishments first time authorised between 01/01/2011	Ocular tissue establishments
and 31/12/2011 (more than 1 answer possible):	HSC tissue establishments
4.9.3. How many ocular tissue establishments?	1
4.9.5. How many HSC tissue establishments?	4 Skin tissue establishments
4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
i aliswei possible).	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.1.1. How many public skin tissue establishments?	2
4.10.1.2. How many private skin tissue establishments?	1
4.10.2.1. How many public musculo-skeletal tissue establishments?	1
4.10.2.2. How many private musculo-skeletal tissue establishments?	0
4.10.3.1. How many public ocular tissue establishments?	4
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue establishments?	2
4.10.4.2. How many private cardiovascular tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	18
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	3
4.10.6.2. How many private cord blood tissue establishments?	6
4.10.8.1. How many public multi-tissue establishments?	2
4.10.8.2. How many private multi-tissue establishments?	1
4.10.9.1. Please specify the type of 'other' public tissues/cells	- pancreatic islets bank - 1
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private tissues/cells	- chondocytes and osteoblasts bank - 1

establishements and how many.	
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	Tissue and cell establishments are authorised every five years (the
authorisation, designation and licensing?	Designation of the Minister of Health is valid for 5 years).
	Inspections for designation follows application prepared by applying
	tissue establishment. At least every two years each tissue
	establishment is subjected to on-site inspection.
5. Inspections (Article 7, Directive 2004/23/EC)	T vv
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	N
5.1.1. If yes, please specify the CA/Department of the CA in charge	National Centre for Tissue and Cell Banking
of inspections.	
5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the	No
inspection scheme of other activities, for example blood,	110
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.3. How many routine inspections of tissue establishments for non-	11
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	3
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	U
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
The condition of the co	

following scrious adverse events or reactions, or suspicion thereof (frion 1/12/01 to 3/12/2011) (s.g. due to a whisteblower)? Please specify.  5.4.3. Nutcome of inspections of ART tissue establishments carried out out in 2011 (011/2011 to 3/12/2011); What was the number of inspections carried out where no shortcomings were observed?  5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments but of lowed by elosension of authoristorion?  5.4.7. What was the number of inspections carried out in ART establishments followed by elosension of authoristorion?  5.4.8. What was the number of other inspections of ART establishments followed by elosension of authoristorion?  5.4.8. What was the number of other inspections of ART establishments followed by elosension of authoristorion?  5.4.8. What was the number of other inspections of ART establishments? Please specify.  5.5. Which type of routine inspections to conduct? (more than 1 answer possible)  5.6. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?  5.8. How many TEs were inspected at least twice between 2008-2011 (0101/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?  5.1. Until 2011, did you implement the requirement concerning the time interval between two inspections of procurement sites outside tissue establishments?  5.1. Did you was at national level the Operational Manual for Competent Authorities on
5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower!) Please specify.  5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (ol1/1/2011 to 31/12/2011). What was the number of inspections carried out in ART establishments where misor shortcomings were observed?  5.4.4. What was the number of inspections carried out in ART establishments where misor shortcomings were noted?  5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective stablishments?  5.4.8. What was the number of inspections of ART establishments? Please specify.  5.5. Which type of routine inspection of outlood of ART establishments? Please specify.  5.6. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections of Art. 7.3.)?  5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside fusions establishments?  5.10. If yes, how many?  5.10. If yes, how many?  5.10. Did you send any of your inspectors to the training courses or gamised by EU-funded projects (e.g. EUSTITE, SOHO Vamps)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO Vamps)?  5.12. Did you request/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 760)?  5.15. Did you organise an inspections of former ment centres or No
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify.  5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011). What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.4.5. What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.7. What was the number of inspections of ART establishments followed by closure of respective establishments?  5.4.8. What was the number of inspections of ART establishments followed by closure of respective establishments?  5.5. Which type of routine inspections of ART establishments? Please specify.  5.6. How do you decide which type of routine inspection to conduct? (more than 1 answer possible)  5.6. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?  5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011);  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?  5.10. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.11. Did you carry out inspections of third parties?  5.12. Did you act at national level the Operational Manual for Competent Authorities on inspection of tissue endel procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/433/Ed]9  5.12. Did you act an action and inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.13. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in co
blower? Please specify.
5.43. Outcome of inspections of ART itssue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed?  5.44. What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.45. What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.46. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.47. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.48. What was the number of other inspections of ART establishments Please specify.  5.54. Which type of routine inspections of ART establishments?  5.61. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?  5.81. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?  5.91. Did you gerform/conduct inspections of procurement sites outside tissue establishments?  5.91. If yes, how many?  5.10. Did you carry out inspections of third parties?  5.10. Did you carry out inspections of third parties?  5.11. Do you use at antional level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art. 7(6))?  5.15. Did you organise any inspections of procurement centres or No
out in 20.11 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed?  5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments followed by ususpension of authorisation?  5.4.7. What was the number of inspections carried out in ART establishments followed by ususpension of authorisation?  5.4.6. What was the number of inspections carried out in ART establishments followed by ususpension of authorisation?  5.4.6. What was the number of inspections carried out in ART establishments followed by ususpension of authorisation?  5.4.7. What was the number of other inspections of ART establishments? Please specify.  5.8. Which type of routine inspections do you conduct? (more than 1 answer possible)  5.9. Which up of routine inspections to conduct?  5.9. Until 2011, did you implement the requirement concerning the time interval between two inspections of Art. 7.3.?  5.9. Did you performiconduct inspections of procurement sites outside tissue establishments?  5.9. Did you performiconduct inspections of procurement sites outside tissue establishments?  5.10. Did you carry out inspections of third parties?  5.11. Did you used an autional level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you request/organise an inspection of a tissue establishment in norther MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you congainse an inspections of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you grainse an inspections of procurement centres or
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5.4.4 What was the number of inspections carried out in ART establishments where minor shortcomings were noted?  5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.7. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.8. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.8. What was the number of other inspections of ART establishments followed by suspension of authorisation?  5.5. Which type of routine inspections of ART establishments? Please specify.  5.6. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?  5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?  5.10. July you carry out inspections of third parties?  5.10. July ou use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you used any of your inspectors to the training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you receive/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of forocurement centres or No
establishments where minor shortcomings were noted?  5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted?  5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.7. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.4.8. What was the number of other inspections of ART establishments? Please specify.  5.5. Which type of routine inspections do you conduct? (more than 1 answer possible)  5.6. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?  5.8. How many TEs were inspected at least twice between 2008-2011 (0101/2008-31/12/2011)?  5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?  5.9.1. If yes, how many?  5.10. Did you carry out inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you sad any of your inspectors to the training courses or an scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you receive/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of a forcurement tenter or the procurement of the collaboration with the NCA in that MS (Art 7(6))?  5.16. Did you organise any inspections of a forcurement centres or No
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establishments where major shortcomings were noted?  5.40. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.47. What was the number of inspections carried out in ART establishments followed by suspension of authorisation?  5.48. What was the number of other inspections of ART establishments? Please specify.  5.5. Which type of routine inspections do you conduct? (more than 1 amswer possible)  5.6. How do you decide which type of routine inspection to conduct?  5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?  5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?  5.9. Did you grary out inspections of firid parties?  5.10. Did you carry out inspections of third parties?  5.10. Did you sard an attoinal level the Operational Manual for Competent Authorities on inspections (Commission 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO Vamps.)?  5.12. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art. 7(6))?  5.14. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art. 7(6))?  5.15. Did you organise any inspections of procurement centres or No
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5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or  No
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MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or  No
5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? 5.15. Did you organise any inspections of procurement centres or No
establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or  No
collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or  No
5.15. Did you organise any inspections of procurement centres or No
tissue establishments in third countries from which tissues and/or
cells were imported in your country (as recorded by 31/12/2011)?
5.16. Have you asked another MS, or have you been requested by
any other MS, on the results and control measures of your
inspections, as part of an enquiry/investigation?
5.17. Would you be interested in developing joint inspections? Joint Yes
inspections should be understood as inspections of tissue
establishments conducted jointly by two or more Member States'
Competent Authorities on their territory or in third countries.
5.18. Do you have any additional comments on inspections?  6. Import/export (Article 9 Directive 2004/23/EC)

6.1. Do you have a register of authorised tissue establishments that	No
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	0
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	Regulation of Minister of Health on exportation and importation of
the equivalent standards of quality and safety for importation of skin	cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485): - donation
from third countries.	procedure, donor selection criteria, laboratory testing, processing,
	storage, distribution and transportation conditions
6.5. Please specify which procedures you have in place for verifying	Regulation of Minister of Health on exportation and importation of
the equivalent standards of quality and safety for importation of	cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485): - donation
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	procedure, donor selection criteria, laboratory testing, processing,
countries.	storage, distribution and transportation conditions
6.6. Please specify which procedures you have in place for verifying	Regulation of Minister of Health on exportation and importation of
the equivalent standards of quality and safety for importation of	cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485): - donation
ophtalmic (cornea, sclera, etc) tissues from third countries.	procedure, donor selection criteria, laboratory testing, processing,
	storage, distribution and transportation conditions
6.7. Please specify which procedures you have in place for verifying	Regulation of Minister of Health on exportation and importation of
the equivalent standards of quality and safety for importation of	cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485): - donation
cardio vascular tissues from third countries.	
cardio vascular tissues from third countries.	procedure, donor selection criteria, laboratory testing, processing,
	storage, distribution and transportation conditions
6.8. Please specify which procedures you have in place for verifying	Regulation of Minister of Health on exportation and importation of
the equivalent standards of quality and safety for importation of	cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485): - donation
haematopoietic stem cells (HSC) (other than cord blood) from third	procedure, donor selection criteria, laboratory testing, processing,
countries.	storage, distribution and transportation conditions
6.9. Please specify which procedures you have in place for verifying	Regulation of Minister of Health on exportation and importation of
the equivalent standards of quality and safety for importation of cord	cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485): - donation
blood from third countries.	procedure, donor selection criteria, laboratory testing, processing,
	storage, distribution and transportation conditions
6.10. Please specify which procedures you have in place for	There is no regulation regarding ART in Poland
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
	LICC. O (LICA) 2 (Atli-)
6.11.1. If yes, please provide the data concerning the	HSC: 9 (USA), 2 (Australia)
number/volume of imported tissues and cells by country of origin.	
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.12.1. If yes, please provide the data concerning the	HSC: 1 (Australia), 1 (Croatia)
number/volume of exported tissues and cells by country of	
destination.	
6.13. Are you aware of any significant changes in 2012 which may	No
	INU
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	A. Export of tissues/cells is authorised only after checking that
and self-sufficiency? (more than 1 answer possible)	local/national needs are fulfilled.
	C. Export of tissues/cells is authorised irrespective of national needs
	E. Import of tissues/cells is authorised based on estimations showing
	that there is chronic deficiency of those tissues/cells
	and the second second of the second s
6.14.1 If A or D were selected please explain how you quantify	Based on current request for particular type of tissue graft from
6.14.1. If A or D were selected, please explain how you quantify	Based on current request for particular type of tissue graft from
local/national needs.	hospitals in Poland.
local/national needs. 6.15. Did you authorise direct imports of tissues/cells to	
local/national needs.  6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	hospitals in Poland. No
local/national needs. 6.15. Did you authorise direct imports of tissues/cells to	hospitals in Poland.
local/national needs.  6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	hospitals in Poland. No
local/national needs.  6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	hospitals in Poland.  No  According to law regulations each procedure of crossing of Polish

	third countries.
7 Distribution/intra community evaluages (Article 22 Directive 26	<u> </u>
7. Distribution/intra community exchanges (Article 23 Directive 20 7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify.	No in general. According to law regulations each procedure of crossing of Polish border of tissues and cells is recognised as import or export. In general there is no differences between other member
	states and third countries. The authorisation of tiissue establishment by adequate CA is an important part of verification. Each tissue or cel graft is distibuted to Polish hospitals with the involment of designated by Polish Minister of Health tiissue establishment.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	Yes
7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify.	- document of accredidation, designation, licencing of tissue establishment by adequate CA; - direct contact with CA from other MS (t.e. country of origin); - procedures of donation, donor selection criteria, laboratory testing, procurement, processing, storage,
	distribution and transportation conditions.
7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	Verification of document of accredidation, designation, licencing of tissue establishment by adequate CA; - direct contact with CA from other MS (t.e. country of origin); - procedures of donation, donor selection criteria, laboratory testing, procurement, processing, storage, distribution and transportation conditions.
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Yes, but only via an authorised TE in my MS
7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No
7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	Yes
7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution	- ocular tissue: 1 (Germany) - heart valves: 20 (Germany) - HSC: 126 (Germany), 8 (Great Britain), 1 (Cyprus), 2 (Czech Republik), 2
to other MS in 2011 (01/01/2011-31/12/2011).	(France), 1 (Spain), 1 (Italy)
7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011)	0
7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS?	No
7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage.	No
7.8. Are brokers actively supplying health professionals/establishments in your country?	No
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligations (Artic	cle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible)	100% (all)
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	http://www.kcbtik.pl/?Zestawienia
8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?	Yes
8.4.1. Please insert the link to the published national annual report.	http://www.kcbtik.pl/?Zestawienia
8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2))	Yes

8.5.1. If yes, please provide us with the link to the register's web site.	http://www.kcbtik.pl/?Banki_Tkanek
8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)?	Yes
8.6.1. If yes, what data are provided to EUROCET? Please specify.	- consolidated activities for tissue and cells regarding donation, procurement, processing, storage and distribution
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in your country?	Yes
9.2. Who assigns the unique code for each donation? (only 1 answer possible)	Tissue establishment
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	Based on review of writen procedure in place regarding set of data and adequate (30 years) period of storage. Procedures and data archivisation is reviewed during each on-site inspection.
9.5. Do you have any additional comments on traceability?	Poland has implemented ISBT 128 coding system in tissue and cell establishments.
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	
10.1.1. If yes, which CA/institution is responsible?	Both National Centre for Tissue and Cell Banking and Polish Transplant Coordinating Center
10.1.2. If yes, please provide a short description of its organisation.  10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	National Centre for Tissue and Cell Banking for tissue establishments, Poltransplant and National Centre for Tissue and Cell Banking for procurement and transplantation. System is based on EUSTITE project deliverables. Management of SAREs by tissue bank was discussed during training courses organised in Poland. Each tissue establishment by implementing quality system managment is responsible for implementation SARE SOP. National Centre for Tissue Banking receives SARE notificantions from tissue establishments. If described case is scored as serious inspection is mandatory. NCTCB is involved in investigation and corrective actions. SAREs related to procurement and clinical use of tissues and cells are magaged together by NCTCB and Poltransplant
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	Yes
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	No
10.4.1. Why not?	All tissue and cells establishments inspectors are responsible for managing of SAREs. They are all trained during EUSTITE or SOHOV7S projects and during internal trainings.
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes
10.6.1. If yes, please provide a brief description.  10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	Tissue establishments are responsible to send SARE notification form to each transplant centers where they distribute tissues and cells. Poland started implementation of electronic notification of SAREs from transplant centers via "Registry" platform administered by Poltransplant. SARE cases are immidiately reported to the Ministry of Health. Minister of Health designates adequate CA for inspection according to writen procedure describing CA's competency.
10 20 jou five recubied to the TES regulating british in recorded	100

at national level?	
10.7.1. Please specify.	Annonimous data are analysed for educational reasons during training courses organised by National Centre for Tissue and Cell Banking.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	Annonimous data are analysed for educational reasons during training courses organised by National Centre for Tissue and Cell Banking
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	0
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes
10.11.1. If yes, please give a short description of the system/procedure.	Notification is dane via e-mail and/or fax communication.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes
10.12.1. If yes, please give a short description of the system/procedure.	Notification is dane via e-mail and/or fax communication.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	No
10.13.2. If no, please specify why not.	Data are provided directly to the European Comission.
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	Yes
10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	Haemovigilance Pharmacovilance Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	5
10.16. Do you have any additional comments on SARE reporting?	
11. Consent and personal data protection (Article 13 and 14, Direc	
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	- potental donor was informed about the riscs related to donation (in written form); - potential donor agreed to became a donor (written agreement for procedure of donation); - potential donor has full competency for legal actions; - in case when potential donor has no full competency for legal actions the decission of legal representative or a court is required.
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed consent (opt-out)
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	No further authorisation is needed
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Interviews with personnel
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art.	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level

13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors and	- Act of 6 November 2008 on the rights of the patient and the
recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	patient's Ombudsman (art.13) - Implementation of coding system for tissues and cells (ISBT 128); - Only codes appear on tissue grafts labels; - Legal requirement of anonimity between donor and recipient.
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	- Act of 6 November 2008 on the rights of the patient and the patient's Ombudsman (art.13) - Implementation of coding system for tissues and cells (ISBT 128); - Only codes appear on tissue grafts labels; - Legal requirement of anonimity between donor and recipient.
11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	No
11.9.1. If no, please specify the circumstances and measures in place.	Act of 6 November 2008 on the rights of the patient and the patient's Ombudsman (art.13)
11.10. Do you have any additional comments on consent and data protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible)	Regular evaluation of medical personnel
12.2. How do you ensure that all requirements related to the	Other
evaluation and selection of donors of reproductive cells are	
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)  Please specify 'other'.	There is no regulation regarding ART in Poland.
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible)	Interview with the donor's family or a person who knew the donor well  Medical records of the donor Interview with the treating physician Interview with the general practitioner Autopsy report
12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	No
12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC?	No
12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?	No
12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011))  12.9. Do you have any additional comments on selection, evaluation	Inspection of tissue establishment Inspection of the centre of human application (e.g. transplantation centre, ART centre)
and procurement?	17.19 Dimetine 2004/22/EG
13. Quality management, responsible person, personnel (Article 10	
13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the	Authorisation requirement Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
The American and the means a accommence review of proceedings,	

records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)).  13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)	Authorisation requirement Inspections Regular evaluation of personnel Mandatory trainings
13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)	Authorisation requirement Inspections Regular evaluation of personnel Mandatory trainings
13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.	Yes  There are training programmes for responsible persons and
	personel of tissue establishments, procurement and transplantation medical personel created and developed during realisation of Transition Facility 2004 project dedicated to National Centre for Tissue and Cell Banking. Trainings (6-7 courses) are organised every year since 2006. Trainigs are free of charge for participants and financed from National Programme for Development of Transplantation Medicine for years: 2010-2020.
13.5. Any additional comments on quality management, responsible person, personnel?	Except of responisible person, each tissue establishment designates quality manager.
14. Reception, processing, storage, labelling and packaging (Art 19	
14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.2. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO) SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible)	authorisation Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)
14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)	SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)
14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)	SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception, processing, storage, labelling and packaging?	External audits are not obligatory, but some of tissue establishments applied for and received ISO accreditaion. JACIE accreditaion programme of procurement and transplantation centers as well as tissue establishments in the field of HSC starts this (2013) year.
15. Third party agreements (Art. 24 Directive 2004/23/EC)	V.
15.1. Are third party agreements foreseen/allowed in your national legislation?	Yes
15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?	Yes
15.1.1.1. Under which circumstances and for which responsibilities?	- the list of third party agreements is a mandatory part of a documentation provided by tissue establishment during application for designation, - third party agreements and related documents (see below) are reviewed during on site inspections, - the responsibility lies on tissue establishment and if such activity of third party is accredited in Poland (eg. laboratory testig, radiation-sterilisation) the certifficate of such accreditation document is required.

15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify.	- obligatory part of application for designation for tissue establishment activities, - third party agreements and related
152 4 11%	documents are reviewed during on-site inspections.
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please provide a	There is no consesus in the Parliament to transpose and then
short description.	implement regulatioons regarding ART.
16.3. In your opinion, in which of the following Directives are there	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	

## A.1.24. Survey response Portugal

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Instituto Português do Sangue e da Transplantação, IP (IPST)
1.1.2. Address of NCA 1:	Avenida Miguel Bombarda, n.º 6; 1000-208 Lisboa
1.1.3. Telephone (central access point):	+351 210 063 063
1.1.4. E-mail (central access point):	transplantacao@ipst.min-saude.pt
1.1.5. Website:	http://ipsangue.org/ipsangue2011/index.php
1.1.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Blood and blood components
	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1	Accreditation, authorisation, licensing of TEs
answer possible)	Other
Please specify 'other':	IPST is responsible for the biovigilance system and the
	authorization of import/export and circulation activities
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Direção-Geral de Saúde
1.2.2. Address of NCA 2:	Alameda Dom Afonso Henriques, 45 - 1049-005 Lisboa
1.2.3. Telephone (central access point):	-+351 21 843 05 00
1.2.4. E-mail (central access point):	sanguetransplantacao@dgs.pt
1.2.5. Website:	www.dgs.pt
1.2.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Blood and blood components
	Human organs
1.2.7. What are the role/tasks of the NCA? (more than 1	Accreditation, authorisation, licensing of TEs
answer possible)	Inspection
	Vigilance
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	Conselho Nacional de Procriação Medicamente Assistida (CNPMA)
1.3.2. Address of NCA 3:	Assembleia da República Palácio de São Bento 1249-068 LISBOA
1.3.3. Telephone (central access point):	+351 21 391 93 03
1.3.4. E-mail (central access point):	cnpma.correio@ar.parlamento.pt
1.3.5. Website:	http://www.cnpma.org.pt
1.3.6. The NCA is responsible for? (more than 1 answer possible)	Reproductive tissues and cells
1.3.7. What are the role/tasks of the NCA? (more than 1	Accreditation, authorisation, licensing of TEs
answer possible)	Inspection
	Vigilance
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and	IPST is a public institute directly dependent of Ministry of
organisation of the National Competent Authority(ies) (e.g.	Health, responsible for: - Coordination of procurement
departments, staffing, number of senior and junior	and transplant of organs, tissues, cells and blood (and blood
inspectors, staff working on EU affairs and legal matters,	components); - National System of Biovigilance and
vigilance officers, budget, independence from government	haemovigilance; - Monitoring the national activity with
etc.).	organs, tissues, cells and blood (and blood components); -
	Authorization of tissue and cells import/export activities; - Proposal of new regulations to the CA (DGS), based on the analysis of national activity. Staff of IPST Transplant department (central services): 1 – IPST Director (PhD, MD)

1 – Transplant National Coordinator (MD.) 2 – Biologists (with 4 years experience in the field of inspections and national coordination) 1 – Jurist/legal advisor IPST, IP is also responsible for: - Public Tissue Bank (amniotic membrane; bone; cardiac valves; blood vessels; skin) -Public Cord Blood Bank; - Histocompatibity centers -Regional Blood Establishments. Diretorate-General of Health is a central organism directly dependent of Ministry of Health, responsible for: -Ouality and safety of organs, tissues, cells and blood; -Monitoring the quality and safety of national activity with organs, tissues, cells and blood; -Authorization of services and activities with organs, tissues, cells and blood and inspections; -Proposal of new regulations to the CA, based on the analysis of national activity Staff of DGS (Central service) Quality and Safety Department (QSD) for cells, tissues and organs: 1 – QSD Director (MD) 1 – Medical Doctor 1 – Manager Hospital/Jurist 1 – Pharmacist and veterinary doctor 1 - Architect DGS is also responsible for the authorization and monitoring of quality and safety of: - Public Tissue Banks (amniotic membrane; bone; cardiac valves; blood vessels; skin) - Public Cord Blood Bank; -Private Cord Blood Banks - Regional Public Blood Establishments CNPMA (National Council for Assisted Reproduction Technologies) was created in 2006, under the Law 32/2006, of 26 July. CNPMA is an independent authority that functions under the aegis of the Portuguese Assembly of the Republic, with powers, in general, to pronounce on ethical, social and legal questions of assisted reproduction technologies. Among others, the Council is responsible for: a) establishing the terms for authorization of centres where assisted reproduction techniques are administered, and of centres where gametes or embryos are preserved and monitoring the activities of those centres; b) updating scientific information on assisted reproduction technologies; c) issuing opinions on the implementation of assisted reproduction techniques within the National Health Service; d) centralizing all relevant information on the application of assisted reproduction techniques, namely registers of donors, beneficiaries and children born, as well as providing information related to donors, within the limited framework permitted by law. National Council for Assisted Reproduction Technologies comprises nine distinguished persons of recognized merit who are especially qualified in the field of the ethical, scientific, social and legal issues raised by assisted reproduction technologies: a) Five members are elected by the Assembly of the Republic; and b) Four members are appointed by the members of Government responsible for health and science. Staff: two policy officers. Regarding inspections and auditing, it is the Ministry of Health administrative body for Health Inspections that is responsible for monitoring public and private ART TE, under the guidance of the CNPMA, which assures initial and permanent training for clinical and laboratory inspectors.

	T
1.6. In case of MS with federal or decentralised systems,	Not applicable
please indicate the roles/tasks of the Regional Competent	
Authority(ies). (more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of	Not applicable
the Regional Competent Authority(ies) and their relation	
with the National Competent Authority(ies) for tissues and	
cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of	By inspecting some procurement centres
procurement"? (more than 1 answer possible)	By inspecting the documentation associated with
	procurement that is available in the tissue establishment
2.12.17	working with procurement centres
2.1.2. How many such authorisations were granted in 2011	None (By this new CA, in charge of these field since the end
(01/01-31/12/2011)?	of 2012)
2.2.1 Please provide the number of procurement centres in	None (By this new CA, in charge of these field since the end
which procurement of "traditional tissues and cells" (skeletal	of 2012)
tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.)	
were carried out in 2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in	None (By this new CA, in charge of these field since the end
which procurement of haematopoietic stem cells (bone	of 2012)
marrow, PBSC, cord blood etc.) were carried out in 2011	012012)
(01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in	28
which procurement of gametes, embryos and other	
reproductive tissues were carried out in 2011 (01/01-	
31/12/2011).	
2.2.4. Please provide the number of procurement centers in	None (By this new CA, in charge of these field since the end
which procurement of tissues/cells for ATMP manufacturing	of 2012)
were carried out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply	Inspections of the site/centre
with the requirements laid down in Art. 5 of Directive	Analysis of the mandatory documentation
2004/23/EC and its implementing Directive 2006/17/EC	
(e.g. trained personnel, conditions accredited, designated,	
authorised, licensed) ? (more than 1 answer possible)	
2.4. Are you also responsible for the accreditation,	No
designation, authorisation or licensing of laboratories	
performing donor testing?	G10 PG0
2.4.2. Which National Authority is in charge of this activity?	CA2 - DGS
2.5. How do you ensure, as CA for T&C, that tests	Inspections of the laboratories
required for donors are carried out only by qualified	Analysis of the mandatory documentation requested from the
laboratories accredited, designated, authorised or licensed	tissue establishment
Art. 5(2))? (more than 1 answer possible)	Since this NCA is dealing with this field (1.1.02012). 2
2.6. Please provide data on qualified laboratories accredited,	Since this NCA is dealing with this field (end of 2012): 2.
authorised or licensed in your country (e.g. number, year of	However there are many other being validated by this CA.
accreditation/authorisation/license, which donor tests are performed etc.).	
2.7. Do you have any additional comments on procurement?	No addicional comments on procurement
	-
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17 3.1. Please specify laboratory tests required for donors of	Anti-HIV 1
non-reproductive tissues and cells in your Member State.	Anti-HIV 2
(more than 1 answer possible)	NAT HIV 1
(more than I answer possible)	HBs AG
	1100710

	T
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	Treponema Pallidum
	HTLV-2
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more	Anti-HIV 2
than 1 answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	HTLV-2
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could	NAT mandatory in Portugal (CNPMA - NCA3): Regarding
you please indicate whether you intend to make it mandatory	reproductive cells, NAT is not mandatory for HIV, HBV and
or to encourage its use? Please specify why or why not (e.g.	HCV (but it requires a second tests on samples collected
number of additional cases detected, cost-benefit etc.).	after quarentine period).
3.4. Do you have concerns on accuracy of the available tests	Yes
and test procedures for deceased donors?	
3.4.1. Please specify why:	Still under analysis by the new CAs (in charge since the end
	of 2012)
3.5. Are any other laboratory tests required for donors of	No
non-reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems	Yes
for testing laboratories?	
3.7.1. Please specify.	International Guidelines
3.8. Do you have any additional comments on testing?	No addicional comments on testing.
4. Accreditation, designation, authorisation or licensing of	tissue establishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue	
establishments under your responsability?	
4.2. Is inspection a prerequisite for the designation,	Yes
authorisation, accreditation or licensing of tissue	
establishments?	
4.2.1. How many inspections were performed in 2011 for	None (By this new CA, in charge of these field since the end
authorising/accrediting/licensing/designating TEs?	of 2012)
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer	During routine inspections
1	During inspections organised for this purpose
possible)	
	By review of a submitted application with supporting
AA Fallaning inspections/sectors (Ad. CA Direct)	documentation
4.4. Following inspections/controls (Art. 6.4, Directive	None (By this new CA, in charge of these field since the end
2004/23/EC), how many	of 2012)
authorisations/accreditation/licenses were suspended in	
2011?	Name (Day this many CA) in phase a Call and Call along the
4.5. Following inspections/controls (Art. 6.4, Directive	None (By this new CA, in charge of these field since the end
2004/23/EC), how many	of 2012)
authorisations/accreditation/licenses were revoked in 2011?	N.
4.6. Do you require TEs to be certified by an external entity	No
to a quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by	the NCA

Agrania da	0.1.2. (11.1.)
4.7. Tissue establishments with authorisation pending	Ocular tissue establishments
approval at 01/01/2011 (more than 1 answer possible):	Cord blood tissue establishments
	Multi-tissue establishments
4.7.3. How many ocular tissue establishments?	Information not yet available by this new CA
4.7.6. How many cord blood tissue establishments?	Information not yet available by this new CA
4.7.8. How many multi-tissue establishments?	Information not yet available by this new CA
4.8. Tissue establishments with authorisations pending	Ocular tissue establishments
approval by 31/12/2011 (more than 1 answer possible):	Cord blood tissue establishments
	Multi-tissue establishments
4.8.3. How many ocular tissue establishments?	Information not availble yet by this new CA
4.8.6. How many cord blood tissue establishments?	Information not yet available by this new CA
4.8.8. How many multi-tissue establishments?	Information not yet available by this new CA
4.9. Tissue establishments first time authorised between	Other tissue establishments
01/01/2011 and 31/12/2011 (more than 1 answer possible):	
4.9.9. Please specify the type of tissues/cells and how many.	Information not yet available by this new CA
4.10. All tissue establishments authorised by 31/12/2011	ART tissue establishments
(more than 1 answer possible):	
4.10.7.1. How many public ART tissue establishments?	10
4.10.7.2. How many private ART tissue establishments?	18
4.11. How many tissues and cells were distributed under the	Tissues and cells distributed in 2011: Bone Marrow: 36
direct agreement of the Competent Authority according to	Peripheral Blood: 555 Cord blood: 11 Heart Valves: 75
Art. 6(5) during 2011? Please provide number(s) per type	Musculoskeletal: NA Amniotic Membrane: 233 units (43385)
tissues/cells.	cm2) ocular tissues: 752
	cinz) ocuiai tissues. 732
4ter. Sanctions	V
4.16. Have penalties for infringements of the national	Yes
provisions pursuant to the Directive been defined (Article	
27)?	
11(1.7)	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	No No addicional comments.
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?	1.5
<ul> <li>4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?</li> <li>5. Inspections (Article 7, Directive 2004/23/EC)</li> </ul>	1.5
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and	1.5
<ul> <li>4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?</li> <li>5. Inspections (Article 7, Directive 2004/23/EC)</li> </ul>	No addicional comments.  Yes
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and	No addicional comments.
<ul> <li>4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?</li> <li>5. Inspections (Article 7, Directive 2004/23/EC)</li> <li>5.1. Is a system in place for organising inspections and control measures of tissue establishments?</li> </ul>	No addicional comments.  Yes
<ul> <li>4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?</li> <li>5. Inspections (Article 7, Directive 2004/23/EC)</li> <li>5.1. Is a system in place for organising inspections and control measures of tissue establishments?</li> <li>5.1.1. If yes, please specify the CA/Department of the CA in</li> </ul>	No addicional comments.  Yes  DGS - Departamento da Qualidade na Saúde (DGS-NCA2).
<ul> <li>4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?</li> <li>5. Inspections (Article 7, Directive 2004/23/EC)</li> <li>5.1. Is a system in place for organising inspections and control measures of tissue establishments?</li> <li>5.1.1. If yes, please specify the CA/Department of the CA in</li> </ul>	Yes  DGS - Departamento da Qualidade na Saúde (DGS-NCA2). (CNPMA - NCA3): For ART it is the Ministry of Health
<ul> <li>4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?</li> <li>5. Inspections (Article 7, Directive 2004/23/EC)</li> <li>5.1. Is a system in place for organising inspections and control measures of tissue establishments?</li> <li>5.1.1. If yes, please specify the CA/Department of the CA in</li> </ul>	Yes  DGS - Departamento da Qualidade na Saúde (DGS-NCA2). (CNPMA - NCA3): For ART it is the Ministry of Health administrative body for Health Inspections (IGAS) in
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4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Yes  DGS - Departamento da Qualidade na Saúde (DGS-NCA2). (CNPMA - NCA3): For ART it is the Ministry of Health administrative body for Health Inspections (IGAS) in collaboration with CNPMA. (DGS-NCA2): CA team is constituted by 4 elements and 2 of them (one medical doctor and one pharmacist) have done the CATIE's course and 6 designated experts, for the time
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Yes  DGS - Departamento da Qualidade na Saúde (DGS-NCA2). (CNPMA - NCA3): For ART it is the Ministry of Health administrative body for Health Inspections (IGAS) in collaboration with CNPMA. (DGS-NCA2): CA team is constituted by 4 elements and 2 of them (one medical doctor and one pharmacist) have done the CATIE's course and 6 designated experts, for the time being; the inspections are also performed by inspectors from
4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Yes  DGS - Departamento da Qualidade na Saúde (DGS-NCA2). (CNPMA - NCA3): For ART it is the Ministry of Health administrative body for Health Inspections (IGAS) in collaboration with CNPMA. (DGS-NCA2): CA team is constituted by 4 elements and 2 of them (one medical doctor and one pharmacist) have done the CATIE's course and 6 designated experts, for the time
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5.3.1. How many inspections of tissues establishments for	None (By this new CA, in charge of these field since the end
non-reproductive tissues/cells were conducted in 2011 (from	of 2012)
1/1/2011 to 31/12/2011) following serious adverse events or	
reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues	None (By this new CA, in charge of these field since the end
establishments for non-reproductive tissues/cells were	of 2012)
conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due	
to a whistle-blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	None (By this new CA, in charge of these field since the end
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	of 2012)
What was the number of inspections carried out where no	
shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	None (By this new CA, in charge of these field since the end
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	of 2012)
What was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	None (By this new CA, in charge of these field since the end
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	of 2012)
What was the number of inspections carried out where major	, ,
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	None (By this new CA, in charge of these field since the end
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	of 2012)
What was the number of inspections carried out that were	
followed by suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	None (By this new CA, in charge of these field since the end
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	of 2012)
What was the number of inspections carried out that were	012012)
followed by closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	None (By this new CA, in charge of these field since the end
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	of 2012)
What was the number of other inspections carried out?	012012)
Please specify.	
5.4. How many routine inspections were conducted in ART	10
establishments (from 1/1/2011 to 31/12/2011)?	10
5.4.1. How many inspections were conducted in ART	1
establishments following serious adverse events or reactions,	
or suspicion thereof (from 1/1/2011 to 31/12/2011)?	
	1
5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g.	1
due to a whistle-blower)? Please specify.	
, 1	
5.4.3. Outcome of inspections of ART tissue establishments	0
carried out in 2011 (01/01/2011 to 31/12/2011): What was	
the number of inspections carried out where no shortcomings	
were observed?	
5.4.4. What was the number of inspections carried out in	8
ART establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in	2
ART establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in	0
ART establishments followed by suspension of	
authorisation?	
5.4.7. What was the number of inspections carried out in	0
ART establishments followed by closure of respective	
establishements?	

5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct?	General system-oriented inspections
(more than 1 answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine inspection to	(DGS - NCA2): The routine inspections are decided among
conduct?	those urgent pending from the previous CA; the CA also
	pretend to cover proporcionally public and private
	establishements and blood/T&C E (CNPMA - NCA3): The
	first routine inspections is always a general system-oriented
	inspection; afterwards it may be followed by a thematic
	inspection (just to check the overcome of the diagnosed
	shortcomings) or a desk based reviews if the aim is to
	monitor the implementation of corrective measures.
5.7. Until 2011, did you implement the requirement	No
concerning the time interval between two inspections (Art.	
7.3.)?	
5.7.1. Why not?	Because this new CA only is in charge of these field since
	the end of 2012
5.7.2. How do you prioritise tissue establishments to be	First of all those who are urgent, pending from the previous
inspected?	CA.
5.8. How many TEs were inspected at least twice between	Information not yet available by this new CA
2008-2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement	Yes
sites outside tissue establishments?	
5.9.1. If yes, how many?	Information not yet available for this new CA
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	Not yet analised and organised by this new CA
5.11. Do you use at national level the Operational Manual	Yes
for Competent Authorities on inspection of tissue and cell	
procurement and tissue establishments - Guidelines for	
inspections (Commission Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training	Yes
courses organised by EU-funded projects (e.g. EUSTITE,	
SOHO V&S)?	
5.12.1. If yes, how would you rate the usefulness and	5
efficacy of these training courses on a scale from 1 to 5 (1 =	
not important, 2 = sufficient, 3 = good, 4 = very good, 5 =	
essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA	
in that MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement	No
centres or tissue establishments in third countries from which	
tissues and/or cells were imported in your country (as	
recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been	No
requested by any other MS, on the results and control	
measures of your inspections, as part of an	
enquiry/investigation?	
5.17. Would you be interested in developing joint	Yes
2.2	

inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries.  5.18. Do you have any additional comments on inspections?  6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import-teryor of tissues and cells from third countries?  6.2. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).  6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).  6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.  6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of politalmic (cornea, sclera, etc) tissues from third countries.  6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of politalmic (cornea, sclera, etc) tissues from third countries.  6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6.8. Please specify which procedures you have in place for verifying the quivalent standards of quality and safety for importation of bodd from third countries.  6.9. Please specify which procedures you have in place for verifying the quivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6.10. Please specify which procedures you have in place for verifying the quivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6.11. Did you import tissued selfs from third countries.  6.12. Did you expert standards of quality and safety for impo	inspections? Joint inspections should be understood as	
or more Member States (Competent Authorities on their territory or in third countries.  5.18. Do you have any additional comments on inspections?  6. Inportexport (Article 9 Directive 2004/23/EC)  6.1. Do you have a register of authorised to see the substitution of publication of publicatio		
territory or in third countries  5. IR. Do you have any additional comments on inspections?  6. Import/export (Article 9 Directive 2004/23/EC)  6. 1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and cells from third countries?  6. 2. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).  6. 3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).  6. 5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of masculo-schelat loben, tendons, fascia etc.) tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of oractio vascular tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.  6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues	-	
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destination. 2; Russia: 1; None reproductive tissues/cells were exported	6.12.1. If yes, please provide the data concerning the	Non Reproductive cell (HSC) exported during 2011: Swiss:
	number/volume of exported tissues and cells by country of	1; USA: 11; New Zeland: 1; Canada: 4; Brazil: 1; Uruguai:
6.13. Are you aware of any significant changes in 2012 No	destination.	2; Russia: 1; None reproductive tissues/cells were exported
· · · · · · · · · · · · · · · · · · ·	6.13. Are you aware of any significant changes in 2012	No

which may invalidate the 2011 data on imports/exports of	
tissues/cells between your country and other third countries?	
6.14. What is the relation between import/export of tissues	A. Export of tissues/cells is authorised only after checking
and cells and self-sufficiency? (more than 1 answer possible)	that local/national needs are fulfilled.
	E. Import of tissues/cells is authorised based on estimations
	showing that there is chronic deficiency of those tissues/cells
6.14.1. If A or D were selected, please explain how you	Every year Portugal has to import tissues from other MS, in
quantify local/national needs.	this way is considered that the nationals TE aren't able to
	respond to the need (of public and private) heath institutions
	in Portugal
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	
6.16. Do you have any additional comments on	
import/export?	
7. Distribution/intra community exchanges (Article 23 Direction)	ective 2004/23/EC)
7.1. Do you have intra-community exchanges of tissues and	Yes
cells?	
7.1.1. If yes, how do you address the possible more stringent	The TE must comply with the requirements imposed by the
quality and safety measures established by other Member	MS where the products will be distributed. CA should
States? Please specify.	collaborate in order to evaluate the quality and safety of the
	products distributed in different MS.
7.1.2. If yes, do you have more stringent quality and safety	Yes
measures than in other Member States?	
7.1.2.1. How do you address this difference for tissues and	NAT
cells coming from a MS with minimum quality	
requirements? Please specify.	
7.2. How do you ensure that tissues establishments fulfil the	TE must submit a documented authorization request, also
requirements of Art. 23 of Directive 2004/23/EC regarding	IPST ask for the collaboration of the CA from the MS of
quality of tissues and cells during distribution? Please	origin, in order to determine the compliance of the criteria
specify.	imposed by the Directives and National Legislation.
7.3. Do you allow direct distribution to hospitals/clinics in	No
your MS from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient	No
of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.5. Do you collect data regarding the cross-border exchange	Yes
of tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination,	HSC distributed in other MS: German: 8 Italy: 15 Spain: 14
type of tissue/cell and number of units distributed)	Austria: 1 United Kingdom: 2 France: 6 Greece: 1 Belgium:
concerning distribution to other MS in 2011 (01/01/2011-	1 Sweden: 1 Finland: 1 Slovenia: 1 Netherlands: 2
31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	HSC: German - 41; United Kingdom - 2; Italy - 1; Spain - 1;
tissue/cell and number of units distributed) concerning	Netherlands - 1 Ocular Tissues: Italy - 162 Musculoskeletal:
distribution to other MS in 2011 (01/01/2011-31/12/2011)	Spain - 118 Other tissues: Spain - 21
7.6. Are you aware of any significant changes in 2012 which	No
may invalidate the 2011 data on cross-border exchanges of	
tissues/cells between your country and other EU MS?	
7.7. Do you allow brokerage companies for either	No
distribution in EU and/or import/export of tissues/cells? In	
this context, a brokerage company means a body that	
arranges transactions between a supplier (tissue	
establishment/company selling tissues or cells) and a buyer	
(a tissue establishment/a hospital or clinic/an individual)	
without undertaking activities of processing, preservation or	
storage.	
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7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligation	
8.1. Do you have an annual report model/template on the	Yes
activities of tissue establishments in your Member State?	
(Article 10(1)). If yes, please upload the template.	
8.2. How many tissue establishments submitted annual	60-99%
reports of their activities during 2011. Please provide an	
estimation. (1 answer possible)	
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the	Yes
consolidated activities of all tissue establishments in your	
country?	
8.4.1. Please insert the link to the published national annual	http://ipsangue.org/ipsangue2011/index.php?option=com_co
report.	ntent&view=category&layout=blog&id=75&Itemid=118;
	http://www.cnpma.org.pt/Docs/RELATORIO_ATIVIDADE
	_PMA2011.pdf
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's	http://www.dgs.pt/ms/8/default.aspx?pl=&id=5521&acess=0
web site.	(DGS); CNPMA:
	http://www.cnpma.org.pt/centros_lista.aspx
8.6. Do you provide data regarding tissues and cells activities	Yes
to the EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please	Tissues and cells and HSC forms ART forms
specify.	
8.7. Do you have any additional comments on reporting?	The annual report form is available on line at:
	http://ipsangue.org/ipsangue2011/index.php?option=com_co
	ntent&view=category&layout=blog&id=81&Itemid=124
9. Traceability (Article 8, Directive 2004/23/EC; and Direct	tive 2006/86/EC)
9.1. Was the donor identification system (Art. 8(2))	Yes
implemented in your country?	
9.2. Who assigns the unique code for each donation? (only 1	Tissue establishment
answer possible)	
9.3. How is the data storage for traceability purposes	Both paper records and electronic forms
organised in your tissue establishements (Art 8(4))? (only 1	r. P. P.
answer possible)	
9.4. How do you ensure that the 30 years data storage	The CA validates it in the inspections, analising the available
requirement is respected (Directive 2006/89/EC, Art. 9)?	documentation.
Please specify.	
9.5. Do you have any additional comments on traceability?	(CNPMA - NCA3): Until 31.12.2012 assignment of unique
,	code for each donations was assured by ART TE. Since
	01.01.2013, it is a centralized registry - National Competent
	Authority assigns the unique code for each donation.
10. Notification of serious adverse events and reactions (Ar	
10.1. Do you have a national vigilance system in place (for	Yes
the reporting of serious adverse events and reactions (Article	
11(1))?	
10.1.1. If yes, which CA/institution is responsible?	Instituto Português do Sangue e da Transplantação (IPST)
10.1.1. If yes, which era institution is responsible:	(NCA1); CNPMA (NCA3)
10.1.2. If yes, please provide a short description of its	On-line form for notification of SAR and SAE; each
organisation.	organization (TE, procurement unit, transplant units) have a
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	login and password and can submit notification at anytime;
	in the begging of every year TE must full fill the annual
	reports through the form available also on-line at:
	http://ipsangue.org/ipsangue2011/index.php?option=com_co
	ntent&view=category&layout=blog&id=81&Itemid=124
	Everytime that there are an alert, information is sent to every
	organizations that have requested authorization. CNPMA
	(NCA3): there is a form and standardized procedures to
	report SAE and reactions (urgent notification: within 48
	hours or until 15th of every month for non-urgent SAE/SAR)
	- Everytime that there is an alert, information is sent to the
	responsible person of each ART TE (notification by email).
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do	No
you use the SAR/E (to the CA (2006/76 art 6.4)) templates	
developed to the Annual reporting of the EC also at national	
level?	
10.2.1. If no, what template do you use? You are welcome to	(IPST NCA1) available at:
upload the template if you wish.	http://ipsangue.org/ipsangue2011/index.php?option=com_co
	ntent&view=category&layout=blog&id=81&Itemid=124
	(CNPMA NCA3) available at:
100 B	http://www.cnpma.org.pt/profissionais_notificacao.aspx
10.3. Do you use the Common Approach Document	Yes
developed for the Annual reporting to the EC also at national	
level?	
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in 2011 the	70-99%
SAR/SAE data as requested (please provide the % from the	
total number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the	Yes
transplantation centres when reporting SAR/SAE to the TEs	
which distributed the tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	TE are responsible for collecting the follow up notifications
10.7 D	of all the recipients of the distributed products
10.7. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at national level?	Di da di angla di di
10.7.1. Please specify.	Divulgation of EC Annual reporting
10.8. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at EU level?	
10.8.1. Please specify.	the data is presented only through communications on
100 B	courses and seminars
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of	0
tissues/cells were issued in your country in 2011? Please	
specify the number and which tissues were recalled and why	
(e.g. missing consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify	Yes
Tissue Establishments and procurement sites in case of a	
national rapid alert?	
10.11.1. If yes, please give a short description of the	e-mail communication with the responsible persons of every
system/procedure.	organization that have requested authorization
10.12. Do you have in place a system/procedure to notify	Yes
Tissue Establishments and procurement sites when a rapid	
alert is issued via the EU RATC platform?	

system/procedure.  10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?  10.13.2. If no, please specify why not.  10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?  10.14. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)  10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&amp.S?  10.15. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?  10.16. Do you have any additional comments on SARE reporting?  11. Onsent and personal data protection (Article 13 and 14, Directive 2004/23/EC)  11.1. Please specify your choice of consent system for living tissue/cell donation do you have in place within your Member State?  11.1. Please specify your choice of consent system for living tissue/cell donation do you have in place within your Member State?  11.3. According to your mational legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as for organs?  11.5. Now is this consent verified during inspections? (more than 1 answer possible)  11.6. What measures are in place to ensure that donors'relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)  11.7. What measures are in place to ensure that donors'relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 14(1). Please specify what measures are in place to ensure the confidenciality; levels (inspection/documental analysis)  11.9. Does your national legislation allows disclosure of donor and vice	10.12.1. If yes, please give a short description of the	e-mail communication with the responsible persons of every
No   No   No   Provide data regarding SAR/SAE to the   EUROCET registry (non-mandatory reporting)?   No   No   No   No   No   No   No   N		2 2
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11.1.1. Please specify your choice of consent system for living tissue/cell donation.  11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?  11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)  11.4. Is the consent system for deceased tissue donation the same as for organs?  11.5. How is this consent verified during inspections? (more than 1 answer possible)  11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)  11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.  11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.  11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?  11.9.1. If no, please specify the circumstances and measures in place.  Accordingly with the portuguese law  Presumed consent (opt-out)  No further authorisation is needed  No further authorisation is n	· · · · · · · · · · · · · · · · · · ·	r · · · · · · · · · · · · · · ·
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than I answer possible)  Interviews with personnel  Interviews with personnel  Only trained personnel is allowed to provide such information  only trained personnel is allowed to provide such information  Information  Only trained personnel is allowed to provide such information  on the provided with the appropriate information, as requested by Art. 13(2)? (more than I answer possible)  Interviews with personnel  Only trained personnel is allowed to provide such information  information  The CA verifies the acess levels to the information by the HCP and the procedures in place to ensure the confidenciality.  Interviews with personnel  Only trained personnel is allowed to provide such information  The CA verifies the acess levels to the information by the HCP and the procedures in place to ensure the confidenciality.  The CA validates the procedures in place to ensure the confidenciality levels (inspection/documental analysis)  The CA validates the procedures in place to ensure the confidenciality levels (inspection/documental analysis)  No  (CNPMA- NCA3): Donor's identity is kept confidential except if the donor express consent on contrary and only		Analysis of documentation
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in place. except if the donor express consent on contrary and only	donor data in case of gametes donation?	
	11.9.1. If no, please specify the circumstances and measures	(CNPMA- NCA3): Donor's identity is kept confidential
when the children horn turns 18. Any other case, disclosure	in place.	
when the children both turns 10. Any other case, disclosure		when the children born turns 18. Any other case, disclosure
of donor data is only allowed for weighty reasons		_ · · · · · · · · · · · · · · · · · · ·
recognized by a judicial decision. Since 2013 there is a		
centralized registry with restricted access.		centralized registry with restricted access.
11.10. Do you have any additional comments on consent and	11.10. Do you have any additional comments on consent and	
data protection?	data protection?	
12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)	12. Selection, evaluation and procurement (Article 15 Direction)	ctive 2004/23; Annexes I-IV Directive 2006/17)

12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of	Inspections of TEs and procurement sites
reproductive cells) are respected in your country (Art. 15(1),	Audit of documentation
Annex I Directive 2006/17/EC)? (more than 1 answer	
possible)	
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the	Interview with the donor's family or a person who knew the
evaluation of a deceased donor of tissues/cells? (more than 1	donor well
answer possible)	Medical records of the donor
12.5. Do you have more stringent criteria for selection of	Yes
donors of reproductive cells than those listed in Annex III of	
the Directive 2006/17/EC?	Ago oritorio: 25 for opporto don and an 45 for an arms 1
12.5.1. Please specify.	Age criteria: 35 for oocyte donors and 45 for sperm donor For oocyte donation there is only allowence for 3 oocyte
	pick-ups cycles per donor. For sperm donation, a donor can
	only originate 8 deliveries.
12.6. Do you have more stringent criteria for autologous	No
donation than those listed in Annex I of the Directive	140
2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the	
Annex of Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding	Inspection of tissue establishment
tissues and cells' procurement, packaging and transport are	Audit of tissue establishment
complied with by tissue establishments in your country (Art	Audit of the centre of human application
15(1), Annex IV of Directive 2006/17/EC? (more than 1	11
answer possible)(For this question "audit" means a	
documented review of procedures, records, personnel	
functions, equipment, materials, facilities, and/or vendors in	
order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe	
Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	
evaluation and procurement?	
13. Quality management, responsible person, personnel (A	rticle 16, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your	Authorisation requirement
country have in place a quality system respecting the	Inspections
provisions of the Directive 2004/23/EC Art 16.1? (more than	
1 answer possible). (For this question "audit" means a	
documented review of procedures, records, personnel	
functions, equipment, materials, facilities, and/or vendors in	
order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe	
Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011)).	A.d. i.e.
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)?	Inspections
(more than 1 answer possible)	Other

Please specify 'other'.	HCP titulation (Portuguese Professional Associations)
13.3. How do you ensure an appropriate training for the	Authorisation requirement
personnel directly involved in the activities of tissue	Inspections
establishments? (more than 1 answer possible)	
13.4. Do you have national/regional/local training	Yes
programmes for the personnel of tissue establishments?	
13.4.1. If yes, please specify.	The TE do some training programmes for the personnel of
	TE, in their Activities Plans, accordingly with the law.
13.5. Any additional comments on quality management,	
responsible person, personnel?	
14. Reception, processing, storage, labelling and packaging	(Art 19-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your	Inspections of tissue establishments
country fulfill the requirments of the Art. 19 (Tissue and cell	•
reception) of Directive 2004/23/EC and Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your	Inspections of tissue establishments
country fulfill the requirements of the Art. 20 (Tissue and	
cell processing) of Directive 2004/23/EC? (more than 1	
answer possible)	
14.3. How do you ensure that tissue establishments in your	Inspections of tissue establishments
country fulfill the requirements of Art. 21 (tissue and cell	-F
storage conditions) of Directive 2004/23/EC? (more than 1	
answer possible)	
14.4. How do you ensure that tissue establishments in your	Inspections of tissue establishments
country fulfill the requirements of Art. 22 (labelling,	-F
documentation and packaging) of Directive 2004/23/EC and	
Annex IV of Directive 2006/17/EC? (more than 1 answer	
possible)	
14.5. Any additional comments on reception, processing,	
storage, labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your	Yes
national legislation?	
15.1.1. If yes, have tissue establishments in your Member	Yes
State notified third party agreements?	
15.1.1.1. Under which circumstances and for which	Each time an external activity takes place which influences
responsibilities?	the quality and safety of T and C processed in cooperation
•	with a third party, namely the topics under article 24 of the
	directive, that were included in the portuguese law.
15.1.1.2. How are third party agreements controlled (Art 6.2)	In the inspections and documental analysis
by the Competent Auhtority(ies) in your MS? Please specify.	
15.2. Any additional comments on third party agreements?	No additional comments
16. General comments - implementation	
16.1. Do you have at national level more stringent quality	Yes
and safety requirements than those requested by the EU	
legislation in this field (e.g. restrictions concerning the	
donation/use of certain tissues/cells, mandatory unpaid	
donation etc.)?	
16.1.1. Please specify.	NAT
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Import-export
Directives? Please choose from the options below.	Vigilance
•	Authorisation-accreditation-licensing of TEs
	Other

16.2.1. For all selected options in question 16.2., please	(CNPMA - NCA3): The specificity of ART are such that
provide a short description.	would require more adjusted measures and requirements. We
	welcome the planned introduction of specific chapters
	regarding this field. (DGS - NCA2): This CA is still in
	organization process and has not enough resources for the
	time being.
16.3. In your opinion, in which of the following Directives	No shortcomings
are there shortcomings (if any)? (more than 1 answer	
possible)	

## A.1.25. Survey response Romania

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	National Transplant Agency
1.1.2. Address of NCA 1:	2-8 Constantin Caracas street, 4-th floor, sector 1, 011155 Bucharest
1.1.3. Telephone (central access point):	+40317101473, +40317101474, fax +40213130434,
1.1.4. E-mail (central access point):	ant@transplant.ro
1.1.5. Website:	www.transplant.ro
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Ministry of Health - Public Health and Control in Public Health Directorate
1.2.2. Address of NCA 2:	1-3, Cristian Popisteanu street, sector 1 Bucharest
1.2.3. Telephone (central access point):	+40213072557
1.2.4. E-mail (central access point):	sparvu@ms.ro
1.2.5. Website:	www.ms.ro
1.2.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Human organs
	Pharmaceuticals
	Medical devices
Diagra amagifu lathari	Other health care etc
Please specify 'other':  1.2.7. What are the role/tasks of the NCA? (more than 1 answer	Inspection
possible)	Vigilance
1.3. National Competent Authority 3?	No
1.5. Please give a short description of the legal status and	National Transplant Agency (NTA) is an independent body
organisation of the National Competent Authority(ies) (e.g.	subordinated to the Ministry of Health. The staff consists in 6,5
departments, staffing, number of senior and junior inspectors, staff	positions occupied from 18 approved. NTA does not have
working on EU affairs and legal matters, vigilance officers, budget,	inspectors. NTA has 2 experts representing Romania to the
independence from government etc.).	European institutions and 1 judicial expert. The budget of NTA is
	established by the Ministry of Health. Ministry of Health Romania -
	Public Health and Control in Public Health Directorate The Ministry
	of Health is a governmental institution, financed from the public
	budget. According to the Governmental Decision no 144/2010
	regarding the organizing and functioning of the Ministry of Health,
	there are two directorates with responsibilities in the field of
	transplant: the Public Health and Control in Public Health
	Directorate (PHCPHD) and the Health Care and Public Polices
	Department (HCPPD) The main responsibilities in the field of
	transplant are: - developing of legal acts (HCPPD); - carrying out
	inspections and control regarding the quality and sanitary safety of
	human grafts for therapeutic use and for application of art. 7 form
	the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety
	for the donation, procurement, testing, processing, preservation,
	storage and distribution of human tissues and cellular (PHCPHD) -
	organizing and coordinating the vigilance system and taking the
	necessary measures for food categories in the fields of competence; -
	carrying out official control according to the annual plans of
	PHCPHD as well as control thematic actions initiated at the central
	level and in case of complaints from the population; - coordinating
	the activity of inspectors from the County Public Health Control
	The responsibilities of the County Public Health Directorates
	(CPHCD), are established by the Ministerial Order no. 1078/ 2010
	for organizing and functioning of the CPHDs and the Ministerial

1.6. In case of MS with federal or decentralised systems, please	Order no 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection. We have inspectors how are dedicated to inspect establishments with transplant activities (44 inspectors), but they do inspections in other fields to. They are certificated in the field of medical sciences which was awarded of a university course of study and experience of working within a CA that inspects hospitals, blood establishments, hospital blood banks and tissues and cells establishments. According to the Governmental Decision no. 524/2013 beginning with de the 2nd of September the Ministry of Health is reorganizing. Regarding this decision there will be two other departments: Strategies and Health Policies Department and the Stat Sanitary Inspectorate.
indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	No
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	Other
Please specify 'other':	NTA is not allowed by law to realize inspections but only evaluations. NTA realizes evaluation of the documentation and evaluation of all procurement centers according to the requirements of the EU Directives.
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	35
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	5 (2 skeleletal; 1skin; 2 cornea)
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	3
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	30
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	0
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)	Analysis of the mandatory documentation Other
Please specify 'other':	Evaluation on the site of the centre
2.4. Are you also responsible for the accreditation, designation,	Yes
authorisation or licensing of laboratories performing donor testing?	
2.4.1. Please provide the number of the laboratories performing donor testing.	6 National Transplant Agency being in charge for this activity
2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible)	Analysis of the mandatory documentation requested from the tissue establishment
2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.).	6 accredited laboratories since 2005. Donor tests performed are those in complying with the requirements of the EU Directives.
2.7. Do you have any additional comments on procurement?	No

3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
answer possible)	NAT HIV 1
	HBs AG
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	Treponema Pallidum
	HTLV-2
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
unswer possiole)	NAT HIV 1
	HBs AG
	Anti HBc
	NAT HBV
	Anti HCV-Ab
	NAT HCV
	HTLV-2
	NAT HTLV-2
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	We intend to encourage its use because the superior quality of this
please indicate whether you intend to make it mandatory or to	test and the shorter period for the validation.
encourage its use? Please specify why or why not (e.g. number of	test and the shorter period for the varidation.
additional cases detected, cost-benefit etc.).	No
3.4. Do you have concerns on accuracy of the available tests and test	NO
procedures for deceased donors?	N
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	N
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	V
3.7. Do you request/use international accreditation systems for	Yes
testing laboratories?	N
3.7.1. Please specify.	Not requested but used. Some of the accredited laboratories have
	EFI accreditation.
3.8. Do you have any additional comments on testing?	No
4. Accreditation, designation, authorisation or licensing of tissue es	
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	yes – evaluation performed by NTA, not inspection, 35 evaluations
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	No
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	2
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC.	Λ
4.7. Tissue establishments with authorisation pending approval at	Skin tissue establishments
	Musculo-skeletal tissue establishments
01/01/2011 (more than 1 answer possible):	Ocular tissue establishments
	Ocuiai tissue establishments

	Wag :
	HSC tissue establishments
	Cord blood tissue establishments
151 W 1111 10	ART tissue establishments
4.7.1. How many skin tissue establishments?	0
4.7.2. How many musculo-skeletal tissue establishments?	0
4.7.3. How many ocular tissue establishments?	0
4.7.5. How many HSC tissue establishments?	0
4.7.6. How many cord blood tissue establishments?	0
4.7.7. How many ART tissue establishments?	0
4.8. Tissue establishments with authorisations pending approval by	Skin tissue establishments
31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
1017	ART tissue establishments
4.8.1. How many skin tissue establishments?	1
4.8.2. How many musculo-skeletal tissue establishments?	2
4.8.5. How many HSC tissue establishments?	3
4.8.6. How many cord blood tissue establishments?	7
4.8.7. How many ART tissue establishments?	28
4.9. Tissue establishments first time authorised between 01/01/2011	ART tissue establishments
and 31/12/2011 (more than 1 answer possible):	
4.9.7. How many ART tissue establishments?	4
4.10. All tissue establishments authorised by 31/12/2011 (more than	Skin tissue establishments
1 answer possible):	Musculo-skeletal tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
4.10.1.1. How many public skin tissue establishments?	1
4.10.1.2. How many private skin tissue establishments?	0
4.10.2.1. How many public musculo-skeletal tissue establishments?	2
4.10.2.2. How many private musculo-skeletal tissue establishments?	0
4.10.5.1. How many public HSC tissue establishments?	3
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?	0
4.10.6.2. How many private cord blood tissue establishments?	7
4.10.7.1. How many public ART tissue establishments?	2
4.10.7.2. How many private ART tissue establishments?	26
4.11. How many tissues and cells were distributed under the direct	X
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	No
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Ministry of Health - Public Health and Control in Public Health
of inspections.	Directorate (Stat Sanitary Inspectorate after de 2nd of September.)
5.1.2. If yes, please specify staffing (how many inspectors).	2 inspectors at the Ministry of health and 42 inspectors at county level.
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Organs
	Hospitals

	Others
Please specify other.	laboratories, dental offices
5.3. How many routine inspections of tissue establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	V
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	·
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	In 2011 there were 32 ART establishments
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	We decide the type of the routine inspection to conduct based on the:

	• type of the establishment (complexity of site operations), • number of deficiencies in a previous inspection and compliance with existing
	regulations, • number of adverse events/reactions reported or recalls
5.7 H-612011 4:4: 1 4:4	conducted, • volume of activity including significant changes.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	T
5.8. How many TEs were inspected at least twice between 2008-	There were 49 TEs inspected at least twice between 2008-2011
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	W
5.9.1. If yes, how many?	We inspected 43 hospitals in 2012, 60 hospitals in 2013.
5.10. Did you carry out inspections of third parties?	Yes
5.10.1. If yes, how many?	8
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	5
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	No
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	No
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	0
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	Asking for documentation to prove that the TE complies with the
the equivalent standards of quality and safety for importation of skin	requiements of the EU Directives and checking this documentation
from third countries.	, and a second s
6.5. Please specify which procedures you have in place for verifying	Asking for documentation to prove that the TE complies with the
the equivalent standards of quality and safety for importation of	requiements of the EU Directives and checking this documentation
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	The state of the s
countries.	
6.6. Please specify which procedures you have in place for verifying	Asking for documentation to prove that the TE complies with the
the equivalent standards of quality and safety for importation of	requiements of the EU Directives and checking this documentation
ophtalmic (cornea, sclera, etc) tissues from third countries.	
1 (	

6.7. Please specify which procedures you have in place for verifying	Asking for documentation to prove that the TE complies with the
the equivalent standards of quality and safety for importation of	requiements of the EU Directives and checking this documentation
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	Asking for documentation to prove that the TE complies with the
the equivalent standards of quality and safety for importation of	requiements of the EU Directives and checking this documentation
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	Asking for documentation to prove that the TE complies with the
the equivalent standards of quality and safety for importation of cord	requiements of the EU Directives and checking this documentation
blood from third countries.	
6.10. Please specify which procedures you have in place for	Asking for documentation to prove that the TE complies with the
verifying the equivalent standards of quality and safety for	requiements of the EU Directives and checking this documentation
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	A. Export of tissues/cells is authorised only after checking that
and self-sufficiency? (more than 1 answer possible)	local/national needs are fulfilled.
and self sufficiency. (more than 1 answer possible)	D. Import of tissues/cells is authorised only after checking that
	local/national needs are not fulfilled
6.14.1. If A or D were selected, please explain how you quantify	Checking the stock of tissues and cells in accreditted TE
local/national needs.	Checking the stock of tissues and cens in accredited 112
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	168
	40 corneas in 2011
6.15.1. If yes, please specify the number of cases and for which type of tissues/cells.	40 corneas in 2011
6.16. Do you have any additional comments on import/export?	No
	MA //22 /E-C\
7. Distribution/intra community exchanges (Article 23 Directive 20	
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.1. Do you have intra-community exchanges of tissues and cells? 7.2. How do you ensure that tissues establishments fulfil the	
7.1. Do you have intra-community exchanges of tissues and cells? 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality	No
7.1. Do you have intra-community exchanges of tissues and cells? 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	No Asking for documentation
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS	No
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	No Asking for documentation  Yes, no restrictions apply
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of	No Asking for documentation
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No Asking for documentation  Yes, no restrictions apply
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of	No Asking for documentation  Yes, no restrictions apply
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	No Asking for documentation  Yes, no restrictions apply  No
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of	No Asking for documentation  Yes, no restrictions apply  No
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	No Asking for documentation  Yes, no restrictions apply  No Yes
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.5.1. Please provide us with data (country of destination, type of	No Asking for documentation  Yes, no restrictions apply  No Yes
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution	No Asking for documentation  Yes, no restrictions apply  No Yes
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).	No Asking for documentation  Yes, no restrictions apply  No  Yes  0
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).  7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution	No Asking for documentation  Yes, no restrictions apply  No  Yes  0
7.1. Do you have intra-community exchanges of tissues and cells?  7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.  7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).  7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?  7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?  7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).  7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011)	No Asking for documentation  Yes, no restrictions apply  No  Yes  0
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7.9. Do you have any additional comments on distribution?	No
8. Register of tissue establishments and reporting obligations (Arti	cle 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	
possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	Yes - public by request. They will be soon published on the official
	site www.transplant.ro
8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	
8.4.1. Please insert the link to the published national annual report.	www.transplant.ro
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	www.transplant.ro
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.	all data requested by Eurocet
8.7. Do you have any additional comments on reporting?	No
	1.75
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	Ott
9.2. Who assigns the unique code for each donation? (only 1 answer	Other
possible)	
Please specify 'other'.	the unique national code system under construction
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)  9.4. How do you ensure that the 30 years data storage requirement is	requirement by law
respected (Directive 2006/89/EC, Art. 9)? Please specify.	requirement by law
9.5. Do you have any additional comments on traceability?	No
10. Notification of serious adverse events and reactions (Article 11 10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	Tes
10.1.1. If yes, which CA/institution is responsible?	The Ministry of Health – Public Health and Control in Public Health
10.1.1. If yes, which CA/histitution is responsible:	Directorate (Stat Sanitary Inspectorate after de 2nd of September.)
10.1.2. If yes, please provide a short description of its organisation.	Ministry of Health Romania The Ministry of Health is a
10.1.2. If yes, piease provide a short description of its organisation.	governmental institution, financed from the public and budget.
	According to the Governmental Decision no 144/2010 regarding the
	organizing and functioning of the Ministry of Health, there is one
	directorate responsible in this field: the Public Health and Control in
	Public Health Directorate (PHCPHD). The main responsibility is to
	organize and coordinate the vigilance system at national level. The
	necessary measures are taken by the sanitary inspectors from the
	County Public Health Control. The responsibilities of the County
	Public Health Directorates (CPHCD), are established by the
	Ministerial Order no 824/2006 regarding the Norms for functioning
	and organizing of the sanitary state inspection and the Ministerial
	Order no. 1078/2010 for organizing and functioning of the CPHDs.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	Yes
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.3. Do you use the Common Approach Document developed for	Yes
the Annual reporting to the EC also at national level?	
10.4. Do you have a dedicated vigilance officer in charge of	No
collecting SAR/E from all TEs?	
10.4.1. Why not?	The sanitary inspectors who are responsible for the official control in
1	
	the transplant field are in charge of collecting SAR/E.
10.5. How many tissue establishments provided in 2011 the	the transplant field are in charge of collecting SAR/E.  <50%

SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the	163
tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	We have a V&S system in place covered by the Ministry of Public
10.0.1. 11 yes, pieuse provide a orier description.	Health no. 1763/2007, published in the Official Journal no. 698 from
	16 october 2007.
10.7 Do you give foodbook to the TEs recording CAD/CAE recorded	Yes
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	ies
10.7.1. Please specify.	If the TEs is involved in the recorded SAR/SAE
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?	
10.8.1. Please specify.	If the TEs is involved in the recorded SAR/SAE
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	No
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.2. If no, please specify why not.	The system is not yet operational because the national procedure is
	drafted and has to be approved as a Ministry Order.
10.12. Do you have in place a system/procedure to notify Tissue	No
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.2. If no, please specify why not.	There is no procedure but we inform the National Agency of
	Transplant and the sanitary inspectors form CPHDs
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	not until now
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Pharmacovilance
	Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	5
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	No
11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	Explicit consent (opt-in)
	Evaliait informed concent of the donor
11.1.1. Please specify your choice of consent system for living	Explicit informed consent of the donor
tissue/cell donation.	Evalisit concept (out in)
11.2. What consent system for deceased tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	First degree relatives (including spouse)
donations, please specify who is giving the authorisation for the	
tissue donation? (more than 1 answer possible)	***
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	

provided with the appropriate information, as requested by Art.	
13(2)? (more than 1 answer possible)	Legal requirement
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties	Legai requirement
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	Legal requirement
identity of the receipient is not disclosed to the donor and vice versa.	Logar roquiroment
11.9. Does your national legislation allows disclosure of donor data	No
in case of gametes donation?	
11.9.1. If no, please specify the circumstances and measures in	Only at the specific requirement of the authorities (police, coroner
place.	office).
11.10. Do you have any additional comments on consent and data	No
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 200	
12.1. How do you ensure that all requirements related to the	Inspections of TEs and procurement sites
evaluation and selection of donors (except donors of reproductive	Audit of documentation
cells) are respected in your country (Art. 15(1), Annex I Directive	Regular evaluation of medical personnel
2006/17/EC)? (more than 1 answer possible)	Inquestions of ART contra-
12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are	Inspections of ART centres Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	Regular evaluation of medical personnel
2006/17/EC)? (more than 1 answer possible)	respond or medical personner
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
	Medical records of the donor
	Interview with the treating physician
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	110
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	Inspection of the centre of human application (e.g. transplantation
Directive 2006/17/EC? (more than 1 answer possible)(For this	centre, ART centre)
question "audit" means a documented review of procedures, records,	Audit of the centre of human application
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	No
and procurement?	
13. Quality management, responsible person, personnel (Article 16	, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	Authorization requirement
13.2. How do you ensure that tissue establishments have a	Authorisation requirement

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responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Regular evaluation of personnel
than 1 answer possible)	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	No
the personnel of tissue establishments?	
13.4.2. If no, in which country(ies) is your personnel trained?	EU countries
	Non-EU countries
13.4.2.1. Please specify EU-countries.	Spain, Italy, Germany, UK, Austria
13.4.2.2. Please specify non EU-countries.	USA
13.5. Any additional comments on quality management, responsible	No
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	22 Dimentive 2004/22/EC)
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	No
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	163
15.1.1. If yes, have tissue establishments in your Member State	No
	NO
notified third party agreements?	N.
15.2. Any additional comments on third party agreements?	No
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Authorisation-accreditation-licensing of TEs
Directives? Please choose from the options below.	Inspections
16.2.1. For all selected options in question 16.2., please provide a	For ART - complains of the ART centers that ther equiremnts of the
short description.	EU Directives are excessive for this field For accreditation of TEs
	and inspections - The accreditation issued by National Transplant
	Agency needs to be approved by the Ministry of Health. For
	inspections - since 2012, NTA is not allowed anymore to provide
	inspections but only evaluations of the TEs.
16.3. In your opinion, in which of the following Directives are there	No shortcomings
shortcomings (if any)? (more than 1 answer possible)	
shorteonnings (if any): (more than I allower possible)	

## A.1.26. Survey response Slovakia

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health of the Slovak Republic
1.1.2. Address of NCA 1:	Ministry of Health of the Slovak Republic Limbová 2 837 52
	Bratislava Slovak Republic
1.1.3. Telephone (central access point):	+4212 59373111
1.1.4. E-mail (central access point):	office@health.gov.sk
1.1.5. Website:	www.health.gov.sk
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	Section of Health together with Section of Legislation Department
organisation of the National Competent Authority(ies) (e.g.	of Health Care Ministry of Health of the Slovak Republic
departments, staffing, number of senior and junior inspectors, staff	
working on EU affairs and legal matters, vigilance officers, budget,	
independence from government etc.).	
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	_
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	Regional Competent Authorities can only approve so called
Regional Competent Authority(ies) and their relation with the	Common Examination and Therapeutic Establishments (SVaLZ)
National Competent Authority(ies) for tissues and cells:	which might serve as helper in procurement of tissues and cells
2. Procurement (Article 5 Directive 2004/23/EC)	C
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more	Other
than 1 answer possible)	Office
Please specify 'other':	by administration approval
2.1.2. How many such authorisations were granted in 2011 (01/01-	3
31/12/2011)?	
2.2.1 Please provide the number of procurement centres in which	1
procurement of "traditional tissues and cells" (skeletal tissues,	
cardiovascular tissues, skin, ocular tissues, amniotic membrane,	
pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in	
2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in which	1
procurement of haematopoietic stem cells (bone marrow, PBSC,	
cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in which	1
procurement of gametes, embryos and other reproductive tissues	•
were carried out in 2011 (01/01-31/12/2011).	
2.2.4. Please provide the number of procurement centers in which	0
procurement of tissues/cells for ATMP manufacturing were carried	Ĭ
out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply with the	Analysis of the mandatory documentation
requirements laid down in Art. 5 of Directive 2004/23/EC and its	Analysis of the manualory documentation
implementing Directive 2006/17/EC (e.g. trained personnel,	
conditions accredited, designated, authorised, licensed)? (more than	
conditions accidence, designated, audionsed, nechsed) ( (Inoie mail	
	1
1 answer possible)	No
1 answer possible) 2.4. Are you also responsible for the accreditation, designation,	No
1 answer possible) 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	
1 answer possible) 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? 2.4.2. Which National Authority is in charge of this activity?	SNAS - Slovak National Acreditation Service
1 answer possible) 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? 2.4.2. Which National Authority is in charge of this activity? 2.5. How do you ensure, as CA for T&C, that tests required for	SNAS - Slovak National Acreditation Service Analysis of the mandatory documentation requested from the tissue
1 answer possible) 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? 2.4.2. Which National Authority is in charge of this activity? 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited,	SNAS - Slovak National Acreditation Service
1 answer possible) 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? 2.4.2. Which National Authority is in charge of this activity? 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer	SNAS - Slovak National Acreditation Service Analysis of the mandatory documentation requested from the tissue
1 answer possible) 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? 2.4.2. Which National Authority is in charge of this activity? 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited,	SNAS - Slovak National Acreditation Service Analysis of the mandatory documentation requested from the tissue

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authorised or licensed in your country (e.g. number, year of		
accreditation/authorisation/license, which donor tests are performed		
etc.).		
2.7. Do you have any additional comments on procurement?	NO	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)		
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1	
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2	
answer possible)	HBs AG	
•	Anti HBc	
	Anti HCV-Ab	
	Treponema Pallidum	
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1	
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2	
answer possible)	HBs AG	
uno (vol possiolo)	Anti HBc	
	Anti HCV-Ab	
	Treponema Pallidum	
3.3. If NAT testing is not mandatory in your country, could you	1	
please indicate whether you intend to make it mandatory or to	Proposals were given	
encourage its use? Please specify why or why not (e.g. number of		
additional cases detected, cost-benefit etc.).	N-	
3.4. Do you have concerns on accuracy of the available tests and test	No	
procedures for deceased donors?	N.	
3.5. Are any other laboratory tests required for donors of non-	No	
reproductive tissues and cells in your Member State?		
3.6. Are any other laboratory tests required for donors of	No	
reproductive tissues and cells in your Member State?		
3.7. Do you request/use international accreditation systems for	No	
testing laboratories?		
3.8. Do you have any additional comments on testing?	NO	
4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)		
4. Accreditation, designation, authorisation of ficensing of tissue es	tablishments (Affice 0, Directive 2004/25/EC)	
4.1. Do you have a system of designation, authorisation,	Yes	
4.1. Do you have a system of designation, authorisation,		
<ul><li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li><li>4.2. Is inspection a prerequisite for the designation, authorisation,</li></ul>		
<ul><li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li><li>4.2. Is inspection a prerequisite for the designation, authorisation,</li></ul>	Yes	
4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?	Yes	
<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> </ul>	Yes No	
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<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> <li>4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?</li> <li>4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?</li> </ul>	Yes  No  No  0	
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<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> <li>4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?</li> <li>4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?</li> <li>4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?</li> <li>4bis. Overview of tissue/cells establishments authorised by the NC.</li> <li>4.7. Tissue establishments with authorisation pending approval at</li> </ul>	Yes  No  No  O  No  HSC tissue establishments	
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<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> <li>4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?</li> <li>4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?</li> <li>4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?</li> <li>4bis. Overview of tissue/cells establishments authorised by the NC. 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):</li> <li>4.7.5. How many HSC tissue establishments?</li> <li>4.7.8. How many multi-tissue establishments?</li> <li>4.8. Tissue establishments with authorisations pending approval by</li> </ul>	No No No O No No No A HSC tissue establishments ART tissue establishments Multi-tissue establishments 2 1 1 HSC tissue establishments	
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<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> <li>4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?</li> <li>4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?</li> <li>4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?</li> <li>4bis. Overview of tissue/cells establishments authorised by the NC 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):</li> <li>4.7.5. How many HSC tissue establishments?</li> <li>4.7.8. How many multi-tissue establishments?</li> <li>4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):</li> <li>4.8.5. How many HSC tissue establishments?</li> </ul>	No No No O  No No O  No A  HSC tissue establishments ART tissue establishments Multi-tissue establishments 2 1 1 HSC tissue establishments ART tissue establishments Multi-tissue establishments ART tissue establishments ART tissue establishments Multi-tissue establishments Multi-tissue establishments	
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<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> <li>4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?</li> <li>4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?</li> <li>4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?</li> <li>4bis. Overview of tissue/cells establishments authorised by the NC.</li> <li>4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):</li> <li>4.7.5. How many HSC tissue establishments?</li> <li>4.7.8. How many multi-tissue establishments?</li> <li>4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):</li> <li>4.8.5. How many ART tissue establishments?</li> <li>4.8.7. How many ART tissue establishments?</li> <li>4.8.8. How many multi-tissue establishments?</li> <li>4.8.9. How many MRT tissue establishments?</li> <li>4.8.9. How many multi-tissue establishments?</li> <li>4.8.9. How many multi-tissue establishments?</li> </ul>	No No No O  No No A  HSC tissue establishments ART tissue establishments Multi-tissue establishments 2 1 1 HSC tissue establishments ART tissue establishments 1 1 HSC tissue establishments ART tissue establishments ART tissue establishments ART tissue establishments ART tissue establishments	
<ul> <li>4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?</li> <li>4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?</li> <li>4.3. Are preparation processes authorised?</li> <li>4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?</li> <li>4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?</li> <li>4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?</li> <li>4bis. Overview of tissue/cells establishments authorised by the NC.</li> <li>4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):</li> <li>4.7.5. How many HSC tissue establishments?</li> <li>4.7.8. How many multi-tissue establishments?</li> <li>4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):</li> <li>4.8.5. How many HSC tissue establishments?</li> <li>4.8.7. How many ART tissue establishments?</li> <li>4.8.7. How many ART tissue establishments?</li> </ul>	No A HSC tissue establishments ART tissue establishments Multi-tissue establishments 2 1 1 HSC tissue establishments ART tissue establishments 1 1 1 1 1 1 1	

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4.9.7. How many ART tissue establishments?	1
4.10. All tissue establishments authorised by 31/12/2011 (more than	HSC tissue establishments
1 answer possible):	ART tissue establishments
410.51 11 115 115 115 1 4 0	Multi-tissue establishments
4.10.5.1. How many public HSC tissue establishments?	1
4.10.5.2. How many private HSC tissue establishments?	1
4.10.7.1. How many public ART tissue establishments?	0
4.10.7.2. How many private ART tissue establishments?	1
4.10.8.1. How many public multi-tissue establishments?	1
4.10.8.2. How many private multi-tissue establishments?	0
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	No
pursuant to the Directive been defined (Article 27)?	
4.17. Do you have any additional comments on accreditation,	No
authorisation, designation and licensing?	
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	No
measures of tissue establishments?	
5.1.3. If no, please specify why not.	In preparation
5.2. Does the inspection scheme interact or overlap with the	No
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
5.3. How many routine inspections of tissue establishments for non-	1
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011)?	
5.3.1. How many inspections of tissues establishments for non-	0
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof? 5.3.2. How many other type of inspections of tissues establishments	0
for non-reproductive tissues/cells were conducted in 2011 (from	0
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	1
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	-
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	

5.4. How many routine inspections were conducted in ART	0
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	0
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	2
5.6. How do you decide which type of routine inspection to conduct?	According to needs
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	163
5.8. How many TEs were inspected at least twice between 2008-	0
2011 (01/01/2008-31/12/2011)?	U
5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	NO
outside tissue establishments!	l I
	Pageura of absorpts of inspectors
5.9.2. If no, why not?	Because of absence of inspectors
5.9.2. If no, why not? 5.10. Did you carry out inspections of third parties?	No
5.9.2. If no, why not? 5.10. Did you carry out inspections of third parties? 5.10.2. If no, why not?	No There was no need
5.9.2. If no, why not? 5.10. Did you carry out inspections of third parties? 5.10.2. If no, why not? 5.11. Do you use at national level the Operational Manual for	No
5.9.2. If no, why not?     5.10. Did you carry out inspections of third parties?     5.10.2. If no, why not?     5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement	No There was no need
5.9.2. If no, why not?     5.10. Did you carry out inspections of third parties?     5.10.2. If no, why not?     5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission	No There was no need
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5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses	No There was no need
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5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	No There was no need Yes  Yes
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5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 =	No There was no need Yes  Yes
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	No There was no need Yes  Yes  5
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue	No There was no need Yes  Yes
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that	No There was no need Yes  Yes  5
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	No There was no need Yes  Yes  No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue	No There was no need Yes  Yes  5
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in	No There was no need Yes  Yes  No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	No There was no need Yes  Yes  No No
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5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or	No There was no need Yes  Yes  No No No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	No There was no need Yes  Yes  No No No No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?  5.16. Have you asked another MS, or have you been requested by	No There was no need Yes  Yes  No No No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?  5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your	No There was no need Yes  Yes  No No No No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?  5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	No There was no need Yes  Yes  No No No No
<ul> <li>5.9.2. If no, why not?</li> <li>5.10. Did you carry out inspections of third parties?</li> <li>5.10.2. If no, why not?</li> <li>5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?</li> <li>5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&amp;S)?</li> <li>5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?</li> <li>5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?</li> <li>5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?</li> <li>5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?</li> <li>5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?</li> <li>5.17. Would you be interested in developing joint inspections? Joint</li> </ul>	No There was no need Yes  Yes  No No No No
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<ul> <li>5.9.2. If no, why not?</li> <li>5.10. Did you carry out inspections of third parties?</li> <li>5.10.2. If no, why not?</li> <li>5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?</li> <li>5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&amp;S)?</li> <li>5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?</li> <li>5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?</li> <li>5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?</li> <li>5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?</li> <li>5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?</li> <li>5.17. Would you be interested in developing joint inspections? Joint</li> </ul>	No There was no need Yes  Yes  No No No No No
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5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?  5.10.2. If no, why not?  5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?  5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?  5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?  5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?  5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?  5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States'	No There was no need Yes  Yes  No No No No No

( Long and Long and (Anti-La O Direction 2004/22/EC)	
6. Import/export (Article 9 Directive 2004/23/EC)	NI-
6.1. Do you have a register of authorised tissue establishments that	No
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	0
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	1
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	no import from third countries
the equivalent standards of quality and safety for importation of skin	
from third countries.	
6.5. Please specify which procedures you have in place for verifying	no import from third countries
the equivalent standards of quality and safety for importation of	1
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	no import from third countries
the equivalent standards of quality and safety for importation of	no import from uniti countries
ophtalmic (cornea, sclera, etc) tissues from third countries.	
	no immort from third court-i
6.7. Please specify which procedures you have in place for verifying	no import from third countries
the equivalent standards of quality and safety for importation of	
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	no import from third countries
the equivalent standards of quality and safety for importation of	
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	no import from third countries
the equivalent standards of quality and safety for importation of cord	
blood from third countries.	
6.10. Please specify which procedures you have in place for	no import from third countries
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.12. Did you export tissues/cells from 3rd countries during 2011	No
(01/01/2011-31/12/2011)?	
6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	A. Export of tissues/cells is authorised only after checking that
and self-sufficiency? (more than 1 answer possible)	local/national needs are fulfilled.
6.14.1. If A or D were selected, please explain how you quantify	checking of hospital requests
local/national needs.	ontoning of hospital requests
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	NO .
6.16. Do you have any additional comments on import/export?	no
7. Distribution/intra community exchanges (Article 23 Directive 20	·
7.1. Do you have intra-community exchanges of tissues and cells?	No
7.2. How do you ensure that tissues establishments fulfil the	checking of TE records
requirements of Art. 23 of Directive 2004/23/EC regarding quality	
of tissues and cells during distribution? Please specify.	
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Yes, but only via an authorised TE in my MS
from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient of	Yes
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.4.1. If yes, how many authorisations were given in 2011	0
(01/01/2011 to 31/12/2011)?	
7.4.2. If yes, for which tissues/cells?	according to requests

7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination, type of	valid since 12/12
tissue/cell and number of units distributed) concerning distribution	
to other MS in 2011 (01/01/2011-31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	N/A
tissue/cell and number of units distributed) concerning distribution	
to other MS in 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	no
8. Register of tissue establishments and reporting obligations (Arti	
8.1. Do you have an annual report model/template on the activities	Yes
	ies
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	(0.000/
8.2. How many tissue establishments submitted annual reports of	60-99%
their activities during 2011. Please provide an estimation. (1 answer	
possible)	N.
8.3. Are these reports publicly available? (Article 10(1))	No
8.4. Do you publish a national annual report of the consolidated	No
activities of all tissue establishments in your country?	
8.4.2. If no, why not?	they are kept in paper form
8.5. Is there a publicly accessible register of authorised tissue	No
establishements in place? (Article 10(2))	
8.5.2. If no, why not?	in preparation
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please specify.	according to their data forms
6.6.1. If yes, what data are provided to EUROCET? Flease specify.	5 · · · · · · · · · · · · · · · · · · ·
8.7. Do you have any additional comments on reporting?	no
8.7. Do you have any additional comments on reporting?	no
8.7. Do you have any additional comments on reporting?  9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	no 6/86/EC)
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10.4.1. Why not?	Crystam is not finalized rest
10.4.1. Why not?  10.5. How many tissue establishments provided in 2011 the	System is not finalized yet 70-99%
SAR/SAE data as requested (please provide the % from the total	70-9976
number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the transplantation	No
	NO
centres when reporting SAR/SAE to the TEs which distributed the	
tissues/cells (Art 11.2)?	It : 14 C 4 D 14 (22/2007
10.6.2. If no, how do you ensure that SAR/SAE are reported to the	It is mandaty according to the Government Regulation nr.622/2007
TES?	sec4
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at national level?	: 1 // COA
10.7.1. Please specify.	via letter of CA
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?	
10.8.1. Please specify.	via letter of CA
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	
10.11. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites in case of a national rapid	
alert?	
10.11.1. If yes, please give a short description of the	via phone and e-mail to RP and TE
system/procedure.	
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	via phone and e-mail to RP and TE
system/procedure.	
10.13. Do you provide data regarding SAR/SAE to the EUROCET	Yes
registry (non-mandatory reporting)?	
10.13.1. If yes, please specify what data.	as required by EUROCET
10.14. Do you notify alerts communicated via these tissues and cells	No
national vigilance system also to other national vigilance/alert	
systems?	
10.15. Did you send a vigilance officer/contact point to the trainings	No
organised by the EU-funded project SOHO V&S?	
10.15.2. If no, please specify why not.	There were change of people (person who was already applied
	changed job)
10.16. Do you have any additional comments on SARE reporting?	no
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	
11.1.1. Please specify your choice of consent system for living	signed informed consent
tissue/cell donation.	
11.2. What consent system for deceased tissue/cell donation do you	Presumed consent (opt-out)
have in place within your Member State?	
11.3. According to your national legislation, in case of deceased	Other
donations, please specify who is giving the authorisation for the	
tissue donation? (more than 1 answer possible)	
Please specify 'other'.	Slovak National Transplantation Organization - Registry of non-
	donors
11.4. Is the consent system for deceased tissue donation the same as	Yes
for organs?	
11.5. How is this consent verified during inspections? (more than 1	Analysis of documentation
answer possible)	·
11.6. What measures are in place to ensure that	Information for donors are standardised at national/regional level
donors/relatives/authorising persons on behalf of donors are	
provided with the appropriate information, as requested by Art.	
<u> </u>	ı.

12(2)2 (mare then I anguar magailda)	
13(2)? (more than 1 answer possible)	Only with a state of the time of the third and the
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties	Only unique code of the tissue is given to the third party
(Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure that the	Only unique code of the tissue is given
identity of the receipient is not disclosed to the donor and vice versa.	Only unique code of the dissue is given
11.9. Does your national legislation allows disclosure of donor data	No
	NO
in case of gametes donation?	Only minutes and of constants six six six six six six six six six si
11.9.1. If no, please specify the circumstances and measures in	Only unique code of gametes is given
place.	
11.10. Do you have any additional comments on consent and data	no
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 200	·
12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of reproductive	
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Standardised questionnaires at national level
evaluation and selection of donors of reproductive cells are	
respected in your country (Art 15 (1), Annex III of Directive	
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Medical records of the donor
deceased donor of tissues/cells? (more than 1 answer possible)	Autopsy report
	Other
Please specify 'other'.	other examination if needed
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	no
and procurement?	
13. Quality management, responsible person, personnel (Article 16	, 17, 18 Directive 2004/23/EC)
13.1. How do you ensure that tissue establishments in your country	Inspections
have in place a quality system respecting the provisions of the	
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	
this question "audit" means a documented review of procedures,	
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Inspections
responsible person fulfilling the requirements of Art. 17(1)? (more	
than 1 answer possible)	
than I answer possible)	

	· · ·
13.3. How do you ensure an appropriate training for the personnel	Inspections
directly involved in the activities of tissue establishments? (more	
than 1 answer possible)	
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	Certified training course at the Slovak Medical University
13.5. Any additional comments on quality management, responsible	no
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	2-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	-
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	
Directive 2004/23/EC? (more than 1 answer possible)	
14.3. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	
of Directive 2004/23/EC? (more than 1 answer possible)	
14.4. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
fulfill the requirements of Art. 22 (labelling, documentation and	inspections of tissue establishments
packaging) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	no
labelling and packaging?	IIO
15. Third party agreements (Art. 24 Directive 2004/23/EC)	V
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	N.
15.1.1. If yes, have tissue establishments in your Member State	No
notified third party agreements?	
15.2. Any additional comments on third party agreements?	no
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	Import-export
implementing the requirements in the EU Tissues and Cells	Authorisation-accreditation-licensing of TEs
Directives? Please choose from the options below.	Inspections
16.2.1. For all selected options in question 16.2., please provide a	System of authorisation-acreditation-licensing of TEs and
short description.	inspections system are not finalized yet
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	
16.3.1. How would you suggest to solve these issues in Directive	Preambule 18: As a matter of principle, tissue and cell application
2004/23/EC?	programmes should be founded on the philosophy of voluntary and
	unpaid donation. Article 12 paragraph 2 Member states shall
	endeavour to ensure that the procurement of tissues and cells as such
	is carried out on a non-profit basis. These provisions and paragraphs
	were transponed into Slovak legislation. But still does exist chaos
	what can be paid and what can not be paid, how to handle with
	potential brokers etc. We have to put these problems on agenda of
	our regular meetings with advice of lawyers.
	The state of the join.

## A.1.27. Survey response Slovenia

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Javna agencija Republike Slovenije za zdravila in medicinske
	pripomočke / Agency for Medicinal Products and Medical Devices
	of the Republic of Slovenia
1.1.2. Address of NCA 1:	Ptujska ulica 21 SI-1000 Ljubljana Slovenia
1.1.3. Telephone (central access point):	+386 (0)8 2000 500
1.1.4. E-mail (central access point):	info@jazmp.si
1.1.5. Website:	www.jazmp.si
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Reproductive tissues and cells
	Blood and blood components
	Pharmaceuticals
	Medical devices
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Accreditation, authorisation, licensing of TEs
possible)	Inspection
	Vigilance
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	JAZMP is an Independent agency founded 1.1.2007. The Agency
organisation of the National Competent Authority(ies) (e.g.	was established and operates according to the legislation which
departments, staffing, number of senior and junior inspectors, staff	explicitly states its competences and tasks ("Medicinal Products
working on EU affairs and legal matters, vigilance officers, budget,	Act" (2006, 2008), "Medical Devices Act" (2009), "Blood Supply
independence from government etc.).	Act" (2000, 2004, 2006), "Act on Quality, Safety of Human Tissues
	and Cells" (2007)). JAZMP is organised in 12 sectors. EU issues
16 1 6 16 1 1 1 1 1 1 1	are as a rule treated with very high priority by JAZMP.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	NA
1.7. Could you please describe the competence/mandate of the	NA NA
Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	Von
2.1. Do you authorise the "conditions of procurement"?	Yes  Ry inspecting all procurement centres
2.1. Do you authorise the "conditions of procurement"? 2.1.1. How do you authorise the "conditions of procurement"? (more	Yes By inspecting all procurement centres
2.1. Do you authorise the "conditions of procurement"? 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	By inspecting all procurement centres
2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-	
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2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which	By inspecting all procurement centres
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2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues,	By inspecting all procurement centres  16
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2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	By inspecting all procurement centres  16  10
2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	By inspecting all procurement centres  16  10
2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC,	By inspecting all procurement centres  16  10
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2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried	By inspecting all procurement centres  16  10  14
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<ul> <li>2.1. Do you authorise the "conditions of procurement"?</li> <li>2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)</li> <li>2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?</li> <li>2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).</li> <li>2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).</li> <li>2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).</li> <li>2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).</li> <li>2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)</li> <li>2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?</li> </ul>	By inspecting all procurement centres  16  10  14  3  Inspections of the site/centre Analysis of the mandatory documentation  No
2.1. Do you authorise the "conditions of procurement"?  2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)  2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).  2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).  2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).  2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation,	By inspecting all procurement centres  16  10  14  3  Inspections of the site/centre Analysis of the mandatory documentation

donors are carried out only by qualified laboratories accredited,	establishment
designated, authorised or licensed Art. 5(2))? (more than 1 answer	
possible)	
2.6. Please provide data on qualified laboratories accredited,	NA
authorised or licensed in your country (e.g. number, year of	
accreditation/authorisation/license, which donor tests are performed	
etc.).	
2.7. Do you have any additional comments on procurement?	Please see 3.8
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	Ag HIV
• •	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	This issue was not discused yet.
please indicate whether you intend to make it mandatory or to	This issue was not discused yet.
encourage its use? Please specify why or why not (e.g. number of	
additional cases detected, cost-benefit etc.).	
3.4. Do you have concerns on accuracy of the available tests and test	Yes
procedures for deceased donors?	
3.4.1. Please specify why:	Cases of false-positive HIV test results in deceased donors.
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	- Licences for testing laboratories are in Ministry of Health
3.6. Do you have any additional comments on testing:	competences - Laboratories performing tissues and cells donor
	testings perform also testing for blood donations - The testing
	laboratories are included in national and international testing
	scheemes - Testing laboratories must have quality system in place
	(Legal requirement)
4. Accreditation, designation, authorisation or licensing of tissue es	
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	5
authorising/accrediting/licensing/designating TEs?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
4.5.1. How are mey aumonsed? (more man 1 answer possible)	•
	During inspections organised for this purpose
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	0
how many authorisations/accreditation/licenses were revoked in	
2011?	
	L

4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC	A
4.7. Tissue establishments with authorisation pending approval at	Other tissue establishments
01/01/2011 (more than 1 answer possible):	Other dissue establishments
4.7.9. Please specify the type of tissues/cells and how many.	No pendinng approvals at 01/01/2011.
4.8. Tissue establishments with authorisations pending approval by	Multi-tissue establishments
31/12/2011 (more than 1 answer possible):	With tissue establishments
4.8.8. How many multi-tissue establishments?	5
4.9. Tissue establishments first time authorised between 01/01/2011	Cord blood tissue establishments
and 31/12/2011 (more than 1 answer possible):	Multi-tissue establishments
4.9.6. How many cord blood tissue establishments?	1
4.9.8. How many multi-tissue establishments?	5
4.10. All tissue establishments authorised by 31/12/2011 (more than	Musculo-skeletal tissue establishments
1 answer possible):	Cord blood tissue establishments
i aliswei possioie).	Multi-tissue establishments
4.10.2.1. How many public musculo-skeletal tissue establishments?	1
4.10.2.2. How many private musculo-skeletal tissue establishments?	2
4.10.2.2. Flow many private musculo-skeretar tissue establishments?  4.10.6.1. How many public cord blood tissue establishments?	0
4.10.6.1. How many public cord blood tissue establishments?  4.10.6.2. How many private cord blood tissue establishments?	2
* *	
4.10.8.1. How many public multi-tissue establishments?	16
4.10.8.2. How many private multi-tissue establishments?	
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during	
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	No
4.17. Do you have any additional comments on accreditation,	No
authorisation, designation and licensing?	
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)	
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control	Yes
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?	Yes
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge	Yes Inspection
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Inspection
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).	
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the	Inspection
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood,	Inspection 4 inspectors
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the	Inspection 4 inspectors
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authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)	Inspection  4 inspectors Yes  Blood
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-	Inspection  4 inspectors Yes
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	Inspection  4 inspectors Yes  Blood
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?	Inspection  4 inspectors Yes  Blood 26 inspections in 5 Tissue Establishments
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-	Inspection  4 inspectors Yes  Blood
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	Inspection  4 inspectors Yes  Blood 26 inspections in 5 Tissue Establishments
authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).  5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)  5.2.1. If yes, please specify. (more than 1 answer possible)  5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?  5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or	Inspection  4 inspectors Yes  Blood 26 inspections in 5 Tissue Establishments
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shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	5
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
was the number of inspections carried out where major shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
	U
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	3
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	0
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	0
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	0
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	0
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	3
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	
5.6. How do you decide which type of routine inspection to conduct?	We consider that during the routine inspection general system-
	oriented inspection should be performed.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	23
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	
5.9.1. If yes, how many?	10
5.10. Did you carry out inspections of third parties?	Yes
5.10.1. If yes, how many?	2
5.11. Do you use at national level the Operational Manual for	Yes
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses	Yes
organised by EU-funded projects (e.g. EUSTITE, SOHO	103
V&S)?	
5.12.1. If yes, how would you rate the usefulness and efficacy of	5
these training courses on a scale from 1 to 5 (1 = not important, 2 =	
sufficient, 3 = good, 4 = very good, 5 = essential)?	
surreient, 3 - good, 4 - very good, 3 - essential)!	

T 10 Bil	
5.13. Did you request/organise an inspection of a tissue	No
establishment in another MS in collaboration with the NCA in that	
MS (Art 7(6))?	
5.14. Did you receive/organise an inspection of a tissue	No
establishment in your country at the request of another MS in	
collaboration with the NCA in that MS (Art 7(6))?	
5.15. Did you organise any inspections of procurement centres or	No
	140
tissue establishments in third countries from which tissues and/or	
cells were imported in your country (as recorded by 31/12/2011)?	
5.16. Have you asked another MS, or have you been requested by	Yes
any other MS, on the results and control measures of your	
inspections, as part of an enquiry/investigation?	
5.16.1. If yes, please specify.	We asked for outcomes of inspections: UK: outcome of inspection in
J	one TE NL: outcome of inspection in one TE BE: outcome of
	inspection in one TE DE: outcome of inspection in one TE
5.15 W. 11	
5.17. Would you be interested in developing joint inspections? Joint	Yes
inspections should be understood as inspections of tissue	
establishments conducted jointly by two or more Member States'	
Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	No.
6. Import/export (Article 9 Directive 2004/23/EC)	V
6.1. Do you have a register of authorised tissue establishments that	Yes
are explicitly authorised to perform import/export of tissues and	
celles from/to third countries?	
6.2. Please specify the number of tissue establishments authorised to	6
import tissues and cells from third countries (recorded by	
31/12/2011).	
6.3. Please specify the number of tissue establishments authorised to	6
	O I
export tissues and cells from third countries (recorded by	
31/12/2011).	
6.4. Please specify which procedures you have in place for verifying	Authorisation procedure, Inspections
the equivalent standards of quality and safety for importation of skin	
from third countries.	
6.5. Please specify which procedures you have in place for verifying	Authorisation procedure, Inspections
the equivalent standards of quality and safety for importation of	Tamorisation processies, inspections
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
6.6. Please specify which procedures you have in place for verifying	Authorisation procedure, Inspections
the equivalent standards of quality and safety for importation of	
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	Authorisation procedure, Inspections
the equivalent standards of quality and safety for importation of	The state of the s
cardio vascular tissues from third countries.	
	Authorization procedure Transations
6.8. Please specify which procedures you have in place for verifying	Authorisation procedure, Inspections
the equivalent standards of quality and safety for importation of	
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
6.9. Please specify which procedures you have in place for verifying	Authorisation procedure, Inspections
the equivalent standards of quality and safety for importation of cord	
blood from third countries.	
6.10. Please specify which procedures you have in place for	Authorisation procedure, Inspections
	Authorisation procedure, inspections
verifying the equivalent standards of quality and safety for	
importation of reproductive cells (sperm, egg cells) from third	
countries.	
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	From USA: 3x Achiles Tendom, 1x Bone Tendom with Qurad Hemi
number/volume of imported tissues and cells by country of origin.	Small Bone, 1x Anterior Tibialis Tendom From Bosnia and
number, volume of imported assues and eens by country of origin.	
	Herzegovina: 1x cord blood for autologous storage
(10 D)1 (1) (1) (1) (1) (1) (1) (1)	
6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	No

6.13. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on imports/exports of tissues/cells between	INO
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	C. Export of tissues/cells is authorised irrespective of national needs
and self-sufficiency? (more than 1 answer possible)	C. Export of dissues/cens is audiorised irrespective of national needs
6.15. Did you authorise direct imports of tissues/cells to	Yes
hospitals/clinics in your country?	Tes
6.15.1. If yes, please specify the number of cases and for which type	1 case, inport from USA, infertility treatment, sperm cells (man's
of tissues/cells.	
6.16. Do you have any additional comments on import/export?	authologous sperm) for a couple.  No.
7. Distribution/intra community exchanges (Article 23 Directive 20	·
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	It's member state's right to ensure Q&S, if it is needed.
and safety measures established by other Member States? Please	
specify.	
7.1.2. If yes, do you have more stringent quality and safety measures	No
than in other Member States?	
7.2. How do you ensure that tissues establishments fulfil the	Before cross-border exchange is authorised by Slovene CA, copy of
requirements of Art. 23 of Directive 2004/23/EC regarding quality	valid authorisation of TE issued by relevant national CA is needed.
of tissues and cells during distribution? Please specify.	According to our law, foreigin TE are considered as third parties.
7.3. Do you allow direct distribution to hospitals/clinics in your MS	Other
from TEs in another MS? (only 1 answer possible).	
Please specify 'other'.	We allow direct distribution to hospitals/ clinics, but with special
	authorisation issued for each case. Tissues and cells are used on
	physician's responsability.
7.4. Have you authorised direct distribution to the recipient of	Yes
specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.4.1. If yes, how many authorisations were given in 2011	0
(01/01/2011 to 31/12/2011)?	
7.4.2. If yes, for which tissues/cells?	NA
7.5. Do you collect data regarding the cross-border exchange of	Yes
tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination, type of	To Germany: 77 cord blood units for autologous use (storage) To
tissue/cell and number of units distributed) concerning distribution	Belgium: 446 cord blood units for autologous use (storage)
to other MS in 2011 (01/01/2011-31/12/2011).	
7.5.2. Please provide us with data (country of origin, type of	From Slovenia: 523 units of cord blood for authologous use
tissue/cell and number of units distributed) concerning distribution	(storage)
to other MS in 2011 (01/01/2011-31/12/2011)	
7.6. Are you aware of any significant changes in 2012 which may	No
invalidate the 2011 data on cross-border exchanges of tissues/cells	
between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in EU	No
and/or import/export of tissues/cells? In this context, a brokerage	
company means a body that arranges transactions between a supplier	
(tissue establishment/company selling tissues or cells) and a buyer (a	
tissue establishment/a hospital or clinic/an individual) without	
undertaking activities of processing, preservation or storage.	
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	Companies described in 7.7. can only be the third parties of Slovene
7.5. 20 you have any additional comments on distribution:	Tissue Establishment, authorised for import, export and cross-border
	distribution.
2 Degister of tissue establishments and reporting abligations (Aut)	
Register of tissue establishments and reporting obligations (Arti     8.1. Do you have an annual report model/template on the activities	
1	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.	1009/ (all)
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer	
possible)	N-
8.3. Are these reports publicly available? (Article 10(1))	No

8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	
8.4.1. Please insert the link to the published national annual report.	http://www.slovenija-transplant.si/index.php?id=porocila
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	http://www.slovenija-transplant.si/index.php?id=presajanje-tkiv
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?  8.6.1. If yes, what data are provided to EUROCET? Please specify.	Tissue establishments, tissue banks, their activities and type of
8.0.1. If yes, what data are provided to EUROCET? Trease specify.	tissues and cells
8.7. Do you have any additional comments on reporting?	No.
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer	Other
possible)	
Please specify 'other'.	Procurement centre or tissue establishments, depends on type of
0.2 11	tissue or cells
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Only paper records
9.4. How do you ensure that the 30 years data storage requirement is	There's a legal provision in national legislation.
respected (Directive 2006/89/EC, Art. 9)? Please specify.	There is negative provision in management regionation.
9.5. Do you have any additional comments on traceability?	We have data stored in paper records up to 2013, from 2013 data are
	stored in electronic database. Electronic database includes national
	coding system ( natioanl code is given automaticaly) and is EU
	compatible.
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	A CM First Late 1 Filb is 64 B 1F
10.1.1. If yes, which CA/institution is responsible?	Agency of Medicinal products and medical Devices of the Republic of Slovenia; some tasks, mostly on national level, are assigned to
	Slovenija-transplant.
10.1.2. If yes, please provide a short description of its organisation.	Please see 1.5
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	No
the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the	
Annual reporting of the EC also at national level?	
10.2.1. If no, what template do you use? You are welcome to upload	We use tamplates prepared nationaly, they are templates from
the template if you wish.	Directive 2006/86/EC, Ann III, Part A, B; Annex IV, Part A, B, in
10.3. Do you use the Common Approach Document developed for	slovene language. Yes
the Annual reporting to the EC also at national level?	163
10.4. Do you have a dedicated vigilance officer in charge of	Yes
collecting SAR/E from all TEs?	
10.5. How many tissue establishments provided in 2011 the	100%
SAR/SAE data as requested (please provide the % from the total	
number of TEs authorised in your country).	W.
10.6. Do you have a mandatory procedure for the transplantation	Yes
centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	All SARE should be reported to TE.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at national level?	
10.7.1. Please specify.	At annual meeting of responseble persons the feedback is given to
	the TEs.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded	Yes
at EU level?  10.8.1. Please specify.	At annual meeting of responseble persons the feedback is given to
10.0.1.1 lease specify.	the TEs.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells	0
, , , , , , , , , , , , , ,	<u>l</u>

were issued in your country in 2011? Please specify the number and	
which tissues were recalled and why (e.g. missing consent, quality	
defects etc).	V
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid	Yes
alert?	
	All 1 (TE : C 1/ ( 1 : : E 1 1 1
10.11.1. If yes, please give a short description of the	All relevant TEs are informed/ contacted immidiatly by phone, e-
system/procedure.	mails, personal contacts.
10.12. Do you have in place a system/procedure to notify Tissue	Yes
Establishments and procurement sites when a rapid alert is issued via	
the EU RATC platform?	
10.12.1. If yes, please give a short description of the	All relevant TEs are informed/ contacted immidiatly by phone, e-
system/procedure.	mails, personal contacts.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	Not required by national legislation.
10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert	
systems?	
10.14.1. If yes, please specify which of the following systems are	Haemovigilance
usually contacted. (more than 1 answer possible)	Pharmacovilance
	Medical devices
	Other
Please specify 'other'.	National Institute of Health, in cases of epidemiological alerts.
10.15. Did you send a vigilance officer/contact point to the trainings	Yes
organised by the EU-funded project SOHO V&S?	
10.15.1. If yes, how would you rate the usefulness and efficacy of	5
these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3	
(good) - 4 (very good) to 5 (essential)?	
10.16. Do you have any additional comments on SARE reporting?	No.
11. Consent and personal data protection (Article 13 and 14, Direction)	etive 2004/23/EC)
11. Consent and personal data protection (Article 13 and 14, Direct 11.1. What consent system for living tissue/cell donation do you	etive 2004/23/EC) Explicit consent (opt-in)
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12. Selection, evaluation and procurement (Article 15 Directive 20	04/23: Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of reproductive	Inspections of TEs and procurement sites
cells) are respected in your country (Art. 15(1), Annex I Directive	Audit of documentation
2006/17/EC)? (more than 1 answer possible)	
12.2. How do you ensure that all requirements related to the	Standardised questionnaires at national level
evaluation and selection of donors of reproductive cells are	Inspections of ART centres
respected in your country (Art 15 (1), Annex III of Directive	Audit documentation
2006/17/EC)? (more than 1 answer possible)	
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Interview with the donor's family or a person who knew the donor
deceased donor of tissues/cells? (more than 1 answer possible)	well
·	Medical records of the donor
	Autopsy report
12.5. Do you have more stringent criteria for selection of donors of	No
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	
Directive 2006/17/EC? (more than 1 answer possible)(For this	
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection, evaluation	No.
and procurement?	
13. Quality management, responsible person, personnel (Article 10	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	Events with lecturers, strongly recommendeted for responsible
	person, recomendated for other.
13.5. Any additional comments on quality management, responsible	No.
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 19	9-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your country	Inspections of tissue establishments
	1
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	

Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	
14.5. Any additional comments on reception, processing, storage,	No.
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	Third part agreements for: Transport, Procurement, Testing,
	Processing in cases when TE is not able to perform all tasks. Third
	part agreement for Back-up procedures is legal requirement for all
	TEs.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	Agreemennts should be submitted to CA before authorisation is
Competent Auhtority(ies) in your MS? Please specify.	granted. CA assesses if the agreements are in line with the
	legislation. All variations in agreements should be submitted to CA.
15.2. Any additional comments on third party agreements?	No.
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Procurement provisions
Directives? Please choose from the options below.	Testing provisions
	Traceability
16.2.1. For all selected options in question 16.2., please provide a	ART, procurement and Testing: special law and/or rules in national
short description.	legislation. Tracebility: no unique EU- code is available.
16.3. In your opinion, in which of the following Directives are there	Directive 2004/23/EC
shortcomings (if any)? (more than 1 answer possible)	Directive 2006/17/EC
	Directive 2006/86/EC
16.3.1. How would you suggest to solve these issues in Directive	We support suggestions for changes presented at CA meeting in
2004/23/EC?	Dec2012.
16.3.2. How would you suggest to solve these issues in Directive	We support suggestions for changes presented at CA meeting in
2006/17/EC?	Dec2012.
16.3.3. How would you suggest to solve these issues in Directive	We support suggestions for changes presented at CA meeting in
2006/86/EC?	Dec2012.

## A.1.28. Survey response Spain

1.1. Name of National Competent Authority (NCA) 1: Sinesio Delgando 4-8, Pabellón 3, 28029-Madrid, Spain 1.1.3. Telephone (central access point): +34-90230024	1. Public information	
1.1.3. Telephone (central access point):   1.1.4. E-mail (central access point):   1.1.5. Whestie:		Organización Nacional de Trasplantes
1.1.3. Telephone (central access point):   +34-902300224     1.1.4. E-mail (central access point):   ont@msssl.es     1.1.5. Website:   www.ont.es     1.1.6. The NCA is responsible for? (more than I answer possible)   Non-reproductive tissues and cells		
1.1.5. The NCA is responsible for? (more than 1 answer possible)  1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible)  1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible)  Please specify 'other':  The ONT is a coordinating and technical body for the development of functions related to the procurement and clinical use of organs, tissues and cells.  Other areas of work: training programs; international cooperation; relation with the media; research projects; transplant registries; quality and safety; regulation and ethics; promotion and education.  1.2. National Competent Authority 2?  1.2.1. Name of National Competent Authority 2:  1.2.2. Address of NCA 2;  Ministry of Health, Social Services & Equity. National Commission on ARTs. Pase del Prado 18-20 28071-Madrid  1.2.3. Telephone (central access point): 1.2.4. E-mail (central access point): 1.2.5. Website: 1.2.6. Website: 1.2.6. The NCA is responsible for? (more than 1 answer possible)  Please specify 'other':  The Commission is an advisory board to the Ministry of Health on ARTs and also has a role in providing public information on activities related to ARTs developed by Autonomous Communities, which are in charge of authorization and control of these activities by the centers in their respective territories.  1.3. National Competent Authority 3? 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ise) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.)  No  The Commission is an advisory board to the Ministry of Health on ARTs and also has a role in providing public information on activities related to ARTs developed by Autonomous Communities, which are in charge of authorization and control of these activities by the centers in their respective territories.  No  1.5. Please give a short description of the legal status and construction	1.1.3. Telephone (central access point):	
1.1.5. Website: 1.1.6. The NCA is responsible for? (more than 1 answer possible) 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) 1.2. National Competent Authority 2? 1.3. National Competent Authority 2: 1.4. Salvanian (central access point): 1.5. Website: 1.6. The NCA is responsible for? (more than 1 answer possible) 1.7. What are the role/tasks of the NCA? (more than 1 answer possible) 1.8. National Competent Authority 2: 1.9. National Competent Authority 2: 1.1. National Competent Authority 2: 1.2. National Competent Authority 2: 1.2. National Competent Authority 2: 1.2. National Commission on ARTs. 1.2. National Competent Authority 3: 1.3. National Competent Authority 3: 1.4. Email (central access point): 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ise) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.)  The Commission is an advisory board to the Ministry of Health on ARTs and also has a role in providing public information on activities related to ARTs developed by Autonomous Communities, which are in charge of authorization and control of these activities by the centers in their respective territories.  No 1.5. Please give a short description of the legal status and confidence in the National Competent Authority(ise) (e.g. departments, staffing, number of senior and junior inspec		ont@msssi.es
Diter		3
Diter	1.1.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
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Paseo del Prado 18-20   28071- Madrid     1.2.3. Telephone (central access point):   1.2.4. E-mail (central access point):   1.2.5. Website:   http://www.cnrha.msssi.gob.es/     1.2.6. The NCA is responsible for? (more than 1 answer possible)     1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.8. Website:   http://www.cnrha.msssi.gob.es/     1.2.9. Website:   http://www.cnrha.mssi.gob.es/     1.2.0. Website:   http://www.cnrha.mssi.gob.es/     1.2.0. Website:   http://www.cnrha.mssi.gob.es	1.2.2. Address of NCA 2:	
28071- Madrid     1.2.3. Telephone (central access point):   434915964106     1.2.4. E-mail (central access point):   jrey@msssi.es     1.2.5. Website:   http://www.cnrha.msssi.gob.es/     1.2.6. The NCA is responsible for? (more than 1 answer possible)     1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.8. Website:   Other     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the NCA? (more than 1 answer possible)     1.2.9. What are the role/tasks of the Ministry of Health on ARTs and also base a role in providing public information on activities related to ARTs developed by Autonomous Communities, which are in charge of authorization and control of these activities by the centers in their respective territories. No    1.5. Please give a short description of the legal status and org		
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role to inform the requirements made to the Regional Authorities on some special practices of PGD.		

indicate the roles/tasks of the Regional Competent	Inspection
Authority(ies). (more than 1 answer possible)	Vigilance
Please specify 'other':	Other  The former selected answers are specific of the Regional CAs, however, they are responsible at a regional level for many other elements of the activity.
1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	The healthcare provision in Spain and its organization is transferred to the Regional Authorities (hereinafter, RAs). Each regional authority has its independent healthcare system.  The Interterritorial Council for the National Health System is the common forum to coordinate the health-care in Spain. Consisting of several committees, there is a specific one dealing with donation and transplantation matters, for the discussion as well as political and technical agreements on the area.  As regards the human tissues and cells, all the policies are discussed at the so-called Permanent Commission for Transplantation, the one mentioned above. The RAs are represented in this Committee. It is chaired by the Director of the ONT. As already mentioned, all these representatives discuss and make joint decisions on the affairs included in the agenda of each session.  Regarding the coordination role of the ONT, see answers 1.1.7 and 1.5. The healthcare provision in Spain and its organization is transferred to the Regional Authorities (hereinafter, CCAA). Each Regional Authority has its independent healthcare system.  The Interterritorial Council for the National Health System is the common forum to coordinate the health-care in Spain. Made up by several committees, some of them (the one related to public health; another one coping with benefits of the Spanish Health Care System) have to do with ARTs and its deployment in reproductive general, public or private centers.
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"?	By inspecting all procurement centres
(more than 1 answer possible)	Other
Please specify 'other':	A system for the authorization exists at a national level and is regulated in the Royal Decree. Nevertheless, the RAs provide the authorizations, as already mentioned.
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	86
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	211
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	272
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	There is no disposable information for 2011. As an answer to the requests of Eurocet made through the Italian National Institute of Health, in January 2013 it was sent to Eurocet a list of Spanish centers practicing different activities included in or related to ARTs. The total number of centers included in the list at that time was 390. In march 20th, 2013 it was received a new request from that Institute, on behalf of Eurocet, asking to adapt the list previously sent, which was a copy of the register of centers appearing at the web page of the Spanish Commision on ARTs, to a new format proposed by Eurocet. This new format means the exclusion of a certain number of centers developing some kind of activities related to ARTs, like the ones only being banks of sperm, oocytes or embryos. After some consultations with Eurocet, the last one being answered in September 2th, a new list will be sent along September.
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	There is not a specific authorization for procurement centres for ATMP, nevertheless those centres which are authorized for the procurement of "traditional tissues and cells" hold the authorization as the source of cells to produce Advance Therapies.
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC	Inspections of the site/centre Analysis of the mandatory documentation

and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)  2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?  2.4.1. Please provide the number of the laboratories performing donor testing.  2.4.2. Which National Authority is in charge of this activity?  2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible)  No  There are not available data.  The authorization of control of this activity relies on the RAs. The National authority lays down national requisites and regulat coordinates the transmission of results and the dissemination of oinformation when it is necessary.  Inspections of the laboratories Analysis of the mandatory documentation requested from the tist establishment	sue detail,
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for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more	detail,
	,
2.6. Please provide data on qualified laboratories accredited,  The ONT does not have that kind of information at that level of one of the original data.	,
authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.).  nevertheless it is estimated that the number of qualified labs is si the one for Tissue Establishments.	
2.7. Do you have any additional comments on procurement?	
3. Testing (Art 4; Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non- reproductive tissues and cells in your Member State. (more than 1 answer possible)  Anti-HIV 1 Anti-HIV 2 HBs AG Anti HBc Anti HCV-Ab	
3.2. Please specify laboratory tests required for donors of  Anti-HIV 1	
reproductive tissues and cells in your Member State. (more than Anti-HIV 2	
1 answer possible)  Ag HIV	
HBs AG Anti HBc	
Anti HCV-Ab	
Treponema Pallidum	
3.3. If NAT testing is not mandatory in your country, could you NAT is broadly used.	
please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).  For ART it has not foreseen as for now. Activities are widely de at private centers and controls have not produced any problems very expensive and more traditional methods.	
3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State?	
3.5.1. Please specify.  Anti-HTLV II For HSC it is also required PCR in addition to Anti HCV Ab.	
3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	
3.6.1. Please specify.  Clinical studies are applied to exclude clinical phases of toxopla rubella, herpes, cytomegalovirus, neisseria or Chlamydia, but lat test for these diseases are not mandatory in the absence of clinical symptoms.	oratory
3.7. Do you request/use international accreditation systems for testing laboratories?  Yes (No for ART)	
3.8. Do you have any additional comments on testing?  Some testing laboratories in Spain usually search for international accreditation (ISO, etc) besides the CA authorisation.	ıl
4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)	
4.1. Do you have a system of designation, authorisation, No	
accreditation or licensing for all types of tissue establishments under your responsability?	
4.1.1. Please specify.  A system for the authorization exists at national level and is reg the Royal Decree. Nevertheless, the RAs provide the authorizal already mentioned.	
4.2. Is inspection a prerequisite for the designation, Yes	-

authorisation, accreditation or licensing of tissue establishments?	(No for ART)
4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs?	Data not available at national level.  The inspections are responsibility of the RAs. In general, the procedure for authorization and register of health establishments by the Regional Authorities requires the submission of documentation as well as to carry out inspections and audits.
4.3. Are preparation processes authorised?	Yes (No for ART)
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections During inspections organized for this purpose
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011?	Data not available at national level. Inspections are responsibility of the RAs. In general, the procedure for authorization and register of health establishments by the Regional Authorities requires the submission of documentation as well as to carry out inspections and audits.
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?	None (For ART data are not available at national level)
4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?	No
4.6.1. What is the relation between the independent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer	Other
possible) 4.6.2. Please specify	The certification/accreditation is optional.  TEs may obtain the accreditation by JACIE, ISO, etc. if they apply for it.
4bis. Overview of tissue/cells establishments authorised by the	NCA
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):	ART tissue establishments (The RAs provide the authorizations, as already mentioned. Following the Spanish regulation, the ONT receives the final information including the authorized centers, nevertheless the data pertaining to the 'authorizations pending for approval' remains at the regional level.)
4.7.1. How many ocular tissue establishments?	Please see 4.7
4.7.5. How many HSC tissue establishments?	Please see 4.7
4.7.7. How many ART tissue establishments?	Data not available at national level
4.7.8. How many multi-tissue establishments?	Please see 4.7
4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):	ART tissue establishments
4.8.8. How many multi-tissue establishments?	Please see 4.7
4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	ART tissue establishments
4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible):	ART tissue establishments
4.10.2.1. How many authorised centres (2012 data)	502
4.10.2.2. How many Skin tissue establishments?	42
4.10.3.1. How many Musculo-skeletal tissue establishments?	149
4.10.3.2. How many Ocular tissue establishments	245
4.10.5.1. How many Cardiovascular tissue establishments?	62 valves centres, 83 segments centres
4.10.5.2. How many HSC tissue establishments?	90
4.10.6.1. How many Cord blood tissue establishments?	272
4.10.6.2. How many Multi-tissue establishments?	321
4.10.7.1. Other tissue establishments	194
4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells.	Data not available
4: 0 4	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?	Yes

	regional level
4.16.1.1. How many penalties have been imposed in 2011 (from	None
01/01/2011-31/12/2011)?	For ART data not available
4.16.1.2. What were the reasons for imposing the penalties? Please describe.	NA
4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)	NA
4.17. Do you have any additional comments on accreditation,	Currently, there are several disciplinary proceedings ongoing.
authorisation, designation and licensing?	currently, there are several disciplinary proceedings origonig.
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in	Regional competent authorities (RAs).
charge of inspections.  5.1.2. If yes, please specify staffing (how many inspectors).	Data not available at national level.
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	1 es
pharmaceuticals, etc. (e.g. same inspector team, common	
training, common documentation, etc.)? (more than 1 answer	
possible)	
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood
	Organs
	Pharmaceuticals
	Advanced therapies
	Medical devices
	Hospitals
52.11	Accreditation organisations (e.g. JACIE)
5.3. How many routine inspections of tissue establishments for	Data not available at national level since the competencies for the
non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?	inspections rely on the RAs.
5.3.1. How many inspections of tissues establishments for non-	Please see 5.3
reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) following serious adverse events or	
reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues	Please see 5.3
establishments for non-reproductive tissues/cells were conducted	
in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	Please see 5.3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	Ticase see 3.5
What was the number of inspections carried out where no	
shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	Please see 5.3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	Please see 5.3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where major	
shortcomings were noted?  5.3.6. Outcome of inspections of TEs for non-reproductive	
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	0
What was the number of inspections carried out that were	
followed by suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out that were	
followed by closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	Please see 5.3
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of other inspections carried out? Please	

specify.	
5.4. How many routine inspections were conducted in ART	Data not available
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted Fin ART	NA
establishments following serious adverse events or reactions, or	
suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on	Data not available
ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a	
whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments	Data not available at national level
carried out in 2011 (01/01/2011 to $31/12/2011$ ): What was the	
number of inspections carried out where no shortcomings were	
observed?	
5.4.4. What was the number of inspections carried out in ART	Data not available at national level
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	Data not available at national level
establishments where major shortcomings were noted?	Data not available at mational level
5.4.6. What was the number of inspections carried out in ART	Data not available at national level
establishments followed by suspension of authorisation?	Data not available at national level
5.4.7. What was the number of inspections carried out in ART	Data not available at national level
establishments followed by closure of respective	Data not available at national level
establishments?	
5.4.8. What was the number of other inspections of ART	Data not available at national level
establishments? Please specify.	Data not available at handhal ievel
5.5. Which type of routine inspections do you conduct? (more	General system-oriented inspections
than 1 answer possible)	Desk based reviews
5.6. How do you decide which type of routine inspection to	The regional authority plans ahead the type of inspection.
conduct?	The regional authority plans ahead the type of inspection.
	V.
5.7. Until 2011, did you implement the requirement concerning	Yes
the time interval between two inspections (Art. 7.3.)?	(For ART data not available at national level)
5.7.1. Why not?	Regional Authorities are in charge of inspections.
5.7.2. How do you prioritize tissue establishments to be	The regional authority prioritizes the Tissue Establishement to be
inspected?	inspected.
5.8. How many TEs were inspected at least twice between 2008-	Data not available at national level.
2011 (01/01/2008-31/12/2011)?	Data not available at national level.
5.9. Did you perform/conduct inspections of procurement sites	Yes
outside tissue establishments?	1 65
5.9.1. If yes, how many?	Data not available at national level.
5.10. Did you carry out inspections of third parties?	No
5.10.1 If yes, how many?	Data not available
5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell	Yes  For APT No since the Ministry of Health has no consulty to corry direct
1	For ART No since the Ministry of Health has no capacity to carry direct
procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	inspections of centres in the Authonomous Regions
inspections (Commission Decision 2010/453/EU)?	
5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	Ves
	Yes For APT No.
	For ART No
5.12.1. If yes, how would you rate the usefulness and efficacy of	
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important,	For ART No
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	For ART No 4
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue	For ART No
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in	For ART No 4
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	For ART No 4 No
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue	For ART No 4 No Yes
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in	For ART No 4 No
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	For ART No  4  No  Yes For ART No
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in	For ART No  4  No  Yes For ART No  The inspectors of the HTA (UK) inspected the Transplant Services
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5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?  5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	For ART No  4  No  Yes For ART No  The inspectors of the HTA (UK) inspected the Transplant Services

	authorities have been asked to inspect some centers at the request of
	NCAs of other countries.
5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	No
5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	No
5.17. Would you be interested in developing joint inspections?  Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States'  Competent Authorities on their territory or in third countries.	Yes For ART No
5.18. Do you have any additional comments on inspections?	No No
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries?	No
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).	The authorizations in Spain are given for all the activities at a time, i.e. procurement, processing, storing, distribution, import and export, so that all the TEs are authorized to import and export.  For ART, exchanges of sperm, oocytes or embryos with other countries belonging to the EU, which are the more frequent in ARTs cannot be considered import nor export, and cannot be subject of any kind of special controls.
6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).	Please see 6.2
6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.	The requests to import tissues and cells are received at the ONT from the concerned TE.  The ONT prepares the favorable report which is sent to the Ministry of Health (Public Health General Directorate). Imports are specifically authorized by this DG.  The TE presents the requested documents at the ONT. Since several requirements have to be met, the responsible at the ONT verifies that the standards of quality and safety are equivalents to the Spanish ones.
6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.	Please see 6.4
6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries.	Please see 6.4
6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.	Please see 6.4
6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries.	Please see 6.4
6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries.	Please see 6.4
<ul> <li>6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries.</li> <li>6.11. Did you import tissues/cells from 3rd countries during</li> </ul>	Importation of sperm, oocytes or embryos from third countries not belonging to the UE is very uncommon, reduced to a little number of individual requests. When these cases take place, they are directed to some fixed customs, following the procedure described in 6.4.  Yes
2011 (01/01/2011-31/12/2011)?	For ART not applicable

6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin.	CBU 60, PBSC 49, BM 18, musculoskeletal 700
6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes For ART not applicable
6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination.*	CBU 96, PBSC 3, blood vessel 2, musculoskeletal 25
6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?	No
6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible)	A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.  D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled
6.14.1. If A or D were selected, please explain how you quantify local/national needs.	Each regional authority checks the local needs and the availability of tissues. Then, the ONT does the same at the national level before preparing the report which is sent to the Ministry of Health (Public Health General Directorate). Please see also 6.4.  The HSC are regulated by a different system, based on the Bone Marrow Donors Worldwide (BMDW) Standards.
6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	No
6.16. Do you have any additional comments on import/export?	
7. Distribution/intra community exchanges (Article 23 Directive 2	004/23/EC)
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1 Please specify	The free circulation of tissues and cells among the EU Member States is assumed in Spain.  For ART is the same.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	No
7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	By the inspections
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Other
7.3.1 Please specify	All the tissues and cells are distributed through a Spanish TE except for the distribution of products derived of human tissues such as DBM and lyophilized products which may have a direct distribution to hospital/clinics.  For ART it is only via an authorised TE in my MS
7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No
7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	Yes For ART No
7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).	Germany: CBU 7, PBSC 4, cardiac tissue 49, blood vessel 7, musculoskeletal 54; Austria: CBU 6, PBSC 1, cardiac tissue 6, blood vessel 3; Belgium: CBU 5, PBSC 1; Czech Republic: CBU 1; Croatia: CBU 1; Denmark: CBU 4; France: CBU 48, PBSC 6, BM 2, blood vessel 2, musculoskeletal 30; Greece: CBU 5, cardiac tissue 1, musculoskeletal 202; Netherlands: CBU 20, cardiac tissue 8, blood vessel 7, musculoskeletal 42; Hungary: CBU 6; UK: CBU 23, PBSC 2, skin 72, cardiac tissue 2, Italy: CBU 10, cornea; Poland: PBSC 1;

	Portugal: CBU 1, skin 4, musculoskeletal 115
7.5.2. Please provide us with data (country of origin, type of	Germany: CBU 8, PBSC 134, BM 58;
tissue/cell and number of units distributed) concerning	UK: CBU 3, PBSC 12, BM 8;
distribution to other MS in 2011 (01/01/2011-31/12/2011)	Portugal: PBSC 13, BM 1;
	France: CBU 6, PBSC 7, BM 6;
	Italy: CBU 2, PBSC 2, BM 2, cornea 1;
	Poland: PBSC 2;
	Belgium: CBU 1; Netherlands: musculoskeletal 1243
7.6. Are you aware of any significant changes in 2012 which	No
may invalidate the 2011 data on cross-border exchanges of	
tissues/cells between your country and other EU MS?	
7.7. Do you allow brokerage companies for either distribution in	Yes
EU and/or import/export of tissues/cells? In this context, a	For ART No
brokerage company means a body that arranges transactions	
between a supplier (tissue establishment/company selling tissues	
or cells) and a buyer (a tissue establishment/a hospital or	
clinic/an individual) without undertaking activities of	
processing, preservation or storage.	
7.7.1. Please describe the legal requirements and your role (if	A system for the authorization exists and is regulated in the Royal
any) as a Competent Authority, in their authorization	Decree.
/monitoring or inspection	Nevertheless, the RAs provide the authorizations, as already mentioned.
, momentum of mapounds	The relations of the provide the damentations, as allowing inclined in
7.8. Are brokers actively supplying health	Yes
professionals/establishments in your country?	For ART No
professionals, establishments in your country.	1011111110
7.8.1. Where are the brokers located?	Your country
, io where are are ordered received.	Another country
7.8.2. If the broker is located in another country, how	If the tissues are coming into Spain from a non- EU country, there is a
easy/difficult is it to ensure that safety and quality requirements	thorough document revision.
are met?	anorough document to violen.
	AT.
/.9. Do you have any additional comments on distribution?	No.
7.9. Do you have any additional comments on distribution?  8. Register of tissue establishments and reporting obligations (	
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8. Register of tissue establishments and reporting obligations (8.1. Do you have an annual report model/template on the	Article 10, Directive 2004/23/EC) Yes
8. Register of tissue establishments and reporting obligations ( 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State?	Article 10, Directive 2004/23/EC)  Yes  For ART the report, based on a noncompulsory register on activities in
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	ARTs.
8.7. Do you have any additional comments on reporting?	No.
9. Traceability (Article 8, Directive 2004/23/EC; and Directive	2006/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in your country?	No
9.1.1. If no, why not?	It has been partially implemented, awaiting the final guidance from the Commission.
	For ART, a compulsory general register of donors is not yet implemented. Data of donors are conserved at the centers.
9.2. Who assigns the unique code for each donation? (only 1 answer possible)	Other
Please specify	It has been partially implemented, awaiting the final guidance from the Commission.
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify.	There is an obligation as stated in the regulation. For ART not yet regulated.
9.5. Do you have any additional comments on traceability?	No.
10. Notification of serious adverse events and reactions (Article	e 11 Directive 2004/23, Article 6 Directive 2006/86)
10.1. Do you have a national vigilance system in place (for the	Yes
reporting of serious adverse events and reactions (Article 11(1))?	For ART No
10.1.1. If yes, which CA/institution is responsible?	The ONT as the National Competent Authority, the regional competent authorities and the National Group of Biovigilance. For ART, Regional Authorities are responsible of control of ARTs centers in its own territories
10.1.2. If yes, please provide a short description of its organisation.	The Vigilance Network is constituted by three levels:  1) hospital/centres- all authorized centres (for procurement, processing and transplantation).  2) regional level- regional competent authorities  3) national level- the ONT  The National Group of Biovigilance is responsible for the coordination
	of vigilance tasks and also gives the approval to the annual national report.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	Yes
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes For ART No
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	Yes For ART No
10.4.1. Why not?	Not applicable to ART
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes For ART No
10.6.1. If yes, please provide a brief description.	There is a procedure approved* in 2009 by the Interterritorial Council for the reporting and management of SAR/SAE occurred in procurement centres, tissue establishments and transplantation centres. Please note that the procedure takes into account possible SAR/SAES in living donors at procurement centres.  The system establishes principles and rules for notification and management and respects the internal organisation of the National Health System and the Spanish administration.  * National Vigilance Protocol, accessible at http://www.ont.es/infesp/TejidosPHCelulas/Sistema de Biovigilancia.p

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10.7. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at national level?	For ART No
10.7.1. Please specify	An annual report is provided in a specific meeting to the network, then presented to the Transplantation Committee of the Interterritorial council, and finally sent, in written format, to the network.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes For ART No
10.8.1. Please specify	Alerts are transmitted to the TE through the Vigilance Network
10.9. Do you require your TEs to have a recall procedure?	Yes For ART No
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	None in 2011
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes For ART No
10.11.1. If yes, please give a short description of the system/procedure.	An alert can be quickly transmitted to the vigilance network by an established dissemination procedure, using mail and the 24 hours coordination office at the ONT.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes For ART No
10.12.1. If yes, please give a short description of the system/procedure	The same system is used for EU alerts transmitted via RATC platform.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	No
10.13.2. If no, please specify why not	Because those data are sent to the European Commission.
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	Yes For ART No
10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	Haemovigilance Pharmacovilance Medical devices
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes For ART No
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1(insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	4 very good
10.16. Do you have any additional comments on SARE reporting?	No.
11. Consent and personal data protection (Article 13 and 14, D	irective 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Written consent is a mandatory requisite for living donation. It cannot be carried out without it, likewise i.e. being of age, or good health status.
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed (opt-out) and explicit (opt-in) consent
11.2.1. If you have chosen both consent systems for deceased tissue/cell donation, please specify	Although in Spain there is presumed consent by law (i.e. Ley 30/1979 art.5), in practice the families are always approached and they have the last decision, which is respected (a form is always signed).
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	First degree relatives (including spouse) Other relatives Other
Please specify 'other'.	'Other relatives' are asked (i.e. siblings) for the donation whenever there are no first degree relatives (spouse, parent, or sons/daughters).

	For ART no further authorization is needed
11.4. Is the consent system for deceased tissue donation the same as for organs?	No
11.4.1. If no, please describe the difference.	Sometimes the consent is given for organs and tissues together, and sometimes it is specific for tissues.
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Other
Please specify 'other'.	The consent form remains in the corresponding record for each donor.
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level For ART information for donors are controlled at regional level
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	<ul> <li>Restricted Access to personal information.</li> <li>Confidentiality regulated by Law, and sanctionable in cases it is not fulfilled.</li> <li>Dissociation mechanisms in place.</li> <li>Contracts with third parties establishing such obligation.</li> <li>Data protection supervision at hospital, regional and national level etc.</li> </ul>
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	All those mentioned above plus a specific ban to disclose any information which may allow identification between donor and recipient or to their relatives.
11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	No
11.9.1. If no, please specify the circumstances and measures in place.	Disclosure of donor data can only be done in case of congenital diseases appeared.
11.10. Do you have any additional comments on consent and data protection?	No
12. Selection, evaluation and procurement (Article 15 Directive	e 2004/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible)  12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible)	Inspections of TEs and procurement sites Audit of documentation  Inspections of ART centres
12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC?	No
a deceased donor of tissues/cells? (more than 1 answer possible)	Interview with the donor's family or a person who knew the donor well Medical records of the donor Interview with the treating physician Interview with the general practitioner Autopsy report
12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	No
12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC?	No
12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?	No
12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written	Inspection of tissue establishment Audit of tissue establishment Inspection of the centre of human application (e.g. transplantation centre, ART centre) Audit of the centre of human application

SOP, standards or governments laws and regulations (from	
Council of Europe Guide to the Safety and Quality Assurance	
for the Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	No.
evaluation and procurement?	
13. Quality management, responsible person, personnel (Artic	
13.1. How do you ensure that tissue establishments in your	Authorisation requirement
country have in place a quality system respecting the provisions	Inspections
of the Directive 2004/23/EC Art 16.1? (more than 1 answer	
possible). (For this question "audit" means a documented review	
of procedures, records, personnel functions, equipment,	
materials, facilities, and/or vendors in order to evaluate	
adherence to the written SOP, standards or governments laws	
and regulations (from Council of Europe Guide to the Safety and	
Quality Assurance for the Transplantation of Organs, Tissues	
and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)?	Inspections
(more than 1 answer possible)	Authorization manipulation
13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue	Authorisation requirement Inspections
· ·	Regular evaluation of personnel
establishments? (more than 1 answer possible)	Mandatory trainings
13.4. Do you have national/regional/local training programmes	Yes.
for the personnel of tissue establishments?	For ART No
13.4.1. If yes, please specify.	There are training programmes dedicated to T&C donation and
	transplantation and all aspects related, as well as specific programmes
13.5. Any additional comments on quality management,	dedicated to particular areas (i.e. inspections).
responsible person, personnel?	
14. Reception, processing, storage, labelling and packaging (A	rt 19-22 Directive 2004/23/EC)
14.1. How do you ensure that tissue establishments in your	National regulation/policy for reception of tissues/cells
country fulfill the requirments of the Art. 19 (Tissue and cell	Inspections of tissue establishments
reception) of Directive 2004/23/EC and Annex IV of Directive	
2006/17/EC? (more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your	SOPs for all processes affecting quality and safety are mandatory for
country fulfill the requirements of the Art. 20 (Tissue and cell	authorisation
processing) of Directive 2004/23/EC? (more than 1 answer	Inspections of tissue establishments
possible)	
1/1 4 Horry do you angues that tragge actable belowered an ever-	CODe for procedures associated with storage of times and only
14.3. How do you ensure that tissue establishments in your	SOPs for procedures associated with storage of tissues and cells are
country fulfill the requirements of Art. 21 (tissue and cell storage	mandatory for authorisation
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country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling,	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are
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country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes For ART No
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15. Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes For ART No Yes
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15.1. Are third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes For ART No
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15.1. Are third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes For ART No Yes
country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible)  14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.5. Any additional comments on reception, processing, storage, labelling and packaging?  15.Third party agreements (Art. 24 Directive 2004/23/EC)  15.1. Are third party agreements foreseen/allowed in your national legislation?  15.1.1. If yes, have tissue establishments in your Member State notified third party agreements?  15.1.1.1. Under which circumstances and for which responsibilities?	mandatory for authorisation Inspections of tissue establishments  SOPs for procedures associated with labelling and packaging are mandatory for authorisation Inspections of tissue establishments  No  Yes For ART No  Yes Those allowed in the regulation, i.e, supply of materials, storage, etc.

15.2. Any additional comments on third party agreements?	No
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and	No
safety requirements than those requested by the EU legislation in	
this field (e.g. restrictions concerning the donation/use of certain	
tissues/cells, mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	ART provisions
implementing the requirements in the EU Tissues and Cells	Import-export
Directives? Please choose from the options below.	Traceability
16.2.1. For all selected options in question 16.2., please provide a short description.	Import-export: it is necessary the publication of the Directive with homogeneous criteria of import/export.  Traceability: clarifications on the coding are needed in order to have more functional and traceable systems.  For ART: a high percent of ART centers are private. ART policies are not a priority for many regional authorities, being on the contrary a high priority for a short number of them. National policies are more difficult in this context.
16.3. In your opinion, in which of the following Directives are	No shortcomings
there shortcomings (if any)? (more than 1 answer possible)	

## A.1.29. Survey response Sweden

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Health and Social Care Inspectorate / Inspektionen för vård och Omsorg
1	(IVO)
1.1.2. Address of NCA 1:	IVO Box 45184 104 30 Stockholm Sweden
1.1.3. Telephone (central access point):	+46 10 788 50 00
1.1.4. E-mail (central access point):	registrator@ivo.se
1.1.5. Website:	www.ivo.se
1.1.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Reproductive tissues and cells
possioic)	Blood and blood components
	Human organs
1.1.7. What are the role/tasks of the NCA? (more than 1	Accreditation, authorisation, licensing of TEs
answer possible)	Inspection
answer possible)	Vigilance
1.2. National Competent Authority 2?	Yes
1.2.1 Name of National Competent Authority 2:	
1.2.2. Address of NCA 2:	Medical Products Agency
	Läkemedelsverket Box 26 751 03 Uppsala Sweden
1.2.3. Telephone (central access point):	+46 18 1746 00
1.2.4. E-mail (central access point):	registrator@mpa.se
1.2.5. Website:	www.lakemedelsverket.se
1.2.6. The NCA is responsible for? (more than 1 answer	Pharmaceuticals
possible)	Medical devices
	Other
Please specify 'other':	Tissues and cells for manufacturing of Advanced therpuetic medicinal
	products (ATMP)
1.2.7. What are the role/tasks of the NCA? (more than 1	Accreditation, authorisation, licensing of TEs
answer possible)	Inspection
	Vigilance
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	The National Board of Health and Welfare
1.3.2. Address of NCA 3:	Socialstyrelsen 106 30 Stockholm Sweden
1.3.3. Telephone (central access point):	+46 75 247 30 00
1.3.4. E-mail (central access point):	socialstyrelsen@socialstyrelsen.se
1.3.5. Website:	www.socialstyrelsen.se
1.3.6. The NCA is responsible for? (more than 1 answer	Non-reproductive tissues and cells
possible)	Reproductive tissues and cells
	Blood and blood components
	Human organs
1.3.7. What are the role/tasks of the NCA? (more than 1	Other
answer possible)	
Please specify 'other':	Regulatory, Disease precautions, National registries and statistics
1.4. National Competent Authority 4?	No
1.5. Please give a short description of the legal status and	Health and Social Care Inspectorate: Independent CA with assignment from
organisation of the National Competent Authority(ies) (e.g.	the government to supervise and authorize health care and social care in
departments, staffing, number of senior and junior	Sweden. Total no of staff approx 500 localized as six regional offices and
inspectors, staff working on EU affairs and legal matters,	one central office. The staff consists of expertise in the areas for supervision,
vigilance officers, budget, independence from government	accordingly most personnel holds a degree in medicine- or social sciences
etc.).	alternativly are legal advisors. Supervision according to EU directives is
	centralized to one regional department in Stockholm and those inspectors (3)
	are contact points for EU affairs dealing with Blood, tissues and cells and
	organs. Medical Products Agency: Independent CA responsible for
	regulation and surveillance of the development, manufacturing and sale of
	drugs and other medicinal products. Its operations are largely financed
	through fees. Approximately 750 people work at the agency; most are
	pharmacists and doctors. The agency is divided into four departements;
	Development, Licencing, Supervision and Usage. The agency are actively
	involved in EU matters in the field of pharmaceuticals and medicinal
	poducts. The National Board of health and Welfare: Independent CA with
	results in the results and or neutri and reside. Independent of with

	assignment from the governement to perform follow up, national guidelines, issue bylaws and keep national registries in the areas of Health care and Social care. Total no of staff is approx 400 divided into three departments; Regulation, Statistics and Knowledge based Policy and Guidance. EU matters in these areas are coordinated from the staff of the Director Gerneral
1.6. In case of MS with federal or decentralised systems,	Not applicable
please indicate the roles/tasks of the Regional Competent	
Authority(ies). (more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of	Not applicable;
the Regional Competent Authority(ies) and their relation	
with the National Competent Authority(ies) for tissues and	
cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of	By inspecting some procurement centres
procurement"? (more than 1 answer possible)	By inspecting the documentation associated with procurement that is
Freezenson (Contraction of Property)	available in the tissue establishment working with procurement centres
2.1.2. How many such authorisations were granted in 2011	The TE holds the authorization , only procurement is not authorized.
(01/01-31/12/2011)?	110 12 notes the authorization, only procurement is not authorized.
2.2.1 Please provide the number of procurement centres in	34
which procurement of "traditional tissues and cells" (skeletal	34
tissues, cardiovascular tissues, skin, ocular tissues, amniotic	
membrane, pancreatic islet, hepatocytes, adipose tissue etc.)	
were carried out in 2011 (01/01-31/12/2011).	
2.2.2 Please provide the number of procurement centers in	7
which procurement of haematopoietic stem cells (bone	
marrow, PBSC, cord blood etc.) were carried out in 2011	
(01/01-31/12/2011).	
2.2.3 Please provide the number of procurement centers in	17
which procurement of gametes, embryos and other	
reproductive tissues were carried out in 2011 (01/01-	
31/12/2011).	
2.2.4. Please provide the number of procurement centers in	3
which procurement of tissues/cells for ATMP manufacturing	
were carried out in 2011 (01/01-31/12/2011).	
2.3. How do you ensure that procurement centres comply	Inspections of the site/centre
with the requirements laid down in Art. 5 of Directive	Analysis of the mandatory documentation
2004/23/EC and its implementing Directive 2006/17/EC	Other
(e.g. trained personnel, conditions accredited, designated,	
authorised, licensed) ? (more than 1 answer possible)	
Please specify 'other':	Most of the TE 's (i.e 45 out of 52) also procure the tissues & cells and for
	the other TE's it is the responsibility of the TE to perform audits at the
	procurement center, and the result of these audits are examined during the
	inspection of the TE
2.4. Are you also responsible for the accreditation,	No
designation, authorisation or licensing of laboratories	
performing donor testing?	
2.4.2. Which National Authority is in charge of this activity?	The Swedish Board for Accreditation and Conformity Assessment
	(SWEDAC) www.swedac.se
2.5. How do you ensure, as CA for T&C, that tests	Analysis of the mandatory documentation requested from the tissue
required for donors are carried out only by qualified	establishment
laboratories accredited, designated, authorised or licensed	Other
Art. 5(2))? (more than 1 answer possible)	
Please specify 'other':	The TE are requested to show which laboratory they use for donor testing
	(and have a written agreement if applicable ) The accreditation by
	SWEDAC is publicly available and the laboratory holds an accrediatation
	licence.
2.6. Please provide data on qualified laboratories accredited,	32 laboratories (Clinical microbiology are accredited by SWEDAC)
authorised or licensed in your country (e.g. number, year of	http://search.swedac.se/sv/ackrediteringar?ackomrade=1%3AKlinisk%20mi
accreditation/authorisation/license, which donor tests are	krobiologi.
and a sum of the sum o	

performed etc.).	
2.7. Do you have any additional comments on procurement?	
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/1	7/FC)
3.1. Please specify laboratory tests required for donors of	Anti-HIV 1
non-reproductive tissues and cells in your Member State.	Anti-HIV 2
(more than 1 answer possible)	Ag HIV
( · · · · · · · · · · · · · · · · · · ·	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more	Anti-HIV 2
than 1 answer possible)	Ag HIV
	HBs AG
	Anti HBc
	Anti HCV-Ab
	HTLV-2
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could	Epidemiological data in Sweden does not motivate a legal obligation to
you please indicate whether you intend to make it mandatory	perform NAT testing. The National Board of Helath and Welfare and the
or to encourage its use? Please specify why or why not (e.g.	Swedish Institute for Communicable Disease Control have the
number of additional cases detected, cost-benefit etc.).	responisibility to follow and perform risk assessments of these diseases and
	for the moment we have no indications that NAT testing will be mandatory.
3.4. Do you have concerns on accuracy of the available tests	No
and test procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of	No
non-reproductive tissues and cells in your Member State?	N.
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	V
3.7. Do you request/use international accreditation systems	Yes
for testing laboratories?	TI A 1'44' 1 CWEDAC' 1 1 CC EN 100 15100 2007
3.7.1. Please specify.	The Accreditation by SWEDAC is based on SS-EN ISO 15189:2007
3.8. Do you have any additional comments on testing?	alternatively SS-EN ISO 17025: 2005  All tissue establishments are legally obliged to use an Accredited laboratory
3.8. Do you have any additional comments on testing?	for donor testing, and some may also have additional tests performed
	depending on their own wishes i.e EBV, CMV for HPC donors or
	Chlamydia for oozyte donors.
4. Accreditation, designation, authorisation or licensing of	
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue	165
establishments under your responsability?	
4.2. Is inspection a prerequisite for the designation,	No
authorisation, accreditation or licensing of tissue	
establishments?	
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer	By review of a submitted application with supporting documentation
possible)	, and a series of the series o
4.4. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many	
authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive	0
2004/23/EC), how many	
authorisations/accreditation/licenses were revoked in 2011?	
4.6. Do you require TEs to be certified by an external entity	No
to a quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by	the NCA
4.7. Tissue establishments with authorisation pending	Skin tissue establishments
approval at 01/01/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
	Ocular tissue establishments
	1

	<del>,</del>
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.7.1. How many skin tissue establishments?	0
4.7.2. How many musculo-skeletal tissue establishments?	0
4.7.3. How many ocular tissue establishments?	0
4.7.4. How many cardiovascular tissue establishments?	0
4.7.5. How many HSC tissue establishments?	0
4.7.6. How many cord blood tissue establishments?	0
4.7.7. How many ART tissue establishments?	0
4.7.8. How many multi-tissue establishments?	0
4.7.9. Please specify the type of tissues/cells and how many.	TE's processing Cells for ATMP = 0 pending
4.8. Tissue establishments with authorisations pending	Skin tissue establishments
approval by 31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.8.1. How many skin tissue establishments?	0
4.8.2. How many musculo-skeletal tissue establishments?	0
4.8.3. How many ocular tissue establishments?	0
4.8.4. How many cardiovascular tissue establishments?	0
4.8.5. How many HSC tissue establishments?	0
4.8.6. How many cord blood tissue establishments?	0
4.8.7. How many ART tissue establishments?	1
4.8.8. How many multi-tissue establishments?	0
4.8.9. Please specify the type of tissues/cells and how many.	TE's processing cells for ATMP = 0 pending
4.9. Tissue establishments first time authorised between	Skin tissue establishments
01/01/2011 and 31/12/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
on on 2011 and 31/12/2011 (more than 1 answer possible).	Ocular tissue establishments
	Cardiovascular tissue establishments
	HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.9.1. How many skin tissue establishments?	0
4.9.2. How many musculo-skeletal tissue establishments?	0
4.9.3. How many ocular tissue establishments?	0
4.9.4. How many cardiovascular tissue establishments?	0
4.9.5. How many HSC tissue establishments?	
4.9.6. How many cord blood tissue establishments?	0
4.9.7. How many ART tissue establishments?	0
4.9.8. How many multi-tissue establishments?	0
4.9.9. Please specify the type of tissues/cells and how many.	TE's processing cells for ATMP = 0
4.9.9. Please specify the type of tissues/cells and now many.  4.10. All tissue establishments authorised by 31/12/2011	Skin tissue establishments
	Musculo-skeletal tissue establishments
(more than 1 answer possible):	
	Ocular tissue establishments
	Cardiovascular tissue establishments HSC tissue establishments
	Cord blood tissue establishments
	ART tissue establishments
	Multi-tissue establishments
	Other tissue establishments

Г	
4.10.1.1. How many public skin tissue establishments?	3
4.10.1.2. How many private skin tissue establishments?	0
4.10.2.1. How many public musculo-skeletal tissue	15
establishments?	
4.10.2.2. How many private musculo-skeletal tissue	0
establishments?	
4.10.3.1. How many public ocular tissue establishments?	2
4.10.3.2. How many private ocular tissue establishments?	0
4.10.4.1. How many public cardiovascular tissue	1
establishments?	
4.10.4.2. How many private cardiovascular tissue	0
establishments?	
4.10.5.1. How many public HSC tissue establishments?	5
4.10.5.2. How many private HSC tissue establishments?	0
4.10.6.1. How many public cord blood tissue	1
establishments?	
4.10.6.2. How many private cord blood tissue	0
establishments?	O .
4.10.7.1. How many public ART tissue establishments?	6
4.10.7.2. How many private ART tissue establishments?	10
4.10.7.2. How many private ART tissue establishments? 4.10.8.1. How many public multi-tissue establishments?	5
• 1	
4.10.8.2. How many private multi-tissue establishments?	DIFFERENCE INC. ATMOS. 1
4.10.9.1. Please specify the type of 'other' public tissues/cells	Public TE processing cells for ATMP = 1
establishements and how many.	
4.10.9.2. Please specify the type of 'other' private	Private TE processing cells for ATMP = 1
tissues/cells establishements and how many.	
4.11. How many tissues and cells were distributed under the	0
direct agreement of the Competent Authority according to	
Art. 6(5) during 2011? Please provide number(s) per type	
tissues/cells.	
100000, 00110.	
4ter. Sanctions	
	Yes
4ter. Sanctions	Yes
4ter. Sanctions 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?	Yes
4ter. Sanctions 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? 4.16.1. Have penalties already been imposed?	Yes No
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on	
4ter. Sanctions 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? 4.16.1. Have penalties already been imposed?	
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on	
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?	
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)	No
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and	No
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?	No Yes
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in	Yes  The Health and Social Care Inspectorate (previously the dept of Supervision
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in	Yes  The Health and Social Care Inspectorate (previously the dept of Supervision at National Board of Health and Welfare ) have centralized coordination of the inspections and supervision to one department located in Stockholm. The
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in	Yes  The Health and Social Care Inspectorate (previously the dept of Supervision at National Board of Health and Welfare ) have centralized coordination of
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Yes  The Health and Social Care Inspectorate (previously the dept of Supervision at National Board of Health and Welfare ) have centralized coordination of the inspections and supervision to one department located in Stockholm. The coordinators plan the inspections which are then performed together with a regional inspector .
4ter. Sanctions  4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?  4.16.1. Have penalties already been imposed?  4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing?  5. Inspections (Article 7, Directive 2004/23/EC)  5.1. Is a system in place for organising inspections and control measures of tissue establishments?  5.1.1. If yes, please specify the CA/Department of the CA in	Yes  The Health and Social Care Inspectorate (previously the dept of Supervision at National Board of Health and Welfare ) have centralized coordination of the inspections and supervision to one department located in Stockholm. The coordinators plan the inspections which are then performed together with a
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(from 1/1/2011 to 31/12/2011) following serious adverse	
events or reactions, or suspicion thereof?	
5.3.2. How many other type of inspections of tissues	0
establishments for non-reproductive tissues/cells were	
conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due	
to a whistle-blower)? Please specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	4
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
l ``	
What was the number of inspections carried out where no	
shortcomings were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	18
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where minor	
shortcomings were noted?	
5.3.5. Outcome of inspections of TEs for non-reproductive	2
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out where major	
shortcomings were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	0
	U
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out that were	
followed by suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of inspections carried out that were	
followed by closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011):	
What was the number of other inspections carried out?	
Please specify.	
5.4. How many routine inspections were conducted in ART	16
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART	0
establishments following serious adverse events or reactions,	
or suspicion thereof (from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted	0
on ART establishments (from 1/1/2011 to 31/12/2011) (e.g.	
due to a whistle-blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments	3
	3
carried out in 2011 (01/01/2011 to 31/12/2011): What was	
the number of inspections carried out where no	
shortcomings were observed?	
5.4.4. What was the number of inspections carried out in	13
ART establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in	0
ART establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in	0
ART establishments followed by suspension of	Ĭ
authorisation?	
5.4.7. What was the number of inspections carried out in	0
ART establishments followed by closure of respective	
establishements?	
5.4.8. What was the number of other inspections of ART	0
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct?	General system-oriented inspections
(more than 1 answer possible)	Thematic inspections
()	Desk based reviews
5.6. How do you decide which type of routine inspection to	The general system oriented inspection is always one part, then a
conduct?	theme/focus for the routine inspection is decided by the coordinators,
	depending on occurances during the year (reported SAR/SARE, risk
	assessment or any paricular questions / unclear matters that have been

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	discussed since last inspection round) . Each inspection is preceded by a demand to send certain documentation to the inspector (Respond to a Questionaire and attach relevand documents) and these are reviewed prior to the inspection.
5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)?	No
5.7.1. Why not?	All TE's were authorized 2010, and accordingly inspected for the first time 2010 and 2011. Thereafter the time interval between inspections has not exceeded 2 years.
5.7.2. How do you prioritise tissue establishments to be inspected?	Our first two inspections (2010) were chosen in order to test and evaluate our inspection protocol; we chose one TE that we suspected had everything "in place" and one TE that we suspected to have some problems. Thereafter we evaluated our inspection protocol, and inspected a multi-TE in order to get an overview of the various procedures for different tissues and cells. After this, inspections have been carried out according to their location and the most suited coordinator and according to the time scheme.
5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)?	1 (one of the first pilot TE's that did not have all mandatory routines / documents in place was inspected 2010 and 2011 based on the result of the pilot-inspection)
5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments?	No
5.9.2. If no, why not?  5.10. Did you carry out inspections of third parties?	Most TE's also procure the tissues and cells and if not, we require (and review) a written agreement between the procurement center and the TE.
5.10.2. If no, why not?	Written agreements are required (and reviewed) if any third part is involved in the chain between procurement and clinical use of the T&C . The most pertinent "third part", the laboratory performing donor testing, is Accredited by another CA and we do not intervene or overlap with other CA's inspections. In addition it is the responsibility of the TE to perform audits/review any third part that they have agreement with.
5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	No
5.11.1 If no, which guidelines/regulations are used for inspections at national level?	In principle we follow the Guidelines for inspections, but adapted to the organisation of TE's in Sweden. The regulations "Socialstyrelsens föreskrifter" SOSFS 2009:30, SOSFS 2009:31 and 2009:32 covers Donation - Tissue establishments - and Usage of Tissues and Cells respectively and our inspections are based on these regulations.
5.11.2. If no, please provide a hyperlink to these	http://www.socialstyrelsen.se/sosfs/2009-30;
guidelines/inspections.	http://www.socialstyrelsen.se/sosfs/2009-31; http://www.socialstyrelsen.se/sosfs/2009-32
5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	No
5.12.2. Why not?  5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	Lack of time No
5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	No No
5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	No
5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	No

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5.17. Would you be interested in developing joint	Yes
inspections? Joint inspections should be understood as	
inspections of tissue establishments conducted jointly by two	
or more Member States' Competent Authorities on their	
territory or in third countries.	
5.18. Do you have any additional comments on inspections?	1. Joint inspections would be valuable in particular in the situation where a
	TE has procurement activities in an other MS . 2. The number of
	inspections (non-reproductive tissues and cells) exceeds the total number of
	"minor"- "major"- and "no shortcomings" due to that some TE's have more
	than one site and inspections were carried out on more than one site, wheras
	only one inspection report to the TE was written.
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue	Yes
establishments that are explicitly authorised to perform	
import/export of tissues and celles from/to third countries?	
6.2. Please specify the number of tissue establishments	6
authorised to import tissues and cells from third countries	
(recorded by 31/12/2011).	
6.3. Please specify the number of tissue establishments	6
authorised to export tissues and cells from third countries	
(recorded by 31/12/2011).	
6.4. Please specify which procedures you have in place for	it is the responibility of the importing TE to ensure that quality and safety of
verifying the equivalent standards of quality and safety for	the tissues and cells to be imported corresponds to the same standard as the
importation of skin from third countries.	T&C Directive (no import licences for skin is currently authorized)
6.5. Please specify which procedures you have in place for	it is the responibility of the importing TE to ensure that quality and safety of
verifying the equivalent standards of quality and safety for	the tissues and cells to be imported corresponds to the same standard as the
importation of musculo-skeletal (bone, tendons, fascia etc.)	T&C Directive (one import licence for tendons is currently authorized and
tissues from third countries.	the exporting TE is authorized by FDA)
6.6. Please specify which procedures you have in place for	it is the responibility of the importing TE to ensure that quality and safety of
verifying the equivalent standards of quality and safety for	the tissues and cells to be imported corresponds to the same standard as the
importation of ophtalmic (cornea, sclera, etc) tissues from	T&C Directive ( one import licence for ophtalmic tissue is currently
third countries.	authorized and the exporting TE is authorized by FDA)
6.7. Please specify which procedures you have in place for	it is the responibility of the importing TE to ensure that quality and safety of
verifying the equivalent standards of quality and safety for	the tissues and cells to be imported corresponds to the same standard as the
importation of cardio vascular tissues from third countries.	T&C Directive (no import licences for cardio vascular tissue is currently
importation of cardio vascular tissues from time countries.	authorized)
6.8. Please specify which procedures you have in place for	it is the responibility of the importing TE to ensure that quality and safety of
verifying the equivalent standards of quality and safety for	the tissues and cells to be imported corresponds to the same standard as the
importation of haematopoietic stem cells (HSC) (other than	T&C Directive and they use the following criteria 1. Does the exporting
cord blood) from third countries.	TE hold an other accreditation, FACTS, JACIE, WMDA? 2. if not, a
tota stoody from time countries.	Questionaire with focus on quality and safety and traceability will be sent
	out and depending on the answers the importing TE will accept the HPC.
	Since import of HPC is intended for a given patient in need of a
	transplantation, a risk assessment will be performed by the medically
	responisble person wherafter the dicision will be documented.
6.9. Please specify which procedures you have in place for	see answer to 6.8
verifying the equivalent standards of quality and safety for	
importation of cord blood from third countries.	
6.10. Please specify which procedures you have in place for	It is not legally possible to import frozen reproductive cells from third
verifying the equivalent standards of quality and safety for	countries (Swedish law: Lag 2006:351 om genetisk integritet mm)
importation of reproductive cells (sperm, egg cells) from	http://www.notisum.se/rnp/sls/lag/20060351.htm
third countries.	11.1.1 1.4.2.1.1.1.2.1.1.1.2.1.1.1.2.1.1.1.2.1.1.1.2.1
6.11. Did you import tissues/cells from 3rd countries during	Yes
2011 (01/01/2011-31/12/2011)?	103
6.11.1. If yes, please provide the data concerning the	The import was HPC but number of HPC-units as well as the country of
	I
number/volume of imported tissues and cells by country of	origin is not collected by the CA (only the tot number of tissues / cells
origin.	recieved from another TE is collected and that "other TE " may be National,
6 12 Did you armort ti/11- firm 2 1	within another MS or from third country)
6.12. Did you export tissues/cells from 3rd countries during	Yes
2011 (01/01/2011-31/12/2011)?	12 HDC
6.12.1. If yes, please provide the data concerning the	12 HPC units were exported TO 3rd countries during 2011 . The country of

number/volume of exported tissues and cells by country of destination.	destination is not reported to the CA.
6.13. Are you aware of any significant changes in 2012	No
which may invalidate the 2011 data on imports/exports of	
tissues/cells between your country and other third countries?	
6.14. What is the relation between import/export of tissues	C. Export of tissues/cells is authorised irrespective of national needs
and cells and self-sufficiency? (more than 1 answer possible)	E. Import of tissues/cells is authorised based on estimations showing that
	there is chronic deficiency of those tissues/cells
	F. Other
Please specify 'other':	Import and Export of HPC are performed on a patient based need, and the
	TE's authorized for import/export of HPC decide without additional permit
	from the CA .
6.15. Did you authorise direct imports of tissues/cells to	No
hospitals/clinics in your country?	110
6.16. Do you have any additional comments on	
import/export?	
7. Distribution/intra community exchanges (Article 23 Direction)	
7.1. Do you have intra-community exchanges of tissues and	Yes
cells?	
7.1.1. If yes, how do you address the possible more stringent	We use the interpretation that it is the responsibility of the recieving MS to
quality and safety measures established by other Member	make sure that the delivering MS fulfill the national quality and safety
States? Please specify.	measures. If necessary, the recieving MS may ask the Swedish TE to add
	some assay in the donor testing (i.e NAT assays) or any other additional
	requirement that can be fulfilled.
7.1.2. If yes, do you have more stringent quality and safety	Yes
measures than in other Member States?	
7.1.2.1. How do you address this difference for tissues and	For reproductive cells (sperms) the Swedish law require that the donor
cells coming from a MS with minimum quality	identity must be available to the child at adult age, which prohibits the use of
requirements? Please specify.	frozen sperms from other MS where anonomous donations are allowed.
requirements? I lease specify.	=
	Since it is the responsibility of the recieving MS (i.e the Swedish TE) to
	make sure that Swedish regulations on quality and Safety are fulfilled the
	Swedish TE can not use such tissues and cells without violating the national
	laws and regulations. For other tissues and cells (including ATMP) Sweden
	do not have more stringent quality and safety measures than other MS and
	we rely on the authorization given in each MS to be in accordance with the
	Directive and thecnical directives.
7.2. How do you ensure that tissues establishments fulfil the	It is included in our inspections, to ensure that TE's have validated their
requirements of Art. 23 of Directive 2004/23/EC regarding	methods for distribution.
quality of tissues and cells during distribution? Please	
specify.	
7.3. Do you allow direct distribution to hospitals/clinics in	Yes, but only via an authorised TE in my MS
your MS from TEs in another MS? (only 1 answer possible).	
7.4. Have you authorised direct distribution to the recipient	No
of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	
7.5. Do you collect data regarding the cross-border exchange	Yes
of tissue/cells between your country and other EU MS?	
7.5.1. Please provide us with data (country of destination,	Only the number of (unis) tissues and cells distributed to other EU MS are
type of tissue/cell and number of units distributed)	reported, not the country of destination. During 2011; 33 HPC units and 20
concerning distribution to other MS in 2011 (01/01/2011-	blood vessels were distributed to other EU MS / EES.
31/12/2011).	The state of the s
7.5.2. Please provide us with data (country of origin, type of	= 7.5.1 ??
tissue/cell and number of units distributed) concerning	7.5.1 11
,	
distribution to other MS in 2011 (01/01/2011-31/12/2011)	NI-
7.6. Are you aware of any significant changes in 2012 which	No
	No
distribution in ELL and/or import/overage of tiggues/calle? In	110
distribution in EU and/or import/export of tissues/cells? In	
this context, a brokerage company means a body that	
may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? 7.7. Do you allow brokerage companies for either	

(- tit-l.1i-lt/- lit-1lini-/ in dinid1)	T
(a tissue establishment/a hospital or clinic/an individual)	
without undertaking activities of processing, preservation or	
storage.	N.
7.8. Are brokers actively supplying health	No
professionals/establishments in your country?	
7.9. Do you have any additional comments on distribution?	
8. Register of tissue establishments and reporting obligation	ons (Article 10, Directive 2004/23/EC)
8.1. Do you have an annual report model/template on the	Yes
activities of tissue establishments in your Member State?	
(Article 10(1)). If yes, please upload the template.	
8.2. How many tissue establishments submitted annual	100% (all)
reports of their activities during 2011. Please provide an	
estimation. (1 answer possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	They are as all material within a governmental authority in Sweden
	publicly available upon request.
8.4. Do you publish a national annual report of the	Yes
consolidated activities of all tissue establishments in your	
country?	
8.4.1. Please insert the link to the published national annual	http://www.ivo.se/publiceratmaterial/rapporter/Documents/lagesrapport-for-
report.	vavnadsinrattningar-2011-2012.pdf
8.5. Is there a publicly accessible register of authorised	Yes
tissue establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's	http://www.ivo.se/Tillstand-och-
web site.	1
	register/register/vavnadsinrattningar/Sidor/default.aspx Yes
8.6. Do you provide data regarding tissues and cells	Yes
activities to the EUROCET registry (non-mandatory	
reporting)?	
8.6.1. If yes, what data are provided to EUROCET? Please	All available data, but Eurocet do ask for much more data than specified in
specify.	the Directive and all of these data are not collected by the CA. In particular
	concerning ART (different IVF methods, no.of births ect) and HPC
	(diagnoses, number of searches in different registries etc)
8.7. Do you have any additional comments on reporting?	
9. Traceability (Article 8, Directive 2004/23/EC; and Direc	tive 2006/86/EC)
9.1. Was the donor identification system (Art. 8(2))	No
implemented in your country?	
9.1.1. If no, why not?	All TE's have a donor identification system, but it is not (yet) a common
	coding system for all TE's. Most tissues and cells are procured, storaged
	and used within the same TE or hospital and therefore we have accepted
	local coding systems . For HPC that are distributed between TE's - hospitals
	and cross- borders the ISBT128 coding system is used.
9.2. Who assigns the unique code for each donation? (only 1	Tissue establishment
answer possible)	
9.3. How is the data storage for traceability purposes	Both paper records and electronic forms
organised in your tissue establishements (Art 8(4))? (only 1	
answer possible)	
9.4. How do you ensure that the 30 years data storage	This is included in our inspections, and for those that have only paper the
requirement is respected (Directive 2006/89/EC, Art. 9)?	storage is in fire-resistant cupboards, for the electronic form we make sure
Please specify.	that the TE have required from their information system support that
Troub specify.	electronic storage is accessible also after new versions of software etc.
9.5. Do you have any additional comments on traceability?	stories storage is accessione also after new versions of software etc.
	4: -1 11 Diversitive 2004/22 A 2: 1 C Div 2: 2006/20
10. Notification of serious adverse events and reactions (An	·
10.1. Do you have a national vigilance system in place (for	Yes
the reporting of serious adverse events and reactions (Article	
11(1))?	
10.1.1. If yes, which CA/institution is responsible?	The Health and Social Care Inspectorate (tissues and cells) and the Medical
	Products Agency (ATMP)
10.1.2. If yes, please provide a short description of its	SAR and SAE are reported directly to the coordinators at the CA close to the
organisation.	event/reaction and in addition an annual report of all SAR and SAE should
	follow the annual report for the activity of the TE. The coordinators collect

	<u></u>
	the reports, evaluate the suggested/ performed actions and classify the
	reports according to clasification that should be reported later to the EC. If
	needed the coordinators may ask for additional actions, that have to be
100 A 1	completed before the report is closed.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do	Yes
you use the SAR/E (to the CA (2006/76 art 6.4)) templates	
developed to the Annual reporting of the EC also at national	
level?  10.3. Do you use the Common Approach Document	V
* **	Yes
developed for the Annual reporting to the EC also at national	
level?	N-
10.4. Do you have a dedicated vigilance officer in charge of	No
collecting SAR/E from all TEs? 10.4.1. Why not?	This is the same staff that perform inspections (i.e the coordinators)
10.5. How many tissue establishments provided in 2011 the	<ul><li>1 ms is the same start that perform inspections (i.e the coordinators)</li><li>&lt;50%</li></ul>
SAR/SAE data as requested (please provide the % from the	30/6
total number of TEs authorised in your country).	
10.6. Do you have a mandatory procedure for the	Yes
transplantation centres when reporting SAR/SAE to the TEs	165
which distributed the tissues/cells (Art 11.2)?	
10.6.1. If yes, please provide a brief description.	The user of tissues and cells should report back to the TE both the actual
10.0.1. 11 yes, piease provide a offer description.	usage (i.e recipient identification-that may be coded or if discarded) and if
	any serious adverese events or reactions occured according to the national
	regulation SOSFS 2009:32 on "Usage of Tissues and Cells within health
	care and clinical reseach"
10.7. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at national level?	163
10.7.1. Please specify.	Every second year we invite 2 staff members from each TE to a meeting
10.7.1.1 lease speeily.	where feedback from the recorded SAR/E as well as from inspections is
	provided. In addition we also discuss interpretation questions and other
	relevant issues. A summary of the recorded SAR/E is also provided in the
	written report which is publically available (see Q .8.4.1)
10.8. Do you give feedback to the TEs regarding SAR/SAE	Yes
recorded at EU level?	
10.8.1. Please specify.	At the meeting mentioned above, with the TE but also at other meetings
Total Troub spoons.	where coordinators are invited to speak about issues relevant to the TE's.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of	0
tissues/cells were issued in your country in 2011? Please	
specify the number and which tissues were recalled and why	
(e.g. missing consent, quality defects etc).	
10.11. Do you have in place a system/procedure to notify	Yes
Tissue Establishments and procurement sites in case of a	
national rapid alert?	
10.11.1. If yes, please give a short description of the	The coordinators have a contact list covering all TE 's and an e-mail is sent
system/procedure.	out togther with an alert on our public webpage.
10.12. Do you have in place a system/procedure to notify	Yes
Tissue Establishments and procurement sites when a rapid	
alert is issued via the EU RATC platform?	
10.12.1. If yes, please give a short description of the	see 10.11.1 and the contact list is divided according to the specific tissues
system/procedure.	and cells handled by the TE so only the relevant TE's are notified.
10.13. Do you provide data regarding SAR/SAE to the	No
EUROCET registry (non-mandatory reporting)?	
10.13.2. If no, please specify why not.	We provide data to the EC, and upon request we could provide
.1 3 3	corresponding data also to Eurocet.
10.14. Do you notify alerts communicated via these tissues	Yes
and cells national vigilance system also to other national	
vigilance/alert systems?	
10.14.1. If yes, please specify which of the following	Medical devices
systems are usually contacted. (more than 1 answer possible)	Other
Please specify 'other'.	If applicable we will notify the MPA (i.e tissues and cells for production of
	T TT COLUMN OF THE PERSON OF

	ATMP) If a medical devise is involved in an event regarding T&C the TE is
	obliged to report this event also to the MPA according to SOSFS 2009:31
	kap 11 4§.
10.15. Did you send a vigilance officer/contact point to the	No
trainings organised by the EU-funded project SOHO	
V&S?	
10.15.2. If no, please specify why not.	Lack of time
10.16. Do you have any additional comments on SARE	
reporting?	
	4 P: (1 2004/22/EC)
11. Consent and personal data protection (Article 13 and 1	
11.1. What consent system for living tissue/cell donation do	Explicit consent (opt-in)
you have in place within your Member State?	
11.1.1. Please specify your choice of consent system for	Written and signed consent is required and in case of minors written consent
living tissue/cell donation.	from parents and an additional permit after application to the National Board
	of Health and Welfare is needed.
11.2. What consent system for deceased tissue/cell donation	Presumed (opt-out) and explicit (opt-in) consent
do you have in place within your Member State?	
11.2.1. If you have chosen both consent systems for	If the deseased possible donor has not registered his/her will in the national
deceased tissue/cell dontation, please specify.	donor registry a person who knew the diseased well need to give their
, <u>r</u> , <u>r</u> ,	consent.
11.3. According to your national legislation, in case of	First degree relatives (including spouse)
deceased donations, please specify who is giving the	Other relatives
authorisation for the tissue donation? (more than 1 answer	Non-marital partners
· ·	Friends
possible) 11.4. Is the consent system for deceased tissue donation the	Yes
	Yes
same as for organs?	
11.5. How is this consent verified during inspections? (more	Analysis of documentation
than 1 answer possible)	Interviews with personnel
11.6. What measures are in place to ensure that	Only trained personnel is allowed to provide such information
donors/relatives/authorising persons on behalf of donors are	Information for donors are standardised at national/regional level
provided with the appropriate information, as requested by	
Art. 13(2)? (more than 1 answer possible)	
11.7. What measures are in place to ensure that both donors	Donor code and recipient code is used
and recipients remain unidentifiable when access is given to	
third parties (Art. 14(1)). Please specify.	
11.8. Please specify what measures are in place to ensure	The Donor code is used in the recipient documentation and the recipient
that the identity of the receipient is not disclosed to the	code is used in the donor documentation.
donor and vice versa.	
11.9. Does your national legislation allows disclosure of	Yes
	165
donor data in case of gametes donation?	Displayure of donor ID is only possible for the hourselfild at a left
	Disclosure of donor ID is only possible for the born child at adult age and
data protection?	not for the parents.
12. Selection, evaluation and procurement (Article 15 Direction)	
12.1. How do you ensure that all requirements related to the	Stadardised questionnaires at national levels
evaluation and selection of donors (except donors of	Inspections of TEs and procurement sites
reproductive cells) are respected in your country (Art. 15(1),	-
Annex I Directive 2006/17/EC)? (more than 1 answer	
possible)	
12.2. How do you ensure that all requirements related to the	Standardised questionnaires at national level
evaluation and selection of donors of reproductive cells are	Inspections of ART centres
respected in your country (Art 15 (1), Annex III of Directive	mapocation of ract control
2006/17/EC)? (more than 1 answer possible)	N.
12.3. Do you have more stringent criteria for donor selection	No
than those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the	Interview with the donor's family or a person who knew the donor well
evaluation of a deceased donor of tissues/cells? (more than 1	Medical records of the donor
answer possible)	Interview with the treating physician
12.5. Do you have more stringent criteria for selection of	No
donors of reproductive cells than those listed in Annex III of	
the Directive 2006/17/EC?	
	I .

12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive	No
2006/17/EC?	N.
12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the	No
Annex of Directive 2004/23/EC (Art 15(3)?  12.8. How do you ensure that all requirements regarding	Townsels of the second state of the second
tissues and cells' procurement, packaging and transport are	Inspection of tissue establishment
complied with by tissue establishments in your country (Art	Inspection of the centre of human application (e.g. transplantation centre, ART centre)
15(1), Annex IV of Directive 2006/17/EC? (more than 1	AKT centre)
answer possible)(For this question "audit" means a	
documented review of procedures, records, personnel	
functions, equipment, materials, facilities, and/or vendors in	
order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe	
Guide to the Safety and Quality Assurance for the	
Transplantation of Organs, Tissues and Cells, 2011))	
12.9. Do you have any additional comments on selection,	In combination with inspections document reviews are performed and all TE
evaluation and procurement?	for reproductive tissue are also ART centers, so also the centers for "human
evaluation and procurement:	application" have been inspected.
12.0 12.	
13. Quality management, responsible person, personnel (A	
13.1. How do you ensure that tissue establishments in your	Authorisation requirement
country have in place a quality system respecting the	Inspections
provisions of the Directive 2004/23/EC Art 16.1? (more than	Internal audits
1 answer possible). (For this question "audit" means a	External audits
documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in	
order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe	
Guide to the Safety and Quality Assurance for the	
L transplantation of Organs Tissues and Calle 2011)	
Transplantation of Organs, Tissues and Cells, 2011)).	Authorisation requirement
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)?	Inspections
13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)	Inspections Other
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13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  Please specify 'other'.  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging 14.1. How do you ensure that tissue establishments in your	In case of a change of responsible person, an application together with CV of the new responsible person must be approved by the CA.  Authorisation requirement Inspections Regular evaluation of personnel Other  During inspection we also interview the personell and their possibity to get extended training is one of the questions.  Yes  Personnel working in the laboratory of a TE must be licenced as Biomedical Analysts, other personnel are are licenced nurses, MD's or have a degree in biomedicine depending on their assignement in the TE. Additional training specific for the TE is provided locally as well as by regional and national courses arranged by the National Tissue Council. (Vävnadsrådet; www.vavnad.se)  (Art 19-22 Directive 2004/23/EC) National regulation/policy for reception of tissues/cells
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13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  Please specify 'other'.  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging 14.1. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)	In case of a change of responsible person, an application together with CV of the new responsible person must be approved by the CA.  Authorisation requirement Inspections Regular evaluation of personnel Other  During inspection we also interview the personell and their possibity to get extended training is one of the questions.  Yes  Personnel working in the laboratory of a TE must be licenced as Biomedical Analysts, other personnel are are licenced nurses, MD's or have a degree in biomedicine depending on their assignement in the TE. Additional training specific for the TE is provided locally as well as by regional and national courses arranged by the National Tissue Council. (Vävnadsrådet; www.vavnad.se)  (Art 19-22 Directive 2004/23/EC)  National regulation/policy for reception of tissues/cells Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)
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13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  Please specify 'other'.  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging 14.1. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and	In case of a change of responsible person, an application together with CV of the new responsible person must be approved by the CA.  Authorisation requirement Inspections Regular evaluation of personnel Other  During inspection we also interview the personell and their possibity to get extended training is one of the questions.  Yes  Personnel working in the laboratory of a TE must be licenced as Biomedical Analysts, other personnel are are licenced nurses, MD's or have a degree in biomedicine depending on their assignment in the TE. Additional training specific for the TE is provided locally as well as by regional and national courses arranged by the National Tissue Council. (Vävnadsrådet; www.vavnad.se)  (Art 19-22 Directive 2004/23/EC)  National regulation/policy for reception of tissues/cells Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for authorisation
13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible)  Please specify 'other'.  13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible)  Please specify 'other'.  13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments?  13.4.1. If yes, please specify.  13.5. Any additional comments on quality management, responsible person, personnel?  14. Reception, processing, storage, labelling and packaging 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) 14.2. How do you ensure that tissue establishments in your	In case of a change of responsible person, an application together with CV of the new responsible person must be approved by the CA.  Authorisation requirement Inspections Regular evaluation of personnel Other  During inspection we also interview the personell and their possibity to get extended training is one of the questions.  Yes  Personnel working in the laboratory of a TE must be licenced as Biomedical Analysts, other personnel are are licenced nurses, MD's or have a degree in biomedicine depending on their assignment in the TE. Additional training specific for the TE is provided locally as well as by regional and national courses arranged by the National Tissue Council. (Vävnadsrådet; www.vavnad.se)  (Art 19-22 Directive 2004/23/EC)  National regulation/policy for reception of tissues/cells Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO) SOPs for all processes affecting quality and safety are mandatory for

	External audits of tissue establishments (e.g. ISO)
14.3. How do you ensure that tissue establishments in your	SOPs for procedures associated with storage of tissues and cells are
country fulfill the requirements of Art. 21 (tissue and cell	mandatory for authorisation
storage conditions) of Directive 2004/23/EC? (more than 1	Inspections of tissue establishments
answer possible)	Internal audits of tissue establishments
answer possible)	External audits of tissue establishments (e.g. ISO)
14.4. How do you ensure that tissue establishments in your	SOPs for procedures associated with labelling and packaging are mandatory
country fulfill the requirements of Art. 22 (labelling,	for authorisation
documentation and packaging) of Directive 2004/23/EC and	Inspections of tissue establishments
Annex IV of Directive 2006/17/EC? (more than 1 answer	Internal audits of tissue establishments
possible)	External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception, processing,	External dudits of tissue establishments(e.g. 150)
storage, labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your	Yes
national legislation?	
15.1.1. If yes, have tissue establishments in your Member	Yes
State notified third party agreements?	
15.1.1.1. Under which circumstances and for which	Donor testing: only laboratories that are accredited by SWEDAC are
responsibilities?	accepted and the agreement covers reponsibility issues relating to testing,
	electronic transfer of test results (if applicable), obligation to notify the TE if
	testresults are unreliable/ failures in the compulsary assay comparisons etc.
	Procurement from diseased donors (ocular tissue, skin, heart valves) where
	the agreement covers responibility to perform procurement according to the
	SOP's from the TE and the permission to allow the TE to perform audits.
	Data storage: the TE's processing and distributing allogeneic HPC have
	agreements with the National Registry of Bone Marrow donors (Tobias
	registret) covering the responisbility of the registry to keep and maintain
	records of the donor-identity when the TE only get a donor code as identity.
15.1.1.2. How are third party agreements controlled (Art 6.2)	Before the authorization and during routine inspections.
by the Competent Auhtority(ies) in your MS? Please specify.	
15.2. Any additional comments on third party agreements?	In case of new third party agreements; it is considered as a major change in
	the TE, that has to be approved by the CA (by document review)
16. General comments - implementation	
16.1. Do you have at national level more stringent quality	No
and safety requirements than those requested by the EU	
legislation in this field (e.g. restrictions concerning the	
donation/use of certain tissues/cells, mandatory unpaid	
donation etc.)?	
16.2. Has your Member State encountered any difficulties in	Testing provisions
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	
16.2.1. For all selected options in question 16.2., please	The 24 hr time limit to perform donor testing in case of diseased donor have
provide a short description.	a negative effect on donor availability for procurement as it may take longer
	for the concent to be given.
16.3. In your opinion, in which of the following Directives	Directive 2006/17/EC
are there shortcomings (if any)? (more than 1 answer	
possible)	
16.3.2. How would you suggest to solve these issues in	Annex II 2.4 Change the time limit from 24 hr to 48 hrs since no scientific
Directive 2006/17/EC?	evidence was the basis for the 24 hrs time limit. Annex II 2.5 (b) add for
	clarification: "under these circumstances tissues and cells are in quarantine
	until results from the second test are available and evaluated "

## A.1.30. Survey response United Kingdom

UK -	HFEA
1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Human Fertilisation and Embryology Authority
1.1.2. Address of NCA 2:	Finsbury Tower 103-105 Bunhill Row London EC1Y 8HF United Kingdom
1.1.3. Telephone (central access point):	0207 291 8200
1.1.4. E-mail (central access point):	admin@hfea.gov.uk
1.1.5. Website:	www.hfea.gov.uk
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Reproductive tissues and cells
1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible)	Accreditation, authorisation, licensing of TEs Inspection Vigilance Other
Please specify 'other':	The HFEA is the UK's national regulator for ensuring ART clinics adhere to the requirements of the Human Fertilisation and Embryology Act 1990 (as amended) [the HF&E Act 1990 (as amended)]. The HFEA also licenses and monitors establishments undertaking human or human admixed embryo research. We also maintain a Register of Information. The HFEA Register is a data set on regulated fertility treatments, including the handling and storage of embryos, eggs and sperm.
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.).	The HFEA is an independent regulator, operating as a UK armslength body, sponsored by the Department of Health. It employs approximately 69 staff, divided into three directorates: Compliance and Information, Strategy; Finance, Facilities and Information Technogy. Each of these directorates are led by a Director, reporting to the CEO. The Compliance team has 2 senior inspectors and 10 inspectors (who comprise the inspection and vigilance team), reporting to either the Head of Inspection or the Head of Research Regulation and Clinical Governance. The HFEA also has a board. There are also 12 members of the Authority (the board) who determine HFEA policies and review treatment and research licence applications. Members have a broad range of expertise, from medicine to law and religion to philosophy. To ensure that the HFEA has an objective and independent view, the HFE Act requires the Chair, Deputy Chair and at least half of the HFEA Members are not doctors or scientists involved in human embryo research or fertility treatment.
1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible)	Not applicable
1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells:	Not applicable
2. Procurement (Article 5 Directive 2004/23/EC)	
2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	By inspecting some procurement centres By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres Other
Please specify 'other':	We license and inspect establishments that carry out procurement activities where they also process and use gametes and / or embryos. We also issue a Code of Practice in which we provide advice on the requirements related to conditions of procurement. We may not inspect all procurement centres as some procurement centres operate

2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?  2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	through a third party agreement with a licensed establishment. The Person Responsible (i.e 'responsible persons') at these licensed establishments must ensure that the practices, staff and premises are suitable at any third party establishment. They will do this in a variety of ways, including conducting audits of the third party. The HFEA reviews third party arrangements during a routine inspection of the licensed establishment.  35 HFEA licences were renewed in in 2011. In addition one new licences was granted in 2011.  Procurement of traditional tissue and cells is authorised by the Human Tissue Authority (HTA)
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	Procurement of haematopoietic stem cells is authoroised by the HTA.
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	115 of which 111 are licensed by the HFEA. Four centres procure gametes under third party agreements with a licensed HFEA centre.
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	Procurement of tissue / cells for ATMP manufactoring falls is authorised by the HTA.
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)	Inspections of the site/centre Analysis of the mandatory documentation Other
Please specify 'other':	The HFEA, by law, produces a Code of Practice. The HFEA Code of Practice is intended to help and encourage licensed centres to understand and comply with their legal requirements. It also gives guidance on how centres are expected to go about meeting those requirements. In addition which provide guidance through a regular news letter.
2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	Yes
2.4.1. Please provide the number of the laboratories performing donor testing.	The HFEA does not licence laboratories performing donor testing. The HFEA has made it a condition of all treatment and storage licences issued to tissue establishment that donor testing must be carried out by a qualified laboratory, which has suitably accreditated (for example by the Clinical Pathology Accreditation [CPA (UK) Ltd] or another body accrediting to an equivalent standard). The CPA (UK) Ltd, a private organisation, provides a voluntary national accreditation service. Over 95% of UK labs are CPA accredited.
2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible)	Analysis of the mandatory documentation requested from the tissue establishment Other
Please specify 'other':	During inspections visits to tissue establishments HFEA inspectors will audit the medical records for a number of patients. As part of this audit we look for evidence that the donor testing has been carried out by a qualified laboratory.
2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.).	The HFEA does not accredit, authorise or license laboratories which carry out donor testing. Over 95% of laboratories carrying donor testing are accrediated by the Clinical Pathology Accrediatation [CPA (UK) Ltd).
2.7. Do you have any additional comments on procurement?	The following requirementss are conditions of all licences issued by the HFEA: - Where the sperm is procured at home, the centre must record this in the gamete provider's records No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by

	Directions There must be a decumented system in place that
	Directions There must be a documented system in place that ensures the identification of all gametes and embryos from
	procurement to use or disposal.
2 T-4: (A-4 A A I II I III F P: 4: 200(/17/EC)	production to use of disposar.
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) 3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
	Anti-HIV 2
reproductive tissues and cells in your Member State. (more than 1	
answer possible)	Anti HBc Anti HCV-Ab
	Treponema Pallidum HTLV-2
3.2. Please specify laboratory tests required for donors of	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
answer possione)	Anti HBc
	Anti HCV-Ab
	NAT Chlamydia
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you	NAT testing is not currently mandatory in the UK, with the
please indicate whether you intend to make it mandatory or to	exception of the testing for Chlamydia. The Advisory Committee on
encourage its use? Please specify why or why not (e.g. number of	the Safety of Blood, Tissues and Organs (SaBTO) advises UK
additional cases detected, cost-benefit etc.).	ministers and health departments on the most appropriate ways to
additional cases detected, cost-benefit etc.).	ensure the safety of blood, cells, tissues and organs for
	transfusion/transplantation. SaBTO has recommended NAT, in
	particular product testing rather than donor serum testing.
3.4. Do you have concerns on accuracy of the available tests and test	No
procedures for deceased donors?	
3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	
3.6. Are any other laboratory tests required for donors of	No
reproductive tissues and cells in your Member State?	
3.7. Do you request/use international accreditation systems for	No
testing laboratories?	
3.8. Do you have any additional comments on testing?	The testing of donors of non-reproductives cells comes under the
	authority of the Human Tissue Authority in the UK. Additional
	testing for donors of reproductive tissue and cells is carried in
	accordance with the rquirements set out in Annex 111 of Directive
	2006/17/EC.
4. Accreditation, designation, authorisation or licensing of tissue es	stablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation,	Yes
accreditation or licensing for all types of tissue establishments under	
your responsability?	
4.2. Is inspection a prerequisite for the designation, authorisation,	Yes
accreditation or licensing of tissue establishments?	
4.2.1. How many inspections were performed in 2011 for	37 inspections were performed in 2011 for the purpose of renewing
authorising/accrediting/licensing/designating TEs?	or granting a HFEA licence to tissue establishments.
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	None
how many authorisations/accreditation/licenses were suspended in	
2011?	
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	3 licences were revoked
how many authorisations/accreditation/licenses were revoked in	
2011?	
4.6. Do you require TEs to be certified by an external entity to a	No
quality system standard (e.g. ISO, JACIE, FACT)?	
4bis. Overview of tissue/cells establishments authorised by the NC.	A
4.7. Tissue establishments with authorisation pending approval at	ART tissue establishments
01/01/2011 (more than 1 answer possible):	
4.7.7. How many ART tissue establishments?	4

4.8. Tissue establishments with authorisations pending approval by	ART tissue establishments
31/12/2011 (more than 1 answer possible):	
4.8.7. How many ART tissue establishments?	13
4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):	ART tissue establishments
4.9.7. How many ART tissue establishments?	One
4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible):	ART tissue establishments
4.10.7.1. How many public ART tissue establishments?	66 (42 of these also treat private patients)
4.10.7.2. How many private ART tissue establishments?	45 (27 of these also treat publicly funded patients)
4.11. How many tissues and cells were distributed under the direct	0 - None
agreement of the Competent Authority according to Art. 6(5) during	0 - None
2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	Y.
4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)?	Yes
4.16.1. Have penalties already been imposed?	Yes
4.16.1.1. How many penalties have been imposed in 2011 (from	One licence had a condition placed on it to restrict the number of
01/01/2011-31/12/2011)?	ART treatment cycles which could be carried per month.
4.16.1.2. What were the reasons for imposing the penalties? Please	The Person Responsible had failed to ensure that suitable practices
describe.	(required under section 17(1)(d) of the HF&E Act) were being used
	in the course of the activities being caried out at the ART centre.
4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.)	One licence had a condition placed on it to restrict the number of ART treatment cycles which could be carried per month.
4.17. Do you have any additional comments on accreditation,	In relation to 4.5 three licences were revoked but these were at the
authorisation, designation and licensing?	request of the Person responsible (i.e. the reponsible person), so we
	class these as voluntary revocations. In relation to 4.7.7: four tissue
	establishment were inspected in 2010 but the decision on whether or
	not the HFEA licence should be renewed was not taken until early
	2011. In relation to 4.8.7: 12 tissue eatablishments were inspected
	in 2011 but the decision on whether or not the HFEA licnece should
	be renewed was not taken until early 2012. In adition one of the new
	tissue eatablishments inspected in 2011 was not granted a licnece
	until 2012. In relation to 4.10.7.1: In the UK there are 66 ART
	centres located in NHS [National Health Service(public)] hospitals;
	of these 42 also treat privately funded patients. In relation to
	4.10.7.2: In the UK there are 45 private ART centres; of these 27
	also treat NHS funded patients.
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge	Directorate of Compliance and Information
of inspections.	
5.1.2. If yes, please specify staffing (how many inspectors).	The HFEA has two senior inspectors and 10 inspectors. There are
	also two Heads of Department and a Director. The HFEA also has a
	panel of external advisors who occassionaly form part of the HFEA's
	inspection teams. These external advisors are clinicians, nurses,
	embryologists or counsellor who work in licensed ART centres. A
	list of the HFEA's external advisors mean be found in our annual
	report (http://www.hfea.gov.uk/annual-report.html)
5.2. Does the inspection scheme interact or overlap with the	Yes
inspection scheme of other activities, for example blood,	
pharmaceuticals, etc. (e.g. same inspector team, common training,	
common documentation, etc.)? (more than 1 answer possible)	
1 5 0 1 7 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
5.2.1. If yes, please specify. (more than 1 answer possible)	Others
Please specify other.	As well as being the Competent Authority for tissues and cells for
	As well as being the Competent Authority for tissues and cells for human application, the HFEA is also responsible for ensuring tissue
	As well as being the Competent Authority for tissues and cells for human application, the HFEA is also responsible for ensuring tissue establishments are compliant with the Human Fertilisation and
	As well as being the Competent Authority for tissues and cells for human application, the HFEA is also responsible for ensuring tissue

	admixed embryos in research.
5.3. How many routine inspections of tissue establishments for non-	N/A
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	11/73
<u> </u>	
31/12/2011)?	NI/A
5.3.1. How many inspections of tissues establishments for non-	N/A
reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to	
31/12/2011) following serious adverse events or reactions, or	
suspicion thereof?	
5.3.2. How many other type of inspections of tissues establishments	N/A
for non-reproductive tissues/cells were conducted in 2011 (from	
1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please	
specify.	
5.3.3. Outcome of inspections of TEs for non-reproductive	N/A
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where no shortcomings	
were observed?	
5.3.4. Outcome of inspections of TEs for non-reproductive	N/A
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	IVA
was the number of inspections carried out where minor	
<u> </u>	
shortcomings were noted?	NA
5.3.5. Outcome of inspections of TEs for non-reproductive	N/A
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out where major shortcomings	
were noted?	
5.3.6. Outcome of inspections of TEs for non-reproductive	N/A
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	N/A
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	N/A
	N/A
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	60
establishments (from 1/1/2011 to 31/12/2011)?	
5.4.1. How many inspections were conducted in ART establishments	2
following serious adverse events or reactions, or suspicion thereof	
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	One
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	3
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
	54
5.4.4. What was the number of inspections carried out in ART	54
establishments where minor shortcomings were noted?	50
5.4.5. What was the number of inspections carried out in ART	50
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	0 - None
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	0 - None
establishments followed by closure of respective establishments?	
5.4.8. What was the number of other inspections of ART	3: two to investigate an SARE and one following a complaint/
establishments? Please specify.	whistleblower
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
answer possible)	Desk based reviews
5 C Handa and decide which the Co. C.	
5.6. How do you decide which type of routine inspection to conduct?	The HFEA's continuous monitoring cycle of licensed UK fertility
	centres involves a four year inspection cycle during which the

	majority of centres will receive a four year licence and be inspected
	once every two years. More frequent inspections may be made when
	we have concerns about a centre's compliance - particularly if we
	consider the safety of patients, embryos and gametes are at risk. The
	purpose of an inspection is to: - assess the extent to which centres
	comply with the Human Fertilisation and Embryology Act; licence
	conditions; directions and the provisions of the Code of Practice -
	provide an independent and professional perspective on the running
	of the centre - promote good practice so that centres can improve
	the quality of service they provide to patients and donors
	Compliance with all of the requirements of the HF&E Act 1990 (as
	amended), which incorprates the requirements of the EUTCD, are
	inspected prior to a licence being granted or renewed. An interim
	inspection takes place mid way through the four year inspection
	cycle. During the interim inspection the inspection team evaluates: -
	the action(s) taken by the centre in relation to areas of non-
	compliance identified either at the last inspection visit or through the
	continuous monitoring cycle - compliance against the inspection
	themes (the Authority has decided that a number of areas of practice
	should be looked at all inspections. These are referred to as 'themes'.
	The themes are changed every two years.) The HFEA also
	conducts thematic reviews where we look at compliance against a
	particular requirement e.g. consent to donation and these may
	involve additional inspection visits to tissue establishments. The
	variation of licences is sometimes carried out by desk based reviews.
	For example if a tissue establishment applied to have an additional
	licensed activity added to thier licence we would ask them to submit
	documentation and this would be reviewed without an inspection
	visit being carried out.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	All TEs licensed by the HFEA between 01/01/2008 -31/12/2011
2011 (01/01/2008-31/12/2011)?	were inspected at least twice between 2008 -2011. The HFEA
, , , , , , , , , , , , , , , , , , ,	continues to carry out a site based inspection of all licensed tissue
	establishments every two years.
5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	
5.9.2. If no, why not?	The Person Responsible (the Responsible Person) at HFEA licensed
	tissue establishments are required to have a third party agreement
	with procurement sites. These third party agreements are reviewed
	as part of the inspection process. There are only 4 procurements sites
	that are not licensed by the HFEA.
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	No issues were raised during inspections of the licensed tissue
,	establishments and no series adverse events or reactions were
	reported in relation to third parties.
5.11. Do you use at national level the Operational Manual for	No
Competent Authorities on inspection of tissue and cell procurement	
and tissue establishments - Guidelines for inspections (Commission	
Decision 2010/453/EU)?	
5.11.1. If no, which guidelines/regulations are used for inspections at	We do not use the Operational Manual for Competent Authorities on
national level?	inspection of tissue and cell procurement and tissue establishments -
	Guidelines for inspections, however our inspection guidelines are
	based on this document. We provide licensed tissue establishments
	with numerous guidance on our website, to assist them with
	inspection preparation and guidance on what licensed tissue
	establishments need to do to comply with the HFEA's Code of
	Practice. We use internal standard operating procedures to provide
	guidance for inspectors on how to conduct an inspection. We also
	hold at least on training day for HFEA inspectors and the HFEA's
	external advisors per year. These days are used to ensure consistency
•	ontornal advisors per year. These days are used to clistic collisistency

	between inspectors.
5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	The information on how the HFEA monitors licensed tisues establishment can be found at http://www.hfea.gov.uk/6670.html.  The information on the inspection process can be found at http://www.hfea.gov.uk/6672.html and the information on what licensed tissue establishments need to do to ensure they comply with the HF&E Act 1990 (as amended) and the Code of Practice can be found at http://www.hfea.gov.uk/6676.html.
5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	Yes
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	5
5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	No
5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	No
5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	No
5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	No
5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries.	Yes
5.18. Do you have any additional comments on inspections?	The HFEA continually monitor licensed centres to ensure their compliance with the HF&E Act (as amended), standard licence conditions, additional licence conditions, directions and the Code of Practice. To aid this process the HFEA has developed a tool, known as the Risk Based Assessment Tool, which helps us assess the information provided to us by centres. The Risk Tool analyses information provided to the HFEA through Register submissions and to the HFEA finance directorate to assess quality of service in terms of: - outcomes (in the form of real time analysis of clinical pregnancy rates) - multiple clinical pregnancy rates - submission of critical donor information - incident reporting. Where the analysis shows that a centre's outputs are outside the sector norms we will share this information with the centre and support them in identifying whether there is an opportunity for improvement. The same will apply where clinical multiple birth rates indicate that a centre is not likely to meet HFEA targets; where critical Register submissions are not submitted. A more detailed explanation of the HFEA Risk Tool can be found at http://www.hfea.gov.uk/6674.html.
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries?	Yes
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).	85
6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).	85
6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.	N/A

6.5. Please specify which procedures you have in place for verifying	N/A
the equivalent standards of quality and safety for importation of	
musculo-skeletal (bone, tendons, fascia etc.) tissues from third	
countries.	
	NI/A
6.6. Please specify which procedures you have in place for verifying	N/A
the equivalent standards of quality and safety for importation of	
ophtalmic (cornea, sclera, etc) tissues from third countries.	
6.7. Please specify which procedures you have in place for verifying	N/A
the equivalent standards of quality and safety for importation of	
cardio vascular tissues from third countries.	
6.8. Please specify which procedures you have in place for verifying	N/A
the equivalent standards of quality and safety for importation of	
haematopoietic stem cells (HSC) (other than cord blood) from third	
countries.	
	N/A
6.9. Please specify which procedures you have in place for verifying	N/A
the equivalent standards of quality and safety for importation of cord	
blood from third countries.	
6.10. Please specify which procedures you have in place for	The HFEA requires the tissue establishment in the third country to
verifying the equivalent standards of quality and safety for	be accredited, designated, authorised or licensed under the laws or
importation of reproductive cells (sperm, egg cells) from third	other measures of the country in which it is situated in relation to
countries.	quality and safety.
6.11. Did you import tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
6.11.1. If yes, please provide the data concerning the	In 2011, the UK imported 1104 vials/ampoules/straws of sperm from
number/volume of imported tissues and cells by country of origin.	the following third countries: Australia, USA and Uruguay. The UK
	also imported 297 eggs from the following third countries: Australia,
	Russia and the USA. Embryos were also imported from another
	third country. The HF&E Act 1990 (as amended) prohibits the
	HFEA from disclosing information which could potentially lead to a
	patient being identified, for this reason we are unable to provide the
	quantities imported from third countries and in the case of the
	imported embryos we are also unable to disclose the name of the
	country of origin.
6.12. Did you export tissues/cells from 3rd countries during 2011	Yes
(01/01/2011-31/12/2011)?	
	Y 2011 d YW
6.12.1. If yes, please provide the data concerning the	In 2011, the UK exported 47 vials/ampoules/straws of sperm to the
number/volume of exported tissues and cells by country of	following third countries: Australia, USA and Uzbekistan. The UK
destination.	also exported 96 embryos to the following third countries: American
	Samoa, Australia, Canada, India, Israel, Japan, New Zealand,
	Singapore, South Africa and the USA. The HF&E Act 1990 (as
	amended) prohibits the HFEA from disclosing information which
	could potentially lead to a patient being identified, for this reason we
	are unable to provide the quantities exported to individual third
	countries.
6.13. Are you aware of any significant changes in 2012 which may	No
	110
invalidate the 2011 data on imports/exports of tissues/cells between	
your country and other third countries?	
6.14. What is the relation between import/export of tissues and cells	F. Other
and self-sufficiency? (more than 1 answer possible)	
Please specify 'other':	THe HFEA does not hold information about local/ national needs.
6.15. Did you authorise direct imports of tissues/cells to	No
*	INU
hospitals/clinics in your country?	
6.16. Do you have any additional comments on import/export?	The HFEA has issued General Directions to all tissue
	establishments, licensed to carry out treatment and storage; theses
	Directions set out the requirements which must be met in order to
	permit gametes and / or embryos to be imported or exported. A copy
	of these Directions can be found at:
	http://www.hfea.gov.uk/docs/2009-09-
	09_General_directions_0006
	Import_and_export_of_gametes_and_embryosversion_2.pdf.
1	import and expert or gametes and emerges - version 2.pdf.
	Where a centre wants to export or import gametes or embryos to or

	T
	from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that: i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety ii) the centre has appropriate quality management and traceability systems, and iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination. In each case, a copy of the information retained must be provided to the Authority on request. In all cases, all the requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met.
7. Distribution/intra community exchanges (Article 23 Directive 20	
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify.	It is the responsibility of the Person Responsible to ensure the requirements of other Member States have been met prior to distributing gametes or embryos to tussue establishments in the relevant MS.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	No
7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	Tissue establishments are required to put into place service level agreements with couier compancies which define the obligations for complying with requirements in relation to ensure the quality and saferty of the gametes and embryos are maintained.
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	No
7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No
7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	Yes
7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).	In 2011, the UK distributed 42 vials/ampoules/straws of sperm to the following member states: Cyprus, Denmark, Germany, Greece, Ireland and Spain. The UK also sent 32 embryos to the flowing Member states: Germany, Ireland and Spain. The HF&E Act 1990 (as amended) prohibits the HFEA from disclosing information which could potentially lead to a patient being identified, for this reason we are unable to provide the quantities sent to individual MS.
7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011)	In 2011, the UK received 1003 vials/ampoules/straws of sperm from the following member states: Cyprus, Denmark, Germany, Norway and Spain. The UK also received embryos from a country within the EEA. The HF&E Act 1990 (as amended) prohibits the HFEA from disclosing information which could potentially lead to a patient being identified, for this reason we are unable to provide the quantities received from individual MS and in the case of embryos received we can not disclose the MS from which the embryos were received from.
7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS?	No
7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage.  7.8. Are brokers actively supplying health	No No
professionals/establishments in your country?  7.9. Do you have any additional comments on distribution?	The wording of questions 7.5.1 and 7.5.2 are virtual identical.  Therefore, in relation to question 7.5.1 we have provided data in

	relation to the quantity of gametes and embryos which were
	distributed from the UK to other MS and in relation to question 7.5.2
	we have provided data in relation to the receipt of gametes and
	embryos from other MS into the UK.
8. Register of tissue establishments and reporting obligations (Artic	
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If	
yes, please upload the template.  8.2. How many tissue establishments submitted annual reports of	60-99%
their activities during 2011. Please provide an estimation. (1 answer	00-9970
possible)	
8.3. Are these reports publicly available? (Article 10(1))	Yes
8.3.1. If yes, please insert the link(s) to the report(s).	http://www.hfea.gov.uk/1270.html
8.4. Do you publish a national annual report of the consolidated	Yes
activities of all tissue establishments in your country?	
8.4.1. Please insert the link to the published national annual report.	http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_
	2011 - Annual Register Report.pdf and
	http://www.hfea.gov.uk/1270.html. The HFEA also publishes data in
	relation to each licensed fertility centre (tissue establishment) this
	can be found on our website in the 'Choose a Fertility Clinic' section:
	http://guide.hfea.gov.uk/guide/
8.5. Is there a publicly accessible register of authorised tissue	Yes
establishements in place? (Article 10(2))	
8.5.1. If yes, please provide us with the link to the register's web site.	http://guide.hfea.gov.uk/guide/AllClinics.aspx?x=A
8.6. Do you provide data regarding tissues and cells activities to the	Yes
EUROCET registry (non-mandatory reporting)?	We some the second activity data to the EC and are assume this
8.6.1. If yes, what data are provided to EUROCET? Please specify.	We supply annual activity data to the EC and we assume this information then goes to the EUROCET registry. We complete all
	mandatory reporting.
8.7. Do you have any additional comments on reporting?	The HFEA collects data and statistics about over 60,000 fertility
6.7. Do you have any additional comments on reporting:	treatments performed each year in the UK. We are committed to
	making as much of this information available as possible to aid and
	inform patients, researchers and clinicians. Our 'Fertility treatment
	in 2011 – facts and figures' report presents information about
	patients, treatments and results from 2010 and 2011. It also
	highlights some short term and longer term changes over time. An
	new annual report is published each Autumn. The annual return
	upload only relates to information about treatment cycles involving
	the insemination using partner sperm. Data on all other ART
	treatments e.g. IVF using either partner donation or non-partner
	donation; insemination using non-partner sperm or ICSI using either
	partner or non-partner donation are submitted to the HFEA register
	on a regular basis in accordance with HFEA General Directions
	(http://www.hfea.gov.uk/docs/0005_Collecting_and_recording_infor mation_for_the_HFEA approved.pdf). This information is
	published in the annual report as well as being available on our
	website in the 'Choose a fertility' section.
9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006	
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	- <del></del>
9.2. Who assigns the unique code for each donation? (only 1 answer	Other
possible)	
Please specify 'other'.	Tissue establishments or procurement centres
	Both paper records and electronic forms
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	Both paper records and electronic forms
9.3. How is the data storage for traceability purposes organised in	We require a records retention policy to be in place. We check this is
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible)	
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) 9.4. How do you ensure that the 30 years data storage requirement is	We require a records retention policy to be in place. We check this is in place both at the initial licence application stage and during inspections.
9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) 9.4. How do you ensure that the 30 years data storage requirement is	We require a records retention policy to be in place. We check this is in place both at the initial licence application stage and during

	relating to traceability apply to all licensed ART centres: Traceability and coding T99. The centre must establish, implement and comply with documented procedures to ensure that: a. all gametes and embryos, and b. all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa. T100. The documented procedures referred to in licence condition T99 include the following information: a. the unique and accurate identification of each patient/donor b. the unique and accurate identification of each set of gametes and embryos c. date of procurement d. place of procurement e. type of treatment f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and g. description of all processing steps applied to the procurement, use and storage of gametes and embryos. T101. The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, possessing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying. T102. The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request. T103. The centre must keep data necessary to ensure traceability for a minimum of thirty years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium. T104. Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access t
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
10.1.1. If yes, which CA/institution is responsible?	HFEA
10.1.2. If yes, please provide a short description of its organisation.	The HFEA is a non-department government body responsible for implementing the HF&E Act 1990 (as amended) and is one of the two UK Competent Authorties for implementing the EUTCD.
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	No
10.2.1. If no, what template do you use? You are welcome to upload the template if you wish.	We use the HFEA incident reporting form. The HF&E Act 1990 (as amended) set out the requirments which must be meet by ART centres these rquirments include those set out in the EUTCD but also includes additional requirments in relatio to consent, welfare of the child, legal parnethood. The HFEA also licenses the use of gametes and embryos in treatment. Therefore the incident reporting form reflects our extended powers.
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	No
10.3.1. If no, please specify what guidelines you use.	The HFEA issues guidance on SAERs in the HFEA Code of Practice, see http://www.hfea.gov.uk/3476.html Licensed establishments are required to report SAREs to the HFEA within 24 hours of them being discovered.
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	Yes
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%

10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)?	Yes
10.6.1. If yes, please provide a brief description.	The use of gametes and / or embryos in treatment must take place in a licensed centre. These centres must report all SAERs to the HFEA in accordance with General Directions http://www.hfea.gov.uk/docs/2011-10-01_General_directions_0011Version_2.pdf
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	Report / inspection process / HFEA newsletter / workshops
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	The HFEA notifies establishments about any SARE implications in a regular e-newsletter.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).	No recalls were issued in 2011.
10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert?	Yes
10.11.1. If yes, please give a short description of the system/procedure.	Alerts are uploaded on to the HFEA clinic portal and TEs are notified via email.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes
10.12.1. If yes, please give a short description of the system/procedure.	Alerts are uploaded on to the HFEA clinic portal and TEs are notified via email.
10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)?	Yes
10.13.1. If yes, please specify what data.	The HFEA provides all the requested information to the EUROCET registry.
10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems?	Yes
10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	Medical devices Other
Please specify 'other'.	We communicate alerts to the Medicines and Healthcare products Regulatory Agency and the Human Tissue Authority. We also share details of SAREs reported to us if we believe they could have an impact on medicines and healthcare products and/or non- reproductive tissues and cells.
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	5
10.16. Do you have any additional comments on SARE reporting?	10.5 above is actually not applicable for the HFEA: Establishments report SAREs within 24 hours of their discovery, and not via an annual report. As a result, we may not receive data from every establishment every year, as serious reactions or events may not take place at every establishment. We received a total of 611 incident reports in 2011. We found the training excellent. We follow the EC RATC Platform standard operating procedures when reporting an incident on the RATC platform.
11. Consent and personal data protection (Article 13 and 14, Direc	tive 2004/23/EC)
11.1. What consent system for living tissue/cell donation do you	Explicit consent (opt-in)
have in place within your Member State?	

11.1.1. Please specify your choice of consent system for living tissue/cell donation.	The use of gametes in treatment may only take place if consent has been provided by the gamete provider. In the case of the use of embryos in treatment consent must have been by both gamete providers. The storage of gametes may only take place in consent has been obtained from the gamete provider. The exception to this is that a parent or guardian may consent to the storage of gametes of a child but these gametes may not be used in treatment without consent of the gamete provider i.e. the child when they become capable of providing the necessary consent. The storage of embryos may only take place provided consent has been obtained from both of the partners (or donors) whose gametes were used to create the embryos.
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	Other
Please specify 'other'.	Only the gamete providers may give consent to the use of their gametes or embryos, created using thier gametes, after their death.
11.4. Is the consent system for deceased tissue donation the same as for organs?	No
11.4.1. If no, please describe the difference.	The legislation regarding the consent system for organs is under the regulation of the HTA.
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Interviews with personnel Interviews with living donors Other
Please specify 'other'.	We also conduct traceability audits to verify the consent documentation in randomly selected cases (including matching stored tissue samples to consent files).
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	Only trained personnel is allowed to provide such information Other
Please specify 'other'.	Ensure correct procedures are in place at the initial application assessment stage. Follow up during inspections.
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	The HF&E Act 1990 (as amended)sets out the legal requirements in realtion to the disclosure of information. In summary: A centre may hold information that could lead to the identification of: a) an individual donor or recipient of gametes or embryos b) an individual or couple seeking or receiving treatment services (other than basic partner services), or c) an individual who may have been born as a result of such services or as a result of donated sperm.  The centre may disclose this information only in the specific circumstances set out in the HF&E Act 1990 (as amended). The information may, for example, be disclosed: a) to anyone, provided that it is disclosed in such a way that no individual can be identified from it b) to the Authority c) to another licensed centre to enable that centre to carry out its functions under its licence d) to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child) e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified) f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not
11.8. Please specify what measures are in place to ensure that the	reasonably practicable to obtain their consent to disclosure.  Donor details are not stored in recipient notes and vice versa. This

identity of the receipient is not disclosed to the donor and vice versa.	may not be the case if the donation is directed and the donor is
	known to the recipient (e.g. sibling to sibling, parent to child etc.).
11.9. Does your national legislation allows disclosure of donor data	Yes
in case of gametes donation?	
11.10. Do you have any additional comments on consent and data	
protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the	Other
evaluation and selection of donors (except donors of reproductive	
cells) are respected in your country (Art. 15(1), Annex I Directive	
2006/17/EC)? (more than 1 answer possible)	
Please specify 'other'.	Not applicable - this is regulated by the HTA
12.2. How do you ensure that all requirements related to the	Inspections of ART centres
evaluation and selection of donors of reproductive cells are	Audit documentation
respected in your country (Art 15 (1), Annex III of Directive	Other
2006/17/EC)? (more than 1 answer possible)	
Please specify 'other'.	Audit of medical files during inspections.
12.3. Do you have more stringent criteria for donor selection than	No
those listed in Annex I of the Directive 2006/17/EC?	
12.4. What sources are required in your MS for the evaluation of a	Other
deceased donor of tissues/cells? (more than 1 answer possible)	
Please specify 'other'.	The posthumous use of gametes or embryos created using gametes
1 . 3	from a patient / donor who has since deceased may only be used in
	the gamete provider has been screened in accordance with the
	requirements set out in the EUTCD.
12.5. Do you have more stringent criteria for selection of donors of	Yes
reproductive cells than those listed in Annex III of the Directive	
2006/17/EC?	
12.5.1. Please specify.	Age of donors
12.6. Do you have more stringent criteria for autologous donation	No
than those listed in Annex I of the Directive 2006/17/EC?	110
12.7. Do you require more information on the donation of	No
tissues/cells than the mandatory one as laid down in the Annex of	
Directive 2004/23/EC (Art 15(3)?	
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Audit of tissue establishment
tissue establishments in your country (Art 15(1), Annex IV of	Inspection of the centre of human application (e.g. transplantation
Directive 2006/17/EC? (more than 1 answer possible)(For this	centre, ART centre)
question "audit" means a documented review of procedures, records,	Audit of the centre of human application
personnel functions, equipment, materials, facilities, and/or vendors	Other
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.8.1. Please specify.	Ensure correct procedures are in place at the initial application
	assessment stage. Follow up during inspections.
12.9. Do you have any additional comments on selection, evaluation	ap anning mappediation.
and procurement?	
13. Quality management, responsible person, personnel (Article 16	( 17. 18 Directive 2004/23/FC)
13.1. How do you ensure that tissue establishments in your country	·
have in place a quality system respecting the provisions of the	Authorisation requirement Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
records, personnel functions, equipment, materials, facilities, and/or	External addits
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	Authorization requirement
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections

than Languar naggible)	Pagular avaluation of paragraph
than 1 answer possible)	Regular evaluation of personnel Other
Please specify 'other'.	An individual can be appointed as the Person Responsible
rease specify officer.	(reponsible person) only with the approval of the HFEA. That
	person must complete this Persons Responsible Entry Programme
	(PREP) assessment before the HFEA can consider whether or not to
	approve them.
13.3. How do you ensure an appropriate training for the personnel	Inspections
directly involved in the activities of tissue establishments? (more	Regular evaluation of personnel
than 1 answer possible)	Regular evaluation of personner
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	168
13.4.1. If yes, please specify.	All Persons Responsible are required to complete a PR entry
13.4.1. If yes, picase specify.	programme. Other personnel working within the tissue establishment
	may also complete this training.
12.5. Any additional comments on quality management, responsible	may also complete this training.
13.5. Any additional comments on quality management, responsible	
person, personnel?	
14. Reception, processing, storage, labelling and packaging (Art 1	
14.1. How do you ensure that tissue establishments in your country	National regulation/policy for reception of tissues/cells
fulfill the requirments of the Art. 19 (Tissue and cell reception) of	Inspections of tissue establishments
Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	Internal audits of tissue establishments
(more than 1 answer possible)	
14.2. How do you ensure that tissue establishments in your country	SOPs for all processes affecting quality and safety are mandatory for
fulfill the requirements of the Art. 20 (Tissue and cell processing) of	authorisation
Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.3. How do you ensure that tissue establishments in your country	SOPs for procedures associated with storage of tissues and cells are
fulfill the requirements of Art. 21 (tissue and cell storage conditions)	mandatory for authorisation
of Directive 2004/23/EC? (more than 1 answer possible)	Inspections of tissue establishments
	Internal audits of tissue establishments
14.4. How do you ensure that tissue establishments in your country	SOPs for procedures associated with labelling and packaging are
fulfill the requirements of Art. 22 (labelling, documentation and	mandatory for authorisation
packaging) of Directive 2004/23/EC and Annex IV of Directive	Inspections of tissue establishments
2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national	Yes
legislation?	
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	
15.1.1.1. Under which circumstances and for which responsibilities?	The HF&E Act 1990 (as amended) requires licensed centres to
•	establish written agreements with third parties every time an external
	activity will be carried out that influences the quality and safety of
	gametes procured, tested or processed.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	Third party agreemnt are reviewed during the inspection process.
Competent Auhtority(ies) in your MS? Please specify.	
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	Yes
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.1.1. Please specify.	The HF&E Act 1990 (as amended) provides that only permitted
10.1.1.1 icase specify.	gametes or embryos may be used in treatment.
16.2. Has your Mambar State ansameter Jenne Jiff Jiff	
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	
Directives? Please choose from the options below.	Lay your transfer to the same of the same
16.2.1. For all selected options in question 16.2., please provide a short description.	No specific difficulties to report.

16.3. In your opinion, in which of the following Directives are there	Directive 2006/17/EC
shortcomings (if any)? (more than 1 answer possible)	
16.3.2. How would you suggest to solve these issues in Directive	We would like to see a revision of this Directive and in particular
2006/17/EC?	Annex III. We consider that the technical nature of this Directive
	requires that is reviewed on a regular basis to ensure that it continues
	to reflect scientific development. In particular, we would welcome
	of a review of the requirment to screen and test non-partner donors
	each time gametes are procured and a review of the requirement for
	HTLV testing for all gamete donors

UK -	HTA
1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Human Tissue Authority (HTA)
1.1.2. Address of NCA 1:	151 Buckingham Palace Road London SW1W 9SZ United Kingdom
1.1.3. Telephone (central access point):	+4420 7269 1900
1.1.4. E-mail (central access point):	enquiries@hta.gov.uk
1.1.5. Website:	www.hta.gov.uk
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Non-reproductive tissues and cells
	Blood and blood components
	Human organs
	Other
Please specify 'other':	The HTA licenses organisations in England, Wales and Northern
	Ireland that remove, store and use human tissue for purposes outside
	of direct patient treatment, under the authority of the Human Tissue
	Act 2004. These other purposes include anatomy, research, post-
	mortem examination, teaching, and public display. In Scotland, the
1.1.7. What are the role/tasks of the NCA? (more than 1 answer	Human Tissue (Scotland) Act 2006 applies.  Accreditation, authorisation, licensing of TEs
possible)	Inspection
possioic)	Vigilance
	Other
Please specify 'other':	The HTA also gives approval for organ and bone marrow donations
	from living people and is involved in policy development and
	implementation.
1.2. National Competent Authority 2?	No
1.5. Please give a short description of the legal status and	The HTA is an independent government watchdog, operating as a
organisation of the National Competent Authority(ies) (e.g.	UK arms-length body, sponsored by the Department of Health. It
departments, staffing, number of senior and junior inspectors, staff	employs approximately 40 staff, divided into four directorates:
working on EU affairs and legal matters, vigilance officers, budget,	Regulation, Communications and Public Affairs, Resources and
independence from government etc.).	Strategy and Quality. Each of these directorates are led by a
	Director, reporting to the CEO. The Regulation team has
	approximately 17 Regulation Managers (RMs) (who comprise the
	inspection and vigilance team), reporting to three Heads of
	Regulation. The Regulation directorate also comprises the licensing
	and scheduling team and Regulation Officers to support RMs and
	Heads. RMs and members of the Strategy and Quality Directorate
	are involved in policy work, including EU affairs. The Resources
	team include legal, finance and governance and business technology Heads. Decisions about the general strategic direction of the HTA
	and complex living organ donation matters are made by a board (12
	members and a Chair). The board delegates responsibility for some
	strategic decision making to the senior management team.
1.6. In case of MS with federal or decentralised systems, please	Not applicable
indicate the roles/tasks of the Regional Competent Authority(ies).	
(more than 1 answer possible)	
1.7. Could you please describe the competence/mandate of the	Not applicable
Regional Competent Authority(ies) and their relation with the	
National Competent Authority(ies) for tissues and cells:	
2. Procurement (Article 5 Directive 2004/23/EC)	

2.1. Do you authorise the "conditions of procurement"?	Yes
2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible)	By inspecting some procurement centres By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres Other
Please specify 'other':	We license and inspect establishments that carry out procurement activities and provide advice on standards related to conditions of procurement. We may not inspect all procurement centres as some procurement centres operate through a third party agreement with a licensed establishment. Designated Individuals (i.e 'responsible persons') must ensure that suitable practices, staff and premises take place at third party establishments, they will do this in a variety of ways, including conducting audits of the third party. The HTA reviews third party arrangements during a routine inspection of the licensed establishment.
2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)?	Nine new licences were granted in 2011 for procurement activity.  We conducted 68 inspections of establishments that were licensed for Procurement in that period.
2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011).	58
2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011).	21
2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011).	Two. This is only applicable for ovarian or testicular tissue.  Procurement of gametes, embryos and other reproductive cells are within the remit of the HFEA.
2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011).	13
2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed)? (more than 1 answer possible)	Inspections of the site/centre Analysis of the mandatory documentation Other
Please specify 'other':	We also require submission of annual activity data by licensed establishments. We investigate allegations made about non-compliance with procurement standards. To ensure continued compliance, we send out correspondence to the sector, for example through the regular HTA newsletter. We run regular workshops for the sector to ensure that they stay up to date with regulatory requirements. Designated Individuals are also required to undergo an online training programme.
2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing?	Yes  There are 98 establishments that are licensed to oversee donor
2.4.1. Please provide the number of the laboratories performing donor testing.	testing. Laboratories are not directly licensed by the HTA. Clinical Pathology Accreditation (CPA), a private organisation, provides a voluntary national accreditation service. over 95% of UK labs are CPA accredited.
2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible)	Inspections of the laboratories Analysis of the mandatory documentation requested from the tissue establishment Other
Please specify 'other':	Any laboratory undertaking testing under the EUTCDs must either be a licensed entity or it must be working under a third party agreement (TPA) with a licensed establishment. We verify that establishments are only using laboratories where there is a TPA in

	place; TPA's must include requirements for reporting serious adverse events and reactions and traceability. Even though we do not always inspect laboratories, we do sometimes include laboratories as part of the inspection, including ascertaining that lab testing is done with CE marked kits.
2.6. Please provide data on qualified laboratories accredited,	There are 98 establishments that are licensed to oversee donor
authorised or licensed in your country (e.g. number, year of	testing. These establishments may include laboratory premises,
accreditation/authorisation/license, which donor tests are performed etc.).	however laboratories are not directly licensed by the HTA. Clinical Pathology Accreditation (CPA), a private organisation, provides a voluntary national accreditation service. We can directly license laboratories for testing, however there are no active licences held by
	TEs that are laboratories only. There was one licence held by a
	laboratory involved in testing in 2011, however this is now inactive.
2.7. Do you have any additional comments on procurement?	The minimum testing requirements can be found in paragraphs 90 – 94 of our Guide to Quality and Safety Assurance for Human Tissues
	and Cells for Patient Treatment . These tests apply to all relevant
	material for the purposes of the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The following
	biological tests must be performed for all donors as a minimum
	requirement: HIV 1 and 2 - Anti-HIV-1,2 Hepatitis B - HBsAg, Anti HBc Hepatitis C - Anti-HCV-Ab Syphilis - Treponema
	pallidum HTLV-I antibody testing must be performed for donors
	living in, or originating from, high-prevalence areas or with sexual
	partners originating from those areas or where the donor's parents
	originate from those areas.
3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)	
3.1. Please specify laboratory tests required for donors of non-	Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
	Anti HBc
	Anti HCV-Ab
	Treponema Pallidum
3.2. Please specify laboratory tests required for donors of	HTLV-2 Anti-HIV 1
reproductive tissues and cells in your Member State. (more than 1	Anti-HIV 2
answer possible)	HBs AG
uno nel possiolo)	Anti HBc
	Anti HCV-Ab
	HTLV-2
	Treponema Pallidum
3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to	NAT testing is not currently mandatory in the UK. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.).	advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing.
	The HTA considers that there is a very strong case for requiring mandatory NAT testing, particularly in instances where you might have a treatment involving donation from multiple donors and where
	the donations are not stored and therefore cannot be retested at 180
3.4. Do you have concerns on accuracy of the available tests and test	days. No
procedures for deceased donors?  3.5. Are any other laboratory tests required for donors of non-	No
reproductive tissues and cells in your Member State?	110
3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State?	No
3.7. Do you request/use international accreditation systems for testing laboratories?	No
3.8. Do you have any additional comments on testing?	Please note for 3.2 this is only applicable for ovarian or testicular tissue which may come under the HTA's remit. Gametes and
	Gametes and

	embryos come under the authority of the Human Fertilisation and Embryology Authority (HFEA) in the UK. Extra tests must be undertaken, for example HTLV-1, when the conditions in Annex 111, 2.4 apply. We do not specifically request or use international accreditation systems for testing laboratories, however, some UK laboratories have European Federation for Immunogenetics Accreditation (EFI). For organ donation audits we do suggest Clinical Pathology Accreditation (a private UK provider), but do not accredit laboratories ourselves. For tissues and cells we ensure that all testing is done using CE marked kits and the correct tests are completed.
4. Accreditation, designation, authorisation or licensing of tissue es	tablishments (Article 6, Directive 2004/23/EC)
4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability?	Yes
4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments?	No
4.3. Are preparation processes authorised?	Yes
4.3.1. How are they authorised? (more than 1 answer possible)	During routine inspections
	By review of a submitted application with supporting documentation
4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC),	Four suspensions took place. These were not suspensions of the
how many authorisations/accreditation/licenses were suspended in 2011?	whole licence, but rather specific licensable activities. For example, one processing activity was suspended on a licence following an inspection and a regulatory action panel where critical shortfalls were found.
4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011?	1 revocation took place.
4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)?	No
4bis. Overview of tissue/cells establishments authorised by the NC	
	1
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
4.7. Tissue establishments with authorisation pending approval at	
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):	Musculo-skeletal tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.2. How many musculo-skeletal tissue establishments?	Musculo-skeletal tissue establishments one establishment storing bone.
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.2. How many musculo-skeletal tissue establishments?  4.8. Tissue establishments with authorisations pending approval by	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments
<ul> <li>4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):</li> <li>4.7.2. How many musculo-skeletal tissue establishments?</li> <li>4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):</li> </ul>	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.2. How many musculo-skeletal tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.8.9. Please specify the type of tissues/cells and how many.	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.2. How many musculo-skeletal tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments?	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.2. How many musculo-skeletal tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.8.9. Please specify the type of tissues/cells and how many.	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.2. How many musculo-skeletal tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.8.9. Please specify the type of tissues/cells and how many.	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments Multi-tissue establishments Multi-tissue establishments
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.2. How many musculo-skeletal tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.8.9. Please specify the type of tissues/cells and how many.  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.1. How many skin tissue establishments?  4.9.2. How many musculo-skeletal tissue establishments?	Musculo-skeletal tissue establishments  one establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments Multi-tissue establishments One. This is also a multi-tissue establishment.  Five with skeletal tissue only, plus one other multi-tissue establishment.  Four with HSC type tissue only. There were an additional two multi-tissue establishments storing HSC type tissue.
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.2. How many musculo-skeletal tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.8.9. Please specify the type of tissues/cells and how many.  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.1. How many skin tissue establishments?  4.9.2. How many musculo-skeletal tissue establishments?  4.9.5. How many HSC tissue establishments?	Musculo-skeletal tissue establishments  One establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments Multi-tissue establishments One. This is also a multi-tissue establishment.  Five with skeletal tissue only, plus one other multi-tissue establishment.  Four with HSC type tissue only. There were an additional two multi-tissue establishments storing HSC type tissue. One. This is also a multi-tissue establishment.
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.2. How many musculo-skeletal tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.8.9. Please specify the type of tissues/cells and how many.  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.1. How many skin tissue establishments?  4.9.2. How many musculo-skeletal tissue establishments?  4.9.5. How many HSC tissue establishments?	Musculo-skeletal tissue establishments  One establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments Multi-tissue establishments One. This is also a multi-tissue establishment.  Five with skeletal tissue only, plus one other multi-tissue establishment.  Four with HSC type tissue only. There were an additional two multi-tissue establishments storing HSC type tissue. One. This is also a multi-tissue establishment.
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible):  4.7.2. How many musculo-skeletal tissue establishments?  4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible):  4.8.8. How many multi-tissue establishments?  4.8.9. Please specify the type of tissues/cells and how many.  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.1. How many skin tissue establishments?  4.9.2. How many musculo-skeletal tissue establishments?  4.9.5. How many HSC tissue establishments?	Musculo-skeletal tissue establishments  One establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments Multi-tissue establishments One. This is also a multi-tissue establishment.  Five with skeletal tissue only, plus one other multi-tissue establishment.  Four with HSC type tissue only. There were an additional two multi-tissue establishments storing HSC type tissue. One. This is also a multi-tissue establishment.
4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): 4.7.2. How many musculo-skeletal tissue establishments? 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): 4.8.8. How many multi-tissue establishments? 4.8.9. Please specify the type of tissues/cells and how many.  4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible):  4.9.1. How many skin tissue establishments?  4.9.2. How many musculo-skeletal tissue establishments?  4.9.5. How many HSC tissue establishments?	Musculo-skeletal tissue establishments  One establishment storing bone.  Multi-tissue establishments Other tissue establishments one multi-tissue establishment and one "other" establishment.  There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves.  Skin tissue establishments Musculo-skeletal tissue establishments HSC tissue establishments Cord blood tissue establishments Multi-tissue establishments One. This is also a multi-tissue establishment.  Five with skeletal tissue only, plus one other multi-tissue establishment.  Four with HSC type tissue only. There were an additional two multi-tissue establishments storing HSC type tissue. One. This is also a multi-tissue establishment.

	HSC tissue establishments
	Cord blood tissue establishments
	Multi-tissue establishments
	Other tissue establishments
4.10.1.1. How many public skin tissue establishments?	Three public TEs with only skin - some multi-tissue establishments
4.10.1.1. How many public skin tissue establishments?	*
	did work with skin tissue and cells among other tissue types. Skin
	establishments were classified as those working with whole skin,
410.10 X	fibroblast and / or keratinocyte cells.
4.10.1.2. How many private skin tissue establishments?	No private TEs with only skin - some multi-tissue establishments did
	work with skin tissue and cells among other tissue types. Skin
	establishments were classified as those working with whole skin
	and/or fibroblast and / or keratinocyte cells.
4.10.2.1. How many public musculo-skeletal tissue establishments?	41 public TEs with only musculo-skeletal - some multi-tissue
	establishments did work with musculo-skeletal tissues and cells
	among other tissue types. Musculo-skeletal establishments were
	classifed as those working with any combination of the following
	bone, tendons/ligaments, cartilage and chondral tissue,
	demineralised bone, acellular bone chips and other skeletal tissue.
4.10.2.2. How many private musculo-skeletal tissue establishments?	19 private TEs, with only musculo-skeletal. In addition some multi-
	tissue establishments did work with musculo-skeletal tissues and
	cells among other tissue types. Musculo-skeletal establishments
	were classifed as those working with any combination of the
	following bone, tendons/ligaments, cartilage and chondral tissue,
	demineralised bone, acellular bone chips and other skeletal tissue.
4.10.3.1. How many public ocular tissue establishments?	Two public TEs with only ocular tissue - some multi-tissue
, F	establishments did work with ocular tissue among other tissue types.
	Establishments were classified as ocular if they worked with cornea,
	sclear, limbal stem cells and / or other ocular tissue. There were
	other ocular establishments classified as multi-establishments if
	working with ocular tissue and amniotic membrane (other).
4.10.3.2. How many private ocular tissue establishments?	One private TE with only ocular tissue. In addition some multi-
4.10.3.2. How many private ocular tissue establishments?	
	tissue establishments did work with ocular tissue among other tissue
	types. Establishments were classified as ocular if they worked with
	cornea, sclear, limbal stem cells and / or other ocular tissue. There
	were other ocular establishments classified as multi-establishments
	if working with ocular tissue and amniotic membrane (other).
4.10.4.1. How many public cardiovascular tissue establishments?	Three public TEs with only cardiovascular tissue - some multi-tissue
	establishments did work with cardiovascular tissue among other
	tissue types. Establishments were classified as cardiovascular if
	reporting work with heart valves, iliac vessels and other vessels.
4.10.4.2. How many private cardiovascular tissue establishments?	One private TEs with only cardiovascular tissue - some multi-tissue
	establishments did work with cardiovascular tissue (particularly
	cardiac and iliac vessels) among other tissue types. Establishments
	were classified as cardiovascular if reporting work with heart valves,
	iliac vessels and other vessels.
4.10.5.1. How many public HSC tissue establishments?	28 public TEs with only HSC type cells - some multi-tissue
	establishments did work with HSC type cells among other tissue
	types. The HTA does not have a specific reporting category for
	HSC. For the purpose of the survey establishments were categorised
	as HSC establishments if working with any combination of the
	following tissue types: PBSCs, bone marrow, cells for donor
	lymphocyte infusions, other blood cells and embryonic stem cells.
4.10.5.2. How many private HSC tissue establishments?	Three private TEs with only HSC. In addition, some multi-tissue
	establishments did work with HSCs among other tissue types. The
	HTA does not have a specific reporting category for HSC. For the
	purpose of the survey establishments were categorised as HSC
	establishments if working with any combination of the following
	tissue types: PBSCs, bone marrow, cells for donor lymphocyte
	infusions, other blood cells and embryonic stem cells.
4.10.6.1. How many public cord blood tissue establishments?	Three public TEs with only cord blood - some multi-tissue establishments did work with cord blood among other tissue types.

	Please note, If an establishment reported cord blood and cord tissue,
	they were categorised as a multi-tissue establishment.
4.10.6.2. How many private cord blood tissue establishments?	Two private TEs with only cord blood - some multi-tissue
	establishments did work with cord blood among other tissue types.  Please note, If an establishment reported cord blood and cord tissue,
	they were categorised as a multi-tissue establishment.
4.10.8.1. How many public multi-tissue establishments?	There were 46 public multi-tissue establishments. The combination
,	of tissue types held varies. There was one establishment, King's Cell
	Isolation Unit that reported two types of "other" cells: pancreatic
	islets and hepatocytes. This was therefore included in the multi-
	tissue establishment category.
4.10.8.2. How many private multi-tissue establishments?	There were 16 private multi-tissue establishments. The combination of tissue types held varies.
4.10.9.1. Please specify the type of 'other' public tissues/cells	There were three public tissue establishments in the other category.
establishements and how many.	There were two that did not report any activity in 2011 and the other was the DRWF Human Islet Isolation Facility - reporting work with
	pancreatic islet cells. There was one establishment, King's Cell
	Isolation Unit that reported two types of "other" cells: pancreatic
	islets and hepatocytes. This was therefore included in the count for
	the multi-tissue establishment category. Other tissue type categories
	reported to the HTA are: "other tissues and / or cells", umbilical cord
	tissue, pancreatic islets, hepatocytes, amniotic membrane, adipose
4.10.9.2. Please specify the type of 'other' private tissues/cells	tissue (e.g. adipocytes).  There were four private tissue establishments in the other category.
establishements and how many.	These were: one that did not report any activity in 2011. The other
establishenous and now many.	three reporting "other" types of tissues and cells were MTS
	Cryostores, BioEden and the London Centre of Aesthetic Surgery.
	Other tissue type categories reported to the HTA are: "other tissues
	and / or cells", umbilical cord tissue, pancreatic islets, hepatocytes,
	amniotic membrane, adipose tissue (e.g. adipocytes).
4.11. How many tissues and cells were distributed under the direct	0
agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells.	
4ter. Sanctions	
4.16. Have penalties for infringements of the national provisions	Yes
pursuant to the Directive been defined (Article 27)?	
4.16.1. Have penalties already been imposed?	Yes
4.16.1.1. How many penalties have been imposed in 2011 (from	There were 11 sanctions on establishments imposed in 2011, of
01/01/2011-31/12/2011)?	varying degrees of severity. There are a range of sanction options open to the HTA ranging from directions and conditions to criminal
	penalties. For 2011, there were no criminal sanctions imposed.
4.16.1.2. What were the reasons for imposing the penalties? Please	There were a number of reasons for imposing the various penalties
describe.	managed through the regulatory decision making process. The
	majority of penalties were imposed following an inspection where
	shortfalls against regulatory requirements had been identified.
4.16.1.3. What kind of penalties were imposed? Please describe (e.g.	
	Penalties imposed included conditions or directions on seven
suspension of authorisation, criminal penalty etc.)	licences, suspensions of specific licensable activities on three
	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties
suspension of authorisation, criminal penalty etc.)	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties
suspension of authorisation, criminal penalty etc.)	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours.
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing and authorisation process. Initial licence application assessments are
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing and authorisation process. Initial licence application assessments are desk-based. From 4.10.8.1 and 4.10.8.2: There is no specific HTA
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing and authorisation process. Initial licence application assessments are desk-based. From 4.10.8.1 and 4.10.8.2: There is no specific HTA reporting category for a multi-tissue establishment. Establishments
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing and authorisation process. Initial licence application assessments are desk-based. From 4.10.8.1 and 4.10.8.2: There is no specific HTA reporting category for a multi-tissue establishment. Establishments report on the full range of cell types, rather than identifying
suspension of authorisation, criminal penalty etc.)  4.17. Do you have any additional comments on accreditation,	licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed.  The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including nonroutine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing and authorisation process. Initial licence application assessments are desk-based. From 4.10.8.1 and 4.10.8.2: There is no specific HTA reporting category for a multi-tissue establishment. Establishments

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	was categorised as multi-tissue if it had more than one tissue in any of the EC categories, this included umbilical cord blood + umbilical cord tissue = multi-tissue, and also cord blood + HSCs = multi-tissue. Some of the eye banks also keep amniotic membrane (other) as well as ocular tissue, so these have been classified as multi-tissue establishments. Where an establishment had multiple "other" types of tissues and cells, this was also categorised as a multi-tissue establishment.
5. Inspections (Article 7, Directive 2004/23/EC)	
5.1. Is a system in place for organising inspections and control	Yes
measures of tissue establishments?	
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	The Regulation directorate at the HTA is in charge of inspections.
5.1.2. If yes, please specify staffing (how many inspectors).	There are 17 (full time equivalent) Regulation Managers carrying out inspections. Inspections typically require one to two inspectors.
5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible)	Yes
5.2.1. If yes, please specify. (more than 1 answer possible)	Blood Organs Advanced therapies Hospitals Accreditation organisations (e.g. JACIE) Others
Please specify other.	As well as being the European competent authority for tissues and cells for human application and organs, the HTA inspects a range of establishments across several sectors in the UK, being: post mortem; anatomy, research and public display.
5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)?	89
5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof?	There were no non-routine inspections conducted as a result of an SAE or SAR. There were seven non-routine inspections conducted of TEs in 2011, but these were for other reasons such as new premises, changes to licensable activities, follow-up from a previous inspection and follow-up for progress made against conditions on the licence.
5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify.	There were seven non routine inspections in 2011 for the following reasons: 1. A move to new premises. 2. A move to new premises. 3. Checking the suitability of proposed in-house testing facilities for donor serology and NAT testing, and also to verify other recent changes to the licence. 4. A more focussed inspection required. 5. To follow up issues found on previous inspection and designated individual suitability. 6. Checking that shortfalls found during previous inspection had been rectified. 7. To assess progress against conditions.
5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed?	16
5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted?	50
5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted?	24
5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	One critical shortfall led to regulatory action panel leading to suspension of processing activity (not entire licence)

was the number of inspections carried out that were followed by	
suspension of authorisation?	
5.3.7. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	U U
was the number of inspections carried out that were followed by	
closure?	
5.3.8. Outcome of inspections of TEs for non-reproductive	0
tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What	
was the number of other inspections carried out? Please specify.	
5.4. How many routine inspections were conducted in ART	N/A
establishments (from 1/1/2011 to 31/12/2011)?	1,17
5.4.1. How many inspections were conducted in ART establishments	N/A
following serious adverse events or reactions, or suspicion thereof	14/11
(from 1/1/2011 to 31/12/2011)?	
5.4.2. How many other type of inspections were conducted on ART	N/A
establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-	
blower)? Please specify.	
5.4.3. Outcome of inspections of ART tissue establishments carried	N/A
out in 2011 (01/01/2011 to 31/12/2011): What was the number of	
inspections carried out where no shortcomings were observed?	
5.4.4. What was the number of inspections carried out in ART	N/A
establishments where minor shortcomings were noted?	
5.4.5. What was the number of inspections carried out in ART	N/A
establishments where major shortcomings were noted?	
5.4.6. What was the number of inspections carried out in ART	N/A
establishments followed by suspension of authorisation?	
5.4.7. What was the number of inspections carried out in ART	N/A
establishments followed by closure of respective establishements?	
5.4.8. What was the number of other inspections of ART	N/A
establishments? Please specify.	
5.5. Which type of routine inspections do you conduct? (more than 1	General system-oriented inspections
answer possible)	Thematic inspections
1 /	Desk based reviews
5.6. How do you decide which type of routine inspection to conduct?	Desk-based reviews generally take place for the initial application
	assessment. Inspections are scheduled within the two year time
	frame using a risk tool to prioritise inspections. The HTA is
	currently modifying its risk assessment tool. Typical factors include
	size of establishment and range of activity, experience of designated
	individual responsible for oversight of the licence and compliance
	history. The risk tool is also being developed to determine whether
	inspections should be general or themed. A recent themed inspection
	pilot used a number of the factors mentioned above, including input
	from Regulation Managers to identify suitable establishments.
5.7. Until 2011, did you implement the requirement concerning the	Yes
time interval between two inspections (Art. 7.3.)?	
5.8. How many TEs were inspected at least twice between 2008-	112 HA licences were inspected at least twice during this period.
2011 (01/01/2008-31/12/2011)?	
5.9. Did you perform/conduct inspections of procurement sites	No
outside tissue establishments?	
5.9.2. If no, why not?	The Designated Individual is responsible for oversight of any third
	parties. Third party agreements (TPAs) are to be reported to the
	HTA, although this is not authorised by the HTA at the time of
	submission. TPAs are reviewed during inspection. Annex C -
	Statutory conditions on licences authorising activities that may
	involve third parties states: "The Licence Holder, and, where
	different, the Designated Individual, any person to whom a licence
	applies, any third party with whom the establishment has a third
	party agreement, and any personnel of either the licensed
	establishment or third party, must secure that all necessary
	arrangements are made to ensure that all information which is
	collected in pursuance of the licence or a third party agreement in

	relation to the licence: (a) is available for the purpose of tracing donations; (b) is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and (c) is held securely and subject to safeguards against unauthorised additions, deletions, modifications and transfer of information."
5.10. Did you carry out inspections of third parties?	No
5.10.2. If no, why not?	The Designated Individual is responsible for oversight of any third parties. Third party agreements (TPAs) are to be reported to the HTA, although this is not authorised by the HTA at the time of submission. TPAs are reviewed during inspection.
5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)?	No
5.11.1. If no, which guidelines/regulations are used for inspections at national level?	We do not use the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections, however our inspection guidelines are based on this document. For example, we have adopted the preparation process dossier template. We provide establishments with the 'Guide to the quality and safety assurance of human tissues and cells for patient treatment' on our website, to assist them with inspection preparation. We use internal standard operating procedures to provide guidance for Regulation managers on how to conduct an inspection including: - REG-SOP-103 Preparing for a routine HTA site visit inspection; - REG-SOP-105 Scheduling and preparing for a joint inspection with the MHRA; and - REG-SOP-106 Conducting a joint inspection with the MHRA.
5.11.2. If no, please provide a hyperlink to these guidelines/inspections.	http://www.hta.gov.uk/_db/_documents/Annex _Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_
	for_Patient_Treatment.pdf
5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)?	Yes
5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)?	5
5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))?	Yes
5.13.1. Could you please explain why?	A Regulation Manager observed an inspection in Germany in 2012 following allegations made against a German tissue establishment about procurement without consent. The HTA participated in this because of potential effects on UK establishments importing tissue from Germany.
5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))?	No
5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)?	No
5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation?	Yes
5.16.1. If yes, please specify.	We do not keep records on the number of requests from or to other member states. We frequently liaise with other competent authorities over issues of mutual interest, such as the results and control measures of inspections, as part of general enquiries or investigations.
5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States'	Yes

Competent Authorities on their territory or in third countries.	
5.18. Do you have any additional comments on inspections?	From 5.2.1: There are a number of other UK healthcare regulatory agencies with work adjoining that of the HTA. In particular, we carry out joint inspections with the Medicines and Healthcare products Regulatory Agency (responsible for blood, devices and medicines) at establishments who are developing Advanced Therapy Medicinal Products. We are also developing similar arrangements with the Human Fertilisation and Embryology Authority which regulates embryos and gametes. For example, establishments where hESCs are derived from embryos and establishments that procure, test, process, store ovarian / testicular tissue. We also inspect sites such as laboratories and hospitals that are also inspected by other accreditation organisations, such as JACIE, NetCord-FACT and the Clinical Pathology Accreditation organisation. Other interactions include work with NHS Blood and Transplant, where work intersects with the MHRA's regulation of the Blood Directives. There has been some engagement with the US Food and Drug Administration to exchange information about establishments.
6. Import/export (Article 9 Directive 2004/23/EC)	
6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries?	Yes
6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011).	63
6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011).	54
6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries.	We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries.	We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries.	We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries.	We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries.	We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries.	We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries.	This is only relevant in the case of ovarian or testicular tissue.  Sperm, egg cells and embryos fall within the remit of the HFEA. We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections.
6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)?	Yes
6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. 6.12. Did you export tissues/cells from 3rd countries during 2011	We do not collect data on specific country of origin. The total number of tissues and cells imported during 2011 was 22539.  Yes
(01/01/2011-31/12/2011)? 6.12.1. If yes, please provide the data concerning the	We do not collect data on specific country of destination The total
number/volume of exported tissues and cells by country of	number of tissues and cells exported during 2011 was 216.

destination.	
6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries?	No
6.14. What is the relation between import/export of tissues and cells	C. Export of tissues/cells is authorised irrespective of national needs
and self-sufficiency? (more than 1 answer possible)	F. Other
Please specify 'other':	We are not responsible for determining national needs, when authorising tissue establishments to import and export tissues and cells. Certain licensed establishments do however take national need into account, for example, NHS Blood and Transplant and the Anthony Nolan Trust, a charity involved in collection and allocation of cord blood cells to address national needs.
6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country?	Yes
6.15.1. If yes, please specify the number of cases and for which type	We have directly authorised one import of a cranial flap autograft
of tissues/cells.	from the USA.
6.16. Do you have any additional comments on import/export?	We provide guidance for TEs in the form of the 'Guide to the quality and safety assurance of human tissues and cells for patient treatment' at: http://www.hta.gov.uk/_db/_documents/AnnexGuide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf Specific guidance on import and export is available from paragraphs 203 - 210. We also provide FAQs on distribution, import and export on our website at: http://www.hta.gov.uk/licensingandinspections/sectorspecificinform ation/tissueandcellsforpatienttreatment/distributionandimportexportf aqs.cfm Further guidance which we provide to all our sectors regulated under the Human Tissue Act 2004 is available in the form of the code of practice 8: import and export of human bodies, body parts and tissue: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codeso fpractice/code8importandexport.cfm For 6.9 specifically: Guidance on import and export related to cord blood is also provided through our guidance document on cord blood: http://www.hta.gov.uk/_db/_documents/Cord_Blood_Guidance_Doc ument_final_draft.pdf We have also directly authorised two exports to date: one heart valve to Egypt and one PBSC autologous sample to the USA. We have seen an increase in the level of oversight required to ensure that products imported from the US meet equivalent standards. HTA is organising meetings with the American Association of Tissue Banks and FDA in October with the aim of starting to address some of the issues. HTA is involved in the Import / Export Working Group and considers that many of the current difficulties of ensuring equivalence will be addressed by the introduction of the proposed Implementing Directive. We also consider that there is scope to explore the value of establishing an EU inspectorate for third countries.
7. Distribution/intra community exchanges (Article 23 Directive 20	
7.1. Do you have intra-community exchanges of tissues and cells?	Yes
7.1.1. If yes, how do you address the possible more stringent quality	Tissue establishments are required to put into place service level
and safety measures established by other Member States? Please	agreements with licensed establishments in other member states to
specify.	define the obligations for complying with relevant requirements across jurisdictions.
7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States?	No
7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify.	Tissue establishments are required to put into place service level agreements with licensed establishments in other member states to define the obligations for complying with relevant requirements across jurisdictions.
7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible).	Other
Please specify 'other'.	We do allow direct distribution to end users, without requiring a

	licence, provided tissues and cells will not be stored for longer than 48 hours.
7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)?	No
7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS?	Yes
7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011).	We do not collect information on country of destination. The total number distributed to other MS in that period was 41271.
7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011)	We do not collect information on country of origin. The total number distributed from other MS in that period was 238244. Please note - the question wording above says "to other MS" this would be the same response as 7.5.1. We have assumed that the question should have read "from other MS".
7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS?	No
7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage.	Yes
7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection.	There are organisations that operate in the UK as intermediaries obtaining tissue for end users, however most of these are licensed as they are engaged in an intermediate storage step. Our role is therefore to authorise these and monitor them through inspection. We currently license one broker, Cryolife. It is only licensed for distribution, import and export, without storage. We have licensed another broker in the past engaged in the activities of distribution, import and export, however storage was also listed on that licence.
7.8. Are brokers actively supplying health	The licence is now inactive. Yes
professionals/establishments in your country? 7.8.1. Where are the brokers located?	V.
7.9. Do you have any additional comments on distribution?	Your country
8. Register of tissue establishments and reporting obligations (Arti	ala 10. Diwastiya 2004/22/EC)
8.1. Do you have an annual report model/template on the activities	Yes
of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template.	
8.2. How many tissue establishments submitted annual reports of	100% (all)
their activities during 2011. Please provide an estimation. (1 answer possible)	
possible) 8.3. Are these reports publicly available? (Article 10(1))	No
possible)	No
possible)  8.3. Are these reports publicly available? (Article 10(1))  8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?  8.4.2. If no, why not?	No  Currently the data are not publicly available, but we direct enquiries about these data to the Eurocet site. UK licensed establishments do not want potentially sensitive commercial information to be made publicly available.
possible)  8.3. Are these reports publicly available? (Article 10(1))  8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?  8.4.2. If no, why not?  8.5. Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))	No  Currently the data are not publicly available, but we direct enquiries about these data to the Eurocet site. UK licensed establishments do not want potentially sensitive commercial information to be made publicly available.  Yes
possible)  8.3. Are these reports publicly available? (Article 10(1))  8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?  8.4.2. If no, why not?  8.5. Is there a publicly accessible register of authorised tissue establishments in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.	No  Currently the data are not publicly available, but we direct enquiries about these data to the Eurocet site. UK licensed establishments do not want potentially sensitive commercial information to be made publicly available.
possible)  8.3. Are these reports publicly available? (Article 10(1))  8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?  8.4.2. If no, why not?  8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2))	No  Currently the data are not publicly available, but we direct enquiries about these data to the Eurocet site. UK licensed establishments do not want potentially sensitive commercial information to be made publicly available.  Yes  http://www.hta.gov.uk/_db/_documents/Licensing_Reports
possible)  8.3. Are these reports publicly available? (Article 10(1))  8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country?  8.4.2. If no, why not?  8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2))  8.5.1. If yes, please provide us with the link to the register's web site.  8.6. Do you provide data regarding tissues and cells activities to the	No  Currently the data are not publicly available, but we direct enquiries about these data to the Eurocet site. UK licensed establishments do not want potentially sensitive commercial information to be made publicly available.  Yes  http://www.hta.gov.uk/_db/_documents/Licensing_ReportsHA_201307021659.pdf

9. Traceability (Article 8, Directive 2004/23/EC; and Directive 200	6/86/EC)
9.1. Was the donor identification system (Art. 8(2)) implemented in	Yes
your country?	
9.2. Who assigns the unique code for each donation? (only 1 answer possible)	Other
Please specify 'other'.	Tissue establishment or procurement centre.
9.3. How is the data storage for traceability purposes organised in	Both paper records and electronic forms
your tissue establishements (Art 8(4))? (only 1 answer possible)	
9.4. How do you ensure that the 30 years data storage requirement is	We require a records retention policy to be in place. We check this is
respected (Directive 2006/89/EC, Art. 9)? Please specify.	in place both at the initial licence application stage and during
0.5 Daniel 1990 -	inspections.
9.5. Do you have any additional comments on traceability?	Di di 2004/02 A di L (D) di 2007/07
10. Notification of serious adverse events and reactions (Article 11	
10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))?	Yes
10.1.1. If yes, which CA/institution is responsible?	HTA
10.1.2. If yes, please provide a short description of its organisation.	The HTA is a government sponsored regulator and the UK
10.1.2. If yes, please provide a short description of its organisation.	Competent Authority for Tissues and Cells and the Competent Authority under the EU Organ Donation Directive. We are an
	independent watchdog which ensures human tissues and organs are
	used safely and ethically and with proper consent. We regulate organisations that remove, store and use tissue for research,
	anatomy, medical treatment, post-mortem examination, teaching and
	display in public. We also give approval for organ and bone marrow
10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use	donations from living people.
the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting of the EC also at national level?	NO
10.2.1. If no, what template do you use? You are welcome to upload the template if you wish.	Licensed establishments in the tissues and cells for patient treatment sector are required to report SAREs to the HTA within 24 hours of them being discovered. Establishments report via our web Portal and reports are assigned to an HTA Regulation Manager (RM) who reviews the establishment's investigation of the matter. Establishments are asked to provide a copy of their internal investigation report within 90 days of submitting the notification. All communication and RM notes about the SAREs are stored against
	the licence record on our licence management system, CRM.
10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	No
10.3.1. If no, please specify what guidelines you use.	We signpost establishments to the EUTITE V&S Tools for reference when they report SAREs. Information and guidance about SAREs reporting is also provided by RMs on inspection and in our Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment on our website, on pages 40-41 and in Annexes C and D. http://www.hta.gov.uk/_db/_documents/AnnexGuide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf
10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs?	No
10.4.1. Why not?	The HTA has a dedicated team of Regulation Managers in place who assess SAREs from establishments. The team have monthly meetings and promote SAREs reporting and learning across the HTA and when on inspection. A Regulation Officer acts as the administrator and data manager for the team and the reporting system is monitored by the team on a 24 hour basis, and any reports received are responded to within 24 hours.
10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country).	100%
10.6. Do you have a mandatory procedure for the transplantation	No
centres when reporting SAR/SAE to the TEs which distributed the	

tissues/cells (Art 11.2)?	
10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs?	The SAREs reporting requirement is outlined in HTA standards and when establishments initially apply for a licence in the tissues and cells for patient treatment sector. Establishments licensed by the HTA are required to have end-user agreements in place with transplantation centres, which include the requirement to report SAREs. Incident reporting is promoted and monitored on inspection.
10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level?	Yes
10.7.1. Please specify.	The HTA provides feedback during inspections, to suggest better practice through lessons learned from SAR/Es. We notify establishments about any SAR/E implications in a regular enewsletter. We are currently organising a SAREs workshop for October 2013 which will share learning and best practice. It will include interactive sessions to allow staff from licensed establishments to discuss SAREs reporting. We are also considering how we can provide further guidance on our website, e.g. by publishing case studies.
10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level?	Yes
10.8.1. Please specify.	The HTA provides feedback during inspections, to suggest better practice through lessons learned from SAREs. We notify establishments about any SARE implications in a regular enewsletter. We are currently organising a SAREs workshop for October 2013 which will share learning and best practice. It will include interactive sessions to allow staff from licensed establishments to discuss SAREs reporting.
10.9. Do you require your TEs to have a recall procedure?	Yes
10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc).  10.11. Do you have in place a system/procedure to notify Tissue	The HTA did not issue any recalls related to the quality and safety of tissues and cells in 2011. We are aware that three establishments issued recalls as follows in 2011: -Recall of heart valves due to faulty packagingRecall of corneas due to microbiological contaminationRecall of corneas which had been released prematurely from quarantine.  Yes
Establishments and procurement sites in case of a national rapid alert?	
10.11.1. If yes, please give a short description of the system/procedure.	Our process is formalised in REG-SOP-033-Preparing and Issuing a Regulatory Alert. A decision to issue a regulatory alert can be made for a number of reasons, including: information from the EU, another CA/regulator, a serious adverse event or reaction or other regulatory action. Once a decision is made to issue an alert, the alert is added to the regulatory alert register. The Head of Media/Communication and Communications Officers are informed and a distribution list and lines to take are prepared. The distribution list is based on data we hold about the activities of potentially affected UK establishments and the tissues/cell types they work with. The alert wording is approved by a Head of Regulation or Director of Regulation and reviewed by the Head of Media/Communication. Once the alert is approved, we issue a statement on our website and email all establishments on the distribution list. The Head of Regulation or Director of Regulation reviews all responses to the alert.
10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform?	Yes
10.12.1. If yes, please give a short description of the system/procedure.	A RATC is one of the reasons we may make a decision to issue a regulatory alert. If we believe UK establishments are affected by the RATC, we will issue a rapid alert following our formal process in REG-SOP-033-Preparing and Issuing a Regulatory Alert. Once a decision is made to issue an alert, the alert is added to the regulatory

	alert register. The Head of Media/Communication and Communications Officers are informed and a distribution list and lines to take are prepared. The distribution list is based on data we hold about the activities of potentially affected UK establishments and the tissues/cell types they work with. The alert wording is approved by a Head of Regulation or Director of Regulation and reviewed by the Head of Media/Communication. Once the alert is approved, we issue a statement on our website and email all establishments on the distribution list. The Head of Regulation or Director of Regulation reviews all responses to the alert.
10.13. Do you provide data regarding SAR/SAE to the EUROCET	No
registry (non-mandatory reporting)?	Reporting not mandatory. We report all mandatory information.
10.13.2. If no, please specify why not. 10.14. Do you notify alerts communicated via these tissues and cells	Yes
national vigilance system also to other national vigilance/alert systems?	
10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible)	Haemovigilance Pharmacovilance Medical devices Other
Please specify 'other'.	We communicate alerts to the Medicines and Healthcare products Regulatory Agency and Human Fertilisation and Embryology Authority. We also share details of SAREs reported to us if we believe they could have an impact on medicines and healthcare products and/or reproductive tissues and cells.
10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S?	Yes
10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)?	5
10.16. Do you have any additional comments on SARE reporting?	10.5 above is actually not applicable for the HTA: Establishments report SAREs within 24 hours of their discovery, and not via an annual report. As a result, we may not receive data from every establishment every year, as serious reactions or events may not take place at every establishment. We received a total of 130 SARE reports in 2011. We found the training excellent. We follow the EC RATC Platform standard operating procedures when reporting an incident on the RATC platform.
11. Consent and personal data protection (Article 13 and 14, Direc	
11.1. What consent system for living tissue/cell donation do you have in place within your Member State?	Explicit consent (opt-in)
11.1.1. Please specify your choice of consent system for living tissue/cell donation.	Consent or authorisation is given by the donor. If a donor is a child, the child or a person with parental responsibility can give consent. If an adult has mental incapacity, an appropriate person can give consent on their behalf, in line with the Mental Capacity Act. Peripheral Blood Stem Cell donations from children are subject to an approval process by HTA volunteer accredited assessors. This involves interviews with the donor and recipient to ensure there are no potential issues around coercion etc. Any difficult cases can be referred to the HTA Board for a final decision.
11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State?	Presumed (opt-out) and explicit (opt-in) consent
11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify.	The Welsh national assembly has recently passed a Bill to change the Welsh position to one of presumed (opt-out)consent. This system is not yet in place, but will be different from the rest of the UK, which currently has an explicit (opt-in) system of consent.
11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible)	First degree relatives (including spouse) Other relatives Non-marital partners Friends Other

Please specify 'other'.	In England, Wales and Northern Ireland a person in life or a person's "nominated representative" can give consent. There is no mention of "nominated representatives" under the Human Tissue (Scotland)  Act.
11.4. Is the consent system for deceased tissue donation the same as for organs?	Yes
11.5. How is this consent verified during inspections? (more than 1 answer possible)	Analysis of documentation Interviews with personnel Other
Please specify 'other'.	We also conduct traceability audits to verify the consent documentation in some randomly selected cases (including matching stored tissue samples to consent files).
11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible)	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
Please specify 'other'.	Ensure correct procedures are in place at the initial application assessment stage. Follow up during two yearly inspections.
11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify.	Donor and recipient numbers are used to ensure donors and recipients are unidentifiable.
11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa.	Donor details are not stored in recipient notes and vice versa. This may not be the case if the donation is directed and the donor is known to the recipient (e.g. sibling to sibling, parent to child etc.).
11.9. Does your national legislation allows disclosure of donor data in case of gametes donation?	No
11.9.1. If no, please specify the circumstances and measures in place.	This is not applicable - gamete donation is regulated by the HFEA. The HTA does not hold information to confirm this.
11.10. Do you have any additional comments on consent and data protection?	
12. Selection, evaluation and procurement (Article 15 Directive 20	04/23; Annexes I-IV Directive 2006/17)
12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive	Inspections of TEs and procurement sites
2006/17/EC)? (more than 1 answer possible)  12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible)	Other
Please specify 'other'.	Not applicable - this is regulated by the HFEA.
12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC?	No
12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible)	Interview with the donor's family or a person who knew the donor well  Medical records of the donor Interview with the treating physician Interview with the general practitioner Autopsy report Other
Please specify 'other'.	Tissue establishments may use a number of sources to evaluate a donor, including those described in 12.4. We do not specify how to evaluate a deceased donor.
12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC?	No
12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC?	No
12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)?	No

	T
12.8. How do you ensure that all requirements regarding tissues and	Inspection of tissue establishment
cells' procurement, packaging and transport are complied with by	Inspection of the centre of human application (e.g. transplantation
tissue establishments in your country (Art 15(1), Annex IV of	centre, ART centre)
Directive 2006/17/EC? (more than 1 answer possible)(For this	Other
question "audit" means a documented review of procedures, records,	
personnel functions, equipment, materials, facilities, and/or vendors	
in order to evaluate adherence to the written SOP, standards or	
governments laws and regulations (from Council of Europe Guide to	
the Safety and Quality Assurance for the Transplantation of Organs,	
Tissues and Cells, 2011))	
12.8.1. Please specify.	Ensure correct procedures are in place at the initial application
12.6.1. I lease specify.	assessment stage. Follow up during two yearly inspections.
12.9. Do you have any additional comments on selection, evaluation	assessment stage. Follow up during two yearry inspections.
and procurement?	
*	(17.10 Pt. 11.200 1/20 Pt.C)
13. Quality management, responsible person, personnel (Article 16	
13.1. How do you ensure that tissue establishments in your country	Authorisation requirement
have in place a quality system respecting the provisions of the	Inspections
Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For	Internal audits
this question "audit" means a documented review of procedures,	External audits
records, personnel functions, equipment, materials, facilities, and/or	
vendors in order to evaluate adherence to the written SOP, standards	
or governments laws and regulations (from Council of Europe Guide	
to the Safety and Quality Assurance for the Transplantation of	
Organs, Tissues and Cells, 2011)).	
13.2. How do you ensure that tissue establishments have a	Authorisation requirement
responsible person fulfilling the requirements of Art. 17(1)? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
than I answer possible)	Mandatory trainings
13.3. How do you ensure an appropriate training for the personnel	Authorisation requirement
	<u> </u>
directly involved in the activities of tissue establishments? (more	Inspections
than 1 answer possible)	Regular evaluation of personnel
	Mandatory trainings
13.4. Do you have national/regional/local training programmes for	Yes
the personnel of tissue establishments?	
13.4.1. If yes, please specify.	We provide e-learning training for designated individuals. All
	designated individuals are required to undertake this training as a
	licence condition. It is open for other registrants. This is available
	here: http://www.hta.gov.uk/trainingandconferences/e-
	1in
	learningcourses.cfm We also run workshops for TE's e.g we
	recently ran one on authorisation of preparation processes and we
13.5. Any additional comments on quality management, responsible	recently ran one on authorisation of preparation processes and we
13.5. Any additional comments on quality management, responsible person, personnel?	recently ran one on authorisation of preparation processes and we
person, personnel?	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.
	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.
person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  -22 Directive 2004/23/EC)
person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 1914.1. How do you ensure that tissue establishments in your country	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  -22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments
person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC?	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  -22 Directive 2004/23/EC) Inspections of tissue establishments
person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  -22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)
person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) 14.2. How do you ensure that tissue establishments in your country	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  D-22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for
person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  -22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for authorisation
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person, personnel?  14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  D-22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments
14. Reception, processing, storage, labelling and packaging (Art 19 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible)	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  D-22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments External audits of tissue establishments (e.g. ISO)
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14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible)  14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions)	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  D-22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation
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14. Reception, processing, storage, labelling and packaging (Art 19) 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible)  14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible)  14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions)	recently ran one on authorisation of preparation processes and we are planning another in September on SAREs.  D-22 Directive 2004/23/EC)  Inspections of tissue establishments Internal audits of tissue establishments (e.g. ISO)  SOPs for all processes affecting quality and safety are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments External audits of tissue establishments External audits of tissue establishments (e.g. ISO)  SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation Inspections of tissue establishments Internal audits of tissue establishments Internal audits of tissue establishments
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2006/17/EC? (more than 1 answer possible)	Internal audits of tissue establishments
	External audits of tissue establishments(e.g. ISO)
14.5. Any additional comments on reception, processing, storage,	
labelling and packaging?	
15. Third party agreements (Art. 24 Directive 2004/23/EC)	
15.1. Are third party agreements foreseen/allowed in your national legislation?	Yes
15.1.1. If yes, have tissue establishments in your Member State	Yes
notified third party agreements?	165
15.1.1.1. Under which circumstances and for which responsibilities?	To conduct licensable activities other than storage.
15.1.1.2. How are third party agreements controlled (Art 6.2) by the	The Human Tissue (Quality and Safety for Human Application)
Competent Auhtority(ies) in your MS? Please specify.	Regulations 2007 (the Regulations) define a third party agreement (TPA) as: "An agreement in writing between a licence holder (or the designated individual on behalf of the licence holder) and another person, which is made in accordance with any directions given by the Authority under section 23(1) of the 2004 Act for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties), and under which the other person: (a) carries out licensed activity (other than storage) on behalf of the licence holder; or (b) supplies to the licence holder any goods or services which may affect the quality or safety of tissue or cells." A TPA may be used to provide a third party with the authority to undertake licensable activities on behalf of a licensed establishment. For this reason, there are stringent criteria that a TPA must meet, set down in paragraph 118 of HTA's Directions 002/2007. For TPAs where a person or establishment is supplying to the licence holder any goods or services which may affect the quality or safety of the tissues or cells, the requirements for the TPA are contained in paragraph 119 of HTA's Directions 002/2007. The HTA has powers to enter and inspect third party premises. The HTA has powers to direct a licensed establishment to put in place a TPA with a supplier of goods or services where it considers this necessary. The HTA equally has powers to direct an individual licensed establishment not to use a named supplier of either goods or services. Under extreme circumstances the HTA may give details of suppliers from whom no licensed establishments in the UK. The term 'service level agreement' is used for agreements between HTA licensed establishments and for agreements with parities from the EU or third countries. We provide FAQs and a 'third party agreement faqs.cfm #SLA. We have further information available about TPA content and HTA powers in our 'Guide to the quality and safety assurance of human tissues and c
15.2. Any additional comments on third party agreements?	
16. General comments - implementation	
16.1. Do you have at national level more stringent quality and safety	No
requirements than those requested by the EU legislation in this field	
(e.g. restrictions concerning the donation/use of certain tissues/cells,	
mandatory unpaid donation etc.)?	
16.2. Has your Member State encountered any difficulties in	No difficulties
implementing the requirements in the EU Tissues and Cells	To difficulties
Directives? Please choose from the options below.	N
16.2.1. For all selected options in question 16.2., please provide a	No specific difficulties to report.

short description.	
16.3. In your opinion, in which of the following Directives are there	Directive 2006/17/EC
shortcomings (if any)? (more than 1 answer possible)	
16.3.2. How would you suggest to solve these issues in Directive	We would like to see a revision of this Directive and in particular
2006/17/EC?	Annex 11. We consider that the technical nature of this Directive
	requires that is reviewed on a regular basis to ensure that it continues
	to reflect scientific development. In particular, we consider that
	there is a reasonable basis to consider making NAT testing
	mandatory in certain situations (i.e multiple donors, one recipient
	and no storage), product testing instead of serum testing in certain
	proscribed situations and a review of the requirement for HTLV
	testing for all tissue types e.g should terminally sterilised products
	be excluded from the requirement?