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COMMISSION STAFF WORKING DOCUMENT

on the application of Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

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 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62EC setting standards of quality and safety for human blood and blood components

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ABBREVIATIONS

EC = European Commission
ECDC = European Centre for Disease Prevention and Control
EEA = European Economic Area
EU = European Union
GMP = good manufacturing practices
HBV = hepatitis B virus
HCV = hepatitis C virus
HIV = human immunodeficiency virus
HLA = human leukocyte antigen
HTLV = human T-cell lymphotropic virus
ISO = International Standards Organisation
NAT = nucleic acid amplification test
NCA = national competent authority
RAB = Rapid Alerts for Blood
SAE = serious adverse event
SAR = serious adverse reaction
SARE = serious adverse reactions and events
SOP = standard operating procedures

Member State and country codes: http://publications.europa.eu/code/en/en-370100.htm

1. INTRODUCTION

This Staff Working Document summarises the results of a questionnaire survey of Member States on the implementation of the EU blood legislation. The survey was conducted in 2013 and the data reported was from 2012. Replies were sent to the Commission by the 28 Member States, Liechtenstein and Norway (Annex 1)[1]. The quality of reporting and information provided by Member States was satisfactory overall, but some answers called for additional clarifications and verifications, which are reflected in this document. Information on the application of the principle of "voluntary and unpaid donation" is summarised in a separate Staff Working Document. These two documents accompany 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 2002/98/EC, 2004/33/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components.

2. IMPLEMENTATION OF THE EU BLOOD LEGISLATION

Overall, the implementation of the EU blood legislation by Member States is considered adequate.

However, many Member States' experts reported difficulties in the interpretation of its scope. In particular, the inclusion of the donation, procurement and testing of blood and blood components 'whatever their intended use' in Article 2 on the scope of Directive 2002/98/EC has raised some questions for blood competent authorities, because it potentially extends the scope beyond transfusion. While it is clear that if the blood or blood components are for the purposes of transfusion, then the processing, storage and distribution are within the scope of the legislation, a number of questions for clarification have been raised at the competent authority meetings on scope issues.

As the legislation in question does not provide a basis for full harmonisation, there are many differences between Member States in the approaches they have taken to implementation. These differences facilitate successful integration of the requirements into national legislation but in some cases they may limit the possibilities for sharing of resources, including blood and blood components themselves.

2.1. General Provisions - Designation of competent authorities

Under Article 4(1) of Directive 2002/98/EC, Member States must designate the competent authority or authorities responsible for implementing the requirements of the Directive. All 28 Member States plus Norway and Liechtenstein have designated a competent authority in accordance with this provision.

In 16 Member States (AT, BE, BG, CY, DK, EE, ES, HR, HU, IE, LU, LV, MT, RO, SI and UK) plus Liechtenstein, there is one designated national competent authority. In nine Member States (CZ, DE, FI, FR, IT, LT, NL, PT and SK), there are two competent authorities at national level. In three Member States (Greece, Sweden, Poland) plus Norway, there are three. More than one competent authority exists in particular where oversight is divided between various activities or types of substances.

[1] In a number of cases clarification requests were sent to Member States to verify the information submitted. It is important to note that while the original replies of Member States are included at Annex 1, 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.

2.1.1. Portfolio of competences of the national competent authorities

Four Member States (EL, ES, LT and LU) reported that their competent authorities were empowered solely for blood and blood components. Figure 1 shows the additional areas of competences of the competent authorities responsible for blood and blood components.

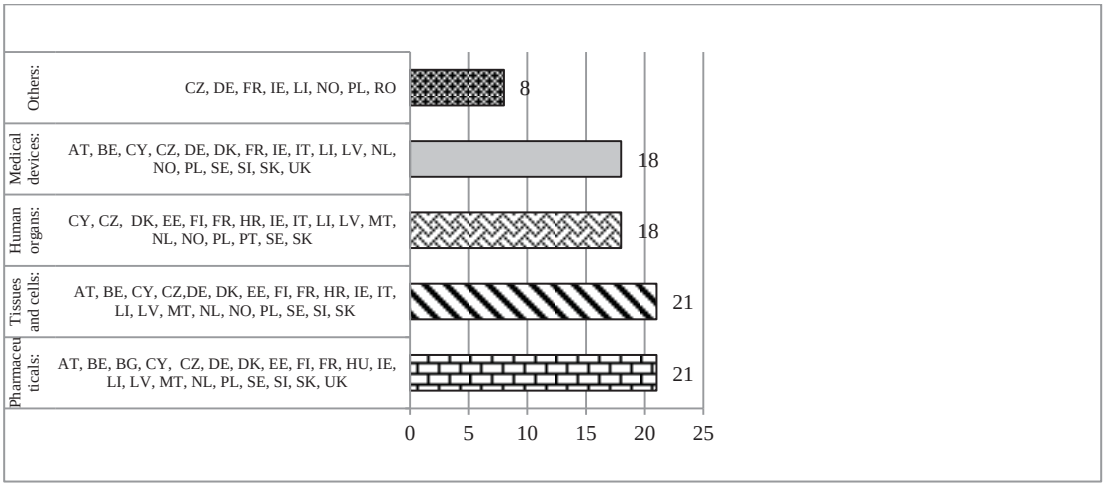

Fig. 1 - Additional competences of national competent authorities

Some Member States reported that their competent authorities have further specific competences, e.g. for: cosmetic products, veterinary products (France, Ireland); tattoo inks, biocides, ancillary products, human breast milk (France); clinical trials approval, protection of animals (Ireland).

Comments

All Member States have appointed competent authorities for blood, which can be considered satisfactory. It is for the Member States to decide on the organisational set-up of their authorities and the designation of different oversight responsibilities.

In most countries, national competent authorities for blood and blood components are also competent for other sectors (primarily tissues & cells, organs, pharmaceuticals and medical devices).

2.1.2. Responsibilities of national competent authorities

There is diversity in the responsibilities assigned to (each of) the designated competent authority(ies) as represented in Table 1.

Table 1 – Roles/tasks of national competent authorities (NCAs)

	Role/ tasks of national competent authorities* NCA1, NCA2, NCA3			
	Authorisation/ Designation/ Accreditation/Licensing	Inspection	Haemovigilance	Others
AT	NCA1	NCA1	NCA1	
BE	NCA1	NCA1	NCA1	
BG		NCA1	NCA1	NCA1
CY	NCA1	NCA1	NCA1	NCA1
CZ	NCA2,	NCA2	NCA2	NCA1; NCA2
DE	NCA2	NCA1;NCA2	NCA1; NCA2	NCA1
DK	NCA1	NCA1	NCA1	NCA1
EE	NCA1	NCA1	NCA1	
EL		NCA1	NCA2	NCA1; NCA2; NCA3
ES			NCA1	NCA1
FI	NCA1	NCA1	NCA1	
FR	NCA1	NCA1	NCA1	NCA1; NCA2;
HR	NCA1	NCA1	NCA1	
HU	NCA1	NCA1		
IE	NCA1	NCA1	NCA1	NCA1
IT			NCA2	NCA1; NCA2
LI	NCA1	NCA1	NCA1	
LT	NCA2	NCA1, NCA2	NCA1	NCA1
LU	NCA1	NCA1	NCA1	
LV	NCA1	NCA1	NCA1	
MT	NCA1	NCA1	NCA1	
NL	NCA1	NCA2		
NO	NCA1	NCA2; NCA3	NCA1	NCA1
PL	NCA1	NCA2	NCA2	NCA2; NCA3
PT	NCA1	NCA1	NCA2	
RO	NCA1	NCA1	NCA1	NCA1
SE	NCA1; NCA2	NCA1; NCA2	NCA1	NCA2; NCA3
SI	NCA1	NCA1	NCA1	
SK	NCA1	NCA2	NCA2	
UK	NCA1	NCA1	NCA1	

*NCA1 – National Competent Authority 1

*NCA2 – National Competent Authority 2

*NCA3 – National Competent Authority 3

National competent authority 1 (NCA 1)

In 22 Member States plus Norway, the NCA1s are responsible for designation, authorisation, accreditation and/or licensing of blood establishments, for inspection in 22 Member States

plus Liechtenstein and for haemovigilance in 20 Member States plus Norway and Liechtenstein.

Many Member States and Norway mentioned that NCA1 has additional functions and responsibilities:

- Coordination of blood services/donation/transfusion (EL, IT, LT, RO, SK);
- National guidelines, implementation of national legislation, policies, legal matters (BG, CZ, DK, EL, IE, ES, IT, RO);
- Import and export of blood components (ES, IT, RO, SK, CZ);
- Personal data protection (EL, SK);
- Recalls of blood components (EL, IE).

National competent authority 2 (NCA2)

The second competent authorities (NCA2) have one or more responsibilities that differ among countries.

In seven Member States, the NCA2 is also responsible for haemovigilance. Six Member States plus Norway mentioned inspection as a main task of NCA2. Four Member States reported designation, authorisation, accreditation and licensing of blood establishments as a main task of NCA2s. Some Member States reported NCA2s being responsible for other tasks such as:

- Epidemiological surveillance of transfusion transmitted infections (EL);
- Coordination and control of national and European provisions, monitoring actions, production of guidelines for quality, safety and appropriate use of blood resources, education and qualification of blood inspectors (IT, SK);
- Pharmaceuticals and medical devices (SE, SK);
- Quality of practices and ethics, health policy, elaboration of legislation proposals, supervision of health agencies (FR);
- Supervision of hospital blood banks (FI, SK, CZ).

National competent authority 3 (NCA3)

In three Member States (Greece, Sweden, Poland) plus Norway, there are three NCAs:

- PL mentioned that NCA3 is responsible for legal issues, data collection, emergencies, budget and funding issues as well as contract management with different blood establishments;
- SE reported that NCA3 is responsible for legislative matters;
- In PL, the main task of NCA3 is organisation and financing;
- NO specified inspection as a main task of the NCA3.

Member States with federal or decentralised systems

In Member States with federal or decentralised systems (IT, DE, HU, ES), the regional competent authorities are responsible for designation, authorisation, accreditation, or licensing of blood establishments, inspection and haemovigilance. Germany explained that the regional competent authorities are entrusted with supervision and continuous monitoring of

compliance with legal provisions. For these purposes, regional authorities grant authorisations of blood establishments and organise inspections. Finland reported that the national competent authority (Valvira) and the six regional state administrative agencies supervise hospital blood banks as a part of other healthcare service providers.

Relations between National and Regional Competent Authorities

Five Member States described existing relations between national and regional competent authorities (DE, FI, FR, ES and IT).

Germany reported that the national competent authority, the Paul-Ehrlich-Institut (PEI) and the regional competent authorities of the *Laender* work together on some activities such as inspections, but have different competences. Regional competent authorities are responsible for activities related to Articles 5 and 8 of Directive 2002/98/EC: monitoring compliance with legal provisions and imposing penalties/sanctions. The national authority is responsible for the marketing authorisation of blood products and pharmacovigilance. The German Federal Government and PEI have different roles and responsibilities to the authorities in the regions (*Laender*).

In Finland, the Finnish Medicines Agency (Fimea) has a centralised supervision of blood establishments, while the supervision of hospital blood banks by the National Supervisory Authority for Welfare and Health (Valvira) and the six regional state administrative agencies is decentralised. Supervision is based on agreed programmes as a part of other healthcare services, which provide guidance and manage related licensing activities. Valvira guides the six regional state administrative agencies and local authorities in the areas of health and social care, alcohol administration and environmental health.

Spain is divided in 17 autonomous communities or regions. Each of these regions has a competent organisation for implementing health policies and for developing regulations at the community level.

In Italy, regional competent authorities are by law entrusted with inspection-based authorisation and accreditation of blood establishments and blood collection units. Inspection programmes and teams are managed by the regional competent authorities, which must include at least one nationally qualified blood inspector. Authorisation and accreditation requirements are defined by national State-Region agreements in compliance with the EU Blood Directives and, where applicable, EU GMPs. The regional blood centres are entrusted, among others tasks, with regional self-sufficiency of blood, components and products, haemovigilance data collection and reporting to the National Blood Centre, regional coordination of blood establishments and blood collection units and interactions with plasma fractionation providers.

Comments

In half of the countries, all main oversight tasks (inspection, authorisation, vigilance) are handled by a single national competent authority. Where more than one competent authority is involved, and in particular where regional/local authorities perform some of these tasks, it is essential to ensure appropriate coordination and communication between all authorities concerned.

To facilitate good regulatory communication between Member States, as well as to comply with the annual reporting requirements to the Commission, a well-informed national coordinating contact is essential, even where competent authority responsibilities are shared among multiple organisations or regions. Irrespective of the organisational set-up in each country, it is important that authorities have appropriate resources at their disposal in order to

ensure their independence from industry, from the professional sector and from other influences. In this respect it could be problematic if an expert works for a national competent authority and – at the same time – for a blood establishment. Several countries suggested addressing this e.g., through regional collaborations between competent authorities of multiple countries. Some Member States called for a common reflection on the organisation of national competent authorities.

Inadequate staffing, e.g. in the inspection department, can bring other, significant risks in terms of oversight. It is also important that staff are adequately trained, an issue that Member States and the Commission have addressed partially in the past and continue to address through ongoing joint actions.

2.2. Obligations on Member State Authorities

2.2.1. Designation/authorisation/accreditation or licensing of blood establishments

Under Article 5(1) of Directive 2002/98/EC, Member States must ensure that activities relating to the collection and testing of human blood and blood components, whatever the intended purpose, and to their preparation, storage and distribution when intended for transfusion, are undertaken only by blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.

Information provided by Member States

Twenty-five Member States plus Norway and Liechtenstein reported that they have a system in place for accreditation/designation/authorisation/licensing of blood establishments and that the responsible NCAs are empowered to give accreditation, designation, authorisation or licences.

In particular, Member States reported that blood establishments are provided with an:

- Authorisation (BG, BE, CZ, ES, DE, DK, FR, HR, IE, NO, SK, SI, UK);
- Accreditation (PL);
- Designation (CY, NL);
- Licence (EE, MT, FI, LT);
- Authorisation/accreditation (IT);
- Authorisation/designation (LV, RO);
- Authorisation/licensing (AT, HU, LI, PT, SE);
- Authorisation/designation/licence (EL);
- Authorisation/accreditation/designation/licence (LU).

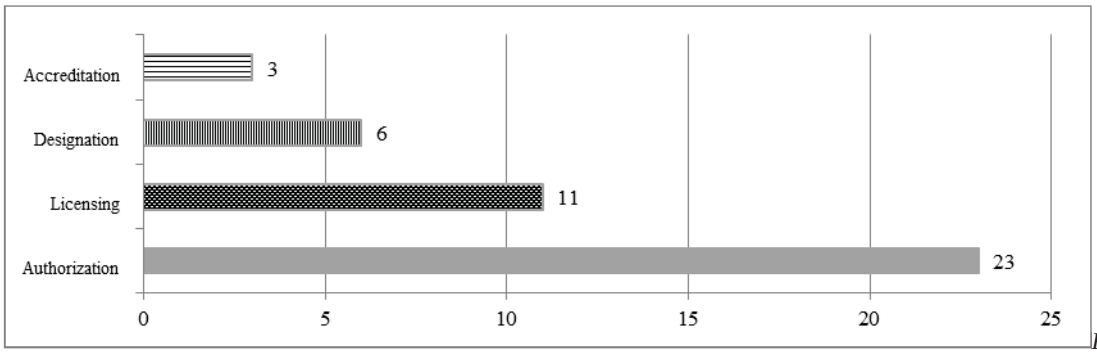

Fig. 2 – Authorisation/accreditation/designation/licence issued by national competent authorities

All blood establishments have effectively received a designation, authorisation, accreditation or licence from the competent authorities in 25 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, LT, LU, LV, MT, NL, PL, SE, SI, SK, UK) plus Liechtenstein and Norway.

Three Member States were not in a position to confirm that all blood establishments were authorised, licensed, designated or accredited in line with the Directive. They reported the following:

- IT reported that all blood establishments were authorised according to pre-existing national requirements. The authorisation process of all blood establishments according to the new regulations complying with the EU Directives were expected to be finalised by the end of 2014. By the end of September 2013, 6% of blood establishments had been authorised according to rules set out in EU legislation. The reasons for the delays were: a) lack of homogeneous performance among regions, b) significant demands of the fulfilment of some GMP requirements and c) an excessive number of blood establishments;
- PT reported that the information on the number of authorised blood establishments was not yet available as some blood establishments were still being evaluated by the new competent authority;
- RO reported that none of the blood establishments were authorised because the authorisation process had not yet been started, but blood establishments were designated (authorisation to function with a yearly renewal) by Law 282/2005. The reported reasons for the delay were: a) delay in setting up the Government Decision on organisation and functionality of BEs, as set up in Law 282/2005 and b) a need to revise the Order on authorisation of BEs and revise and complete the national standards to ensure the legal basis for verification during inspection. In 2013, an administrative reorganisation was foreseen including of the blood transfusion system.

Inspections, accreditation, authorisation, designation and audit were measures reported by all Member States plus Norway and Liechtenstein to ensure the compliance with the requirements of Article 5(1) of Directive 2002/98/EC.

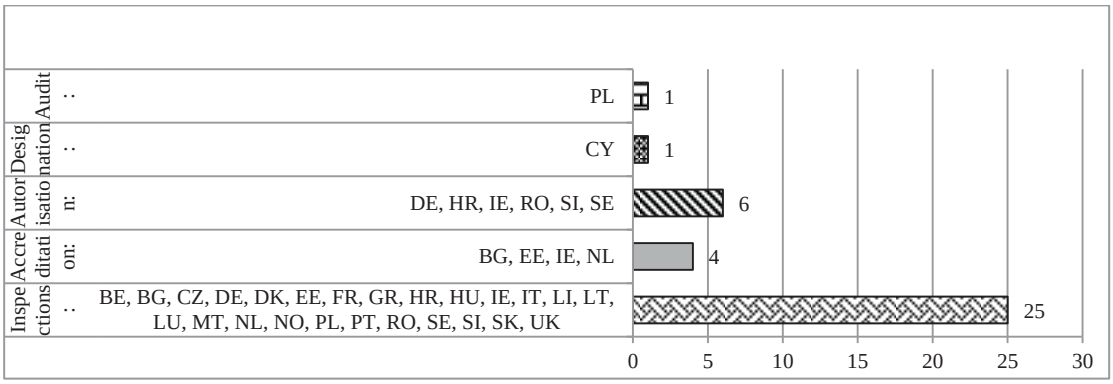

Fig. 3 – Control measures to ensure Article 5 requirements are met

Under Article 5(5), the competent authority or authorities may suspend or revoke the designation/authorisation/accreditation/licence of a blood establishment if it is found to no longer comply with the requirements of the Directives.

Revoked authorisations were reported by Greece, Portugal and Liechtenstein:

- EL reported that authorisations were revoked due to administrative reasons associated with a stepwise centralisation system, starting with the nationwide implementation of NAT testing for HIV, HCV and HBV in September 2008 and followed by the economic crisis and the various structural changes in the national health system (early retirement or suspension of staff, merging of blood services and in certain situations lack of resources delaying procedures);
- PT mentioned as reasons for revoking authorisations: problems with donor testing, poor compliance with good practices and quality system issues.

Comments

All Member States fulfil their obligations to have a system of authorisation as laid down in the EU legislation, applied on almost all of the 1,363 reported blood establishments.

2.2.2. Inspections and control measures

Inspection Systems

Under Article 8(1), Member States must ensure that the competent authority or authorities organise inspections and appropriate control measures in blood establishments. Comprehensive inspection systems were reported to be in place by 27 Member States plus Norway and Liechtenstein. Cyprus explained that the system is not in place due to a lack of trained professionals (four professionals were recently trained under an EU-funded project).

In 26 Member States plus Norway these inspections of blood establishments overlap with other inspections schemes as shown in Figure 4.

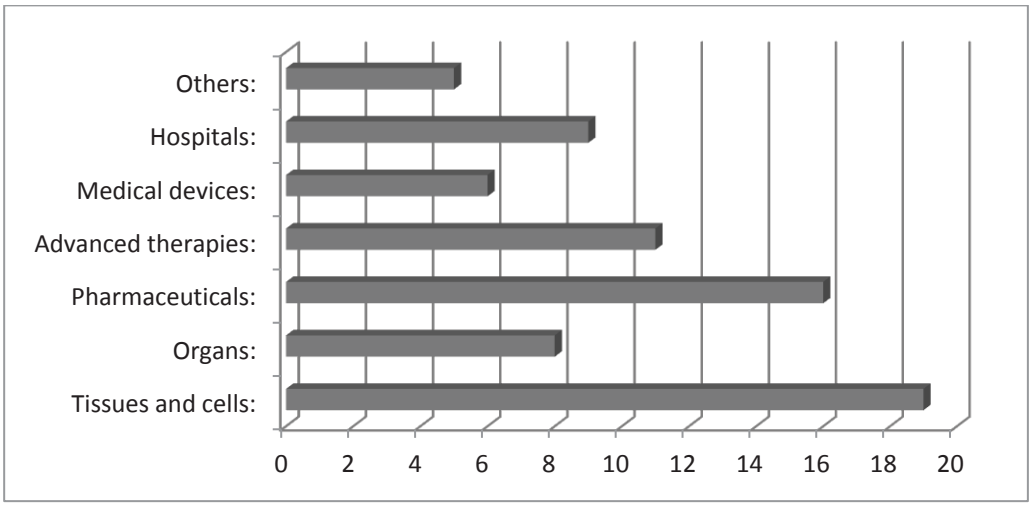

Fig 4 – Overlapping inspection schemes

Responsible authorities

The following table summarises the competent authorities and departments which are in charge of inspections for each Member State.

Country	AT	BE	BG	CY	CZ
CA/ Department	Federal Office for Safety in Health Care (BASG) / AGES Austrian Agency for Health and Food Safety	Federal agency for medicines and health products FAMHP	Executive Director of Bulgarian Drug Agency – inspections direct control CA/Department -" Control of blood transfusion system"- inspections .	Not reported	State Institute for Drug Control, Inspection Division, Clinical Practice and Surveillance over Biological Material Processing
Country	**DE**	**DK**	**EE**	**EL**	**ES**
CA/ Department	Regional Competent Authorities and the National Competent Authority – Paul-Ehrlich-Institut (PEI)	Sundhedsstyrelsen (Danish Health and Medicines Authority)	State Agency of Medicines (SAM), Department of Biologicals	For regular inspections National Blood Centre in cooperation with the Regional Health Authorities. Inspections in specific situations and in case of revocation SEYP (Body of Health Inspectors)	1. The Regional Health Authority Inspection Department 2. Accreditation systems - scientific societies (CAT)
Country	**FI**	**FR**	**HR**	**HU**	**IE**
CA/ Department	The Finnish Medicines Agency (Fimea), Supervision and licences - process, Inspectorate -unit.	Biological Products Inspection Department and Control Department	Ministry of Health Service for blood, tissues and cells inspection	National Institute for Quality- and Organizational Development in Healthcare and Medicines National Institute of Pharmacy Inspection department	The Compliance Department of the Irish Medicines Board (IMB)
Country	**IT**	**LI**	**LT**	**LU**	**LV**
CA/ Department	Regional health authorities	Arzneimittelkontrolle des Amtes für Gesundheit – coordination of inspections delegated to Swissmedic by agreement	Special department / unit in charge of inspections and control measures of BEs has not been established.	Health Directorate - Inspection Sanitaire	State Agency of Medicines. Pharmaceutical activities. Compliance evaluation department
Country	**MT**	**NL**	**NO**	**PL**	**PT**
CA/ Department	The Superintendent of Public Health	Health Care Inspectorate	Norwegian Board of Health Supervision - Dept of planned inspections and Norwegian Medicines Agency- Dept for inspections and narcotic drugs control	Institute of Hematology and Transfusion Medicine (IHTM) – Department of Transfusion Medicine •	Direccao Geral de Saude (DGS) - Department of Quality in Health
Country	**RO**	**SE**	**SI**	**SK**	**UK**
CA/ Department	Public Health and Control in Public Health Directorate (PHCPHD)- inspection coordination Public Health County Authority- department of inspection.	Health and Social Care Inspectorate: Medical Products Agency: Department of inspection	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Agency for Medicinal products and Medical Devices of the Republic of Slovenia)	Inspection Section of The State Institute for Drug Control.	Medicines Inspectorate, Inspection, Enforcement & Standards Division, MRHA

Table 2- Competent authority (CA) and department in the authority in charge of inspections/Member State

Empowerment

The number of full-time inspectors in these competent authorities ranges from 1 to 113. Cyprus, Spain and Lithuania did not provide answers on the number of inspectors. Germany clarified that it was not appropriate to provide the numbers of inspectors since the inspectors typically are based within the regional competent authorities, whereas the Paul Ehrlich Institute, as competent higher federal authority, typically participates with an expert function.

Under Article 8(3) of Directive 2002/98/EC, the competent authorities must be empowered to inspect blood establishments, as well as facilities of any third parties on their own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection. Twenty-five Member States plus Norway reported compliance with this Article.

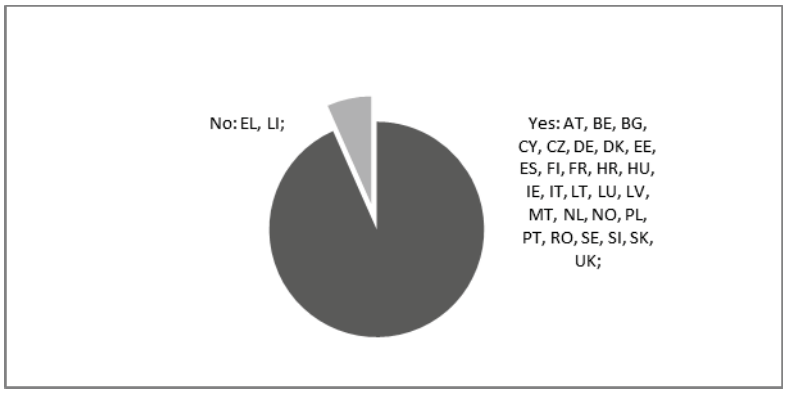

Fig. 5 – Inspector empowerment

The answers from Greece and Liechtenstein did not clarify the powers of inspectors.

Training and support

Member States were asked their views on projects funded by the Commission for training inspectors (Eustite, EUBIS, and CATIE), including participation and usefulness, rating them from 1 (not important) to 5 (essential). Twenty-five Member States, plus Liechtenstein and Norway had sent (or intended to send) their inspectors to the training courses funded by the European Union. The training courses were classified as very good and essential by 21 Member States plus Liechtenstein, and as good by three Member States plus Norway. No Member State considered the training courses as not important and only Austria classified them as sufficient.

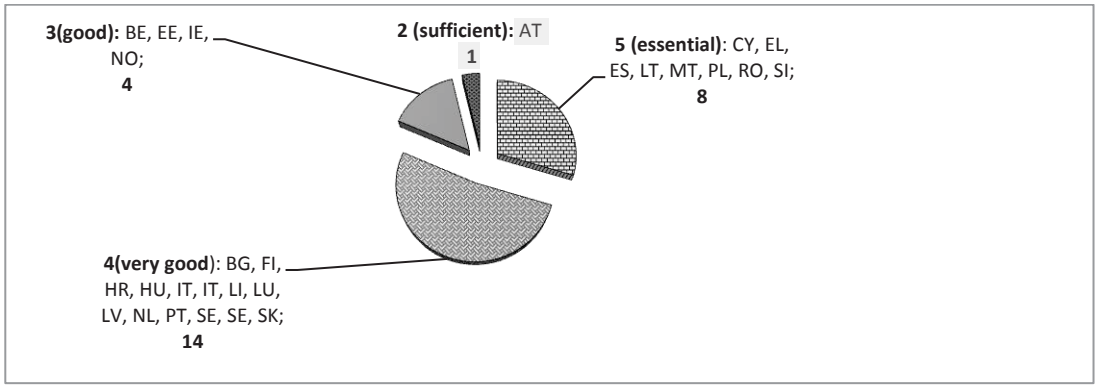

Fig. 5 – Training Course evaluation

Denmark justified not sending inspectors for training courses due to lack of human resources, Czech Republic mentioned internal reasons (not specified), France explained difficulties due to ANSM reorganisation (in 2013, one inspector attended one training course) and the United Kingdom cited extensive experience in inspecting blood establishments and third countries since a change in national legislation in 1992.

Ten Member States (EE, HR, HU, IE, IT, LV, MT, PL RO and UK) reported international collaboration on inspections with other Member States, such as an inspection of a blood establishment in another Member States, an inspection of a blood establishment in a third

country, or responding to requests from other Member States regarding the results and control measures of their own inspections.

Twenty-five Member States plus Liechtenstein and Norway use the Council of Europe Guide to the preparation, use and quality assurance of blood components at national level. 18 Member States rated the guide as useful/helpful to excellent. Luxembourg reported that they had plans to use the guide in the future.

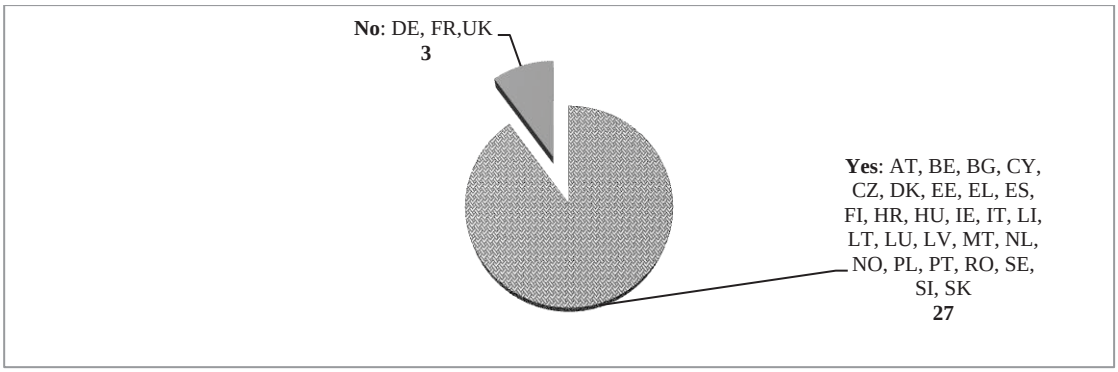

Fig. 6 – Use of the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components at national level/country

Comments

Whilst overall Member States appear to correctly implement the provisions concerning inspections, a number of Member States reported difficulties related to staffing, which makes it difficult to comply with the required 2-year inspection interval. Many considered that a risk-based approach to inspection scheduling would be more effective and efficient instead of the required 2-year inspection interval. Also there is a need to clarify the basis of an inspection, i.e., desk-based assessments versus on-site inspections.

Inspector powers and inspector training were regularly commented upon. The value of international projects, at EU level and co-ordinated by the Council of Europe, are clearly appreciated by most of the competent authorities in order to help maintain an adequate level of training and know-how within the groups of inspectors.

2.2.3. Inspections of blood establishments

Inspection Plan

In 17 Member States plus Norway inspections are planned based on a risk-based approach.

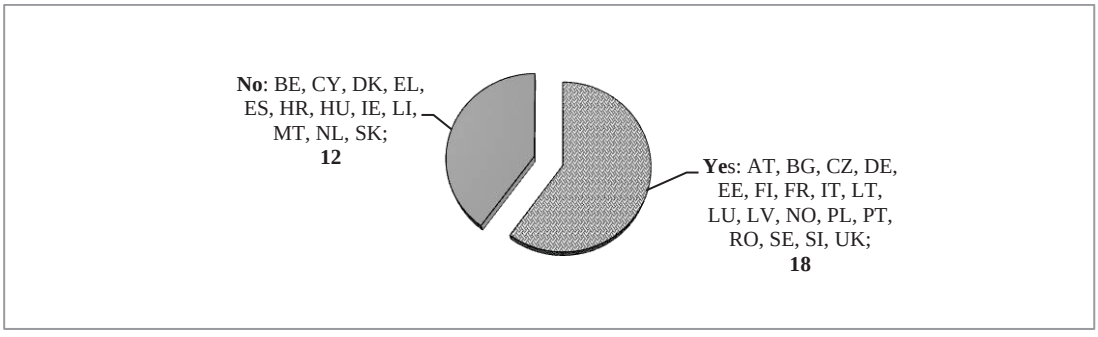

Fig. 7 – Risk-based approach to inspection

Number and type of inspections

The answers provided by Member States were not detailed enough to perform a complete analysis concerning the number and type of inspections (routine, following serious adverse events or reactions and other) in 2012. However, in 2012, 22 Member States plus Norway reported 775 general system oriented on-site inspections. Cyprus, Hungary, Luxembourg and Liechtenstein reported that no inspections were performed in 2012. Data was not provided by Austria, Belgium and Denmark.

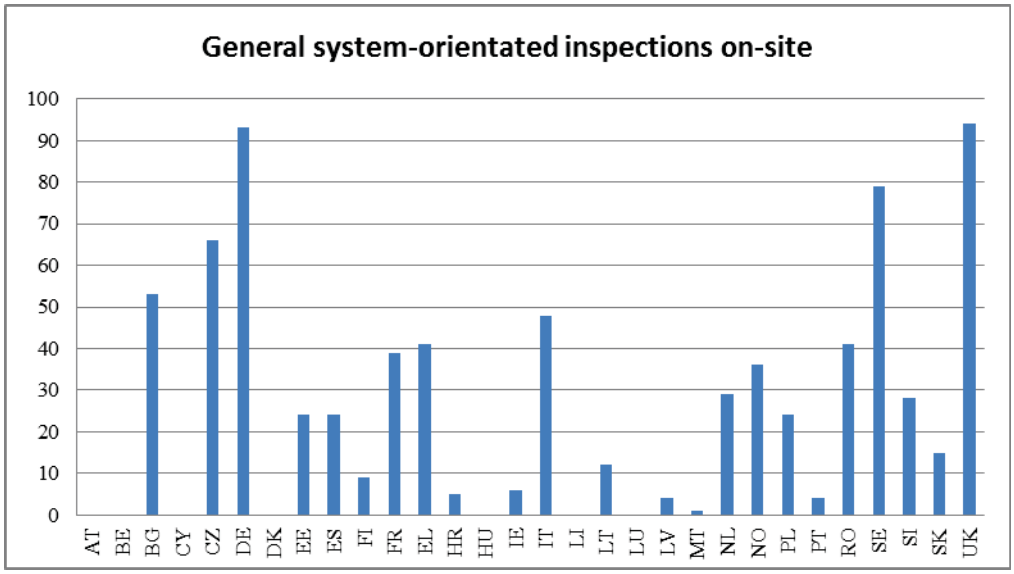

Fig. 9 – Number of system-oriented on-site inspections per country

Fourteen Member States reported 161 thematic/limited on-site inspections in 2012. Sweden reported 15 desk-based inspections and 79 on-site inspections. Slovenia reported that 15 inspections were performed between 1 January 2008 and 1 December 2012.

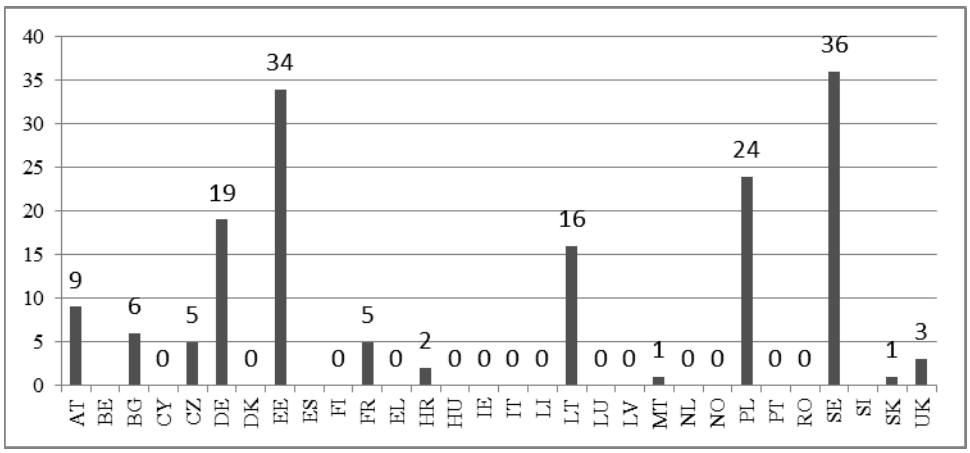

Fig. 10 - Number of thematic inspections per country

As set out in the Article 8(4) of Directive 2002/98/EC, the competent authorities must organise inspections and carry out control measures as appropriate in the event of a serious adverse reaction or event (SARE). Nine Member States (BG, DE, EE, FR, HR, IT, LT, PL, RO, SK) reported 21 inspections following a SARE or a suspected SARE. The UK reported that SARE information was considered as a risk indicator when planning and scheduling inspections, but was not necessarily a trigger for an immediate inspection. PL explained that

immediate inspections follow every SARE and are analysed by a special team. In 2012, 22 cases were analysed in Poland.

Additional information on inspections was provided as follows:

- BG reported 30 routine and five non-routine (following SARE) inspections in hospitals performing transfusion of blood and blood components as a part of their medical activities;
- In ES, 24 blood establishments were inspected, of which five were on-site inspections for accreditation and seven for monitoring, 16 ISO Norm 9001 inspections (nine for accreditation and seven for monitoring) and eight "other" without specification;
- FR reported seven inspections regarding enhancement of the processing of the amotosalen plasma (plasma pathogen reduced/pathogen inactivated), four inspections of haemovigilance organisations and three at mobile collection sessions;
- LT reported three inspections due to a whistle-blower.

Difficulties complying with the required two year intervals when inspecting blood establishments

In the last three years, 559 BEs were inspected at least twice as reported by 20 Member States plus Liechtenstein and Norway. However, CY, EL HR, IT, LU, MT, PT reported that none of their blood establishments were inspected at least twice in the last three years.

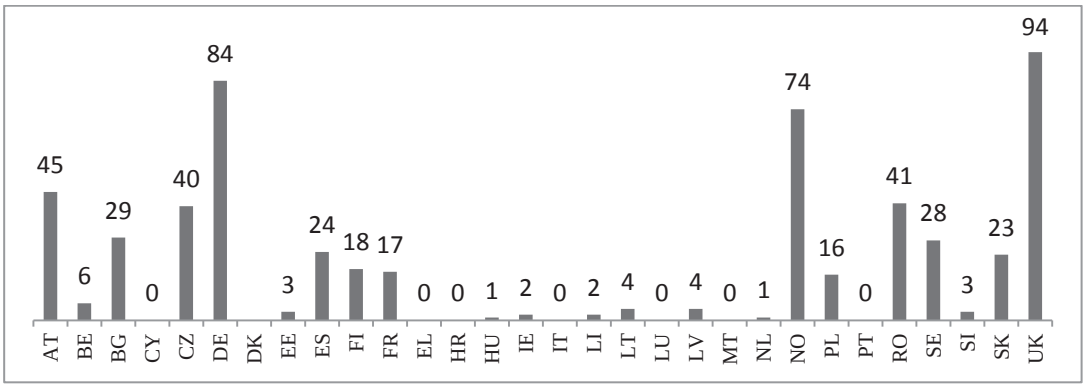

Fig. 11 – Number of blood establishments inspected at least twice in the last 3 years/country

Half of the reporting countries considered it difficult to comply with the two-year inspection interval required by Article 8(2) of Directive 2002/98/EC.

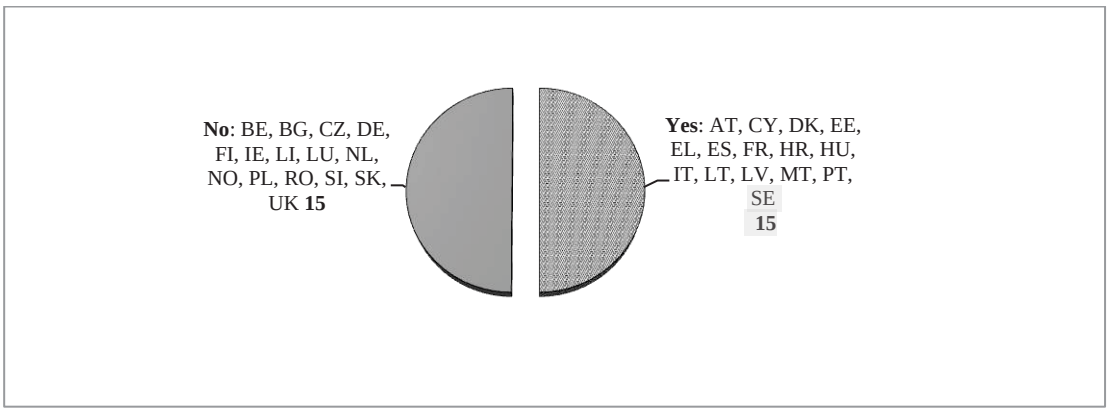

Fig. 12 – Difficulties in complying with inspections every two years

The reasons mentioned by Member States experiencing difficulties were: lack of human resources, current definitions in the EU Blood Directive 2002/98/EC not providing sufficient detail in the description of site activities (e.g. mobile or satellite sites) (Germany) and few results compared to the time and effort invested. Member States who did not report such difficulties quoted a sufficient number of inspectors, inspections performed by more than one competent authority, small numbers of authorised blood establishments and blood banks managed through an accreditation body, and existing adequate resources assigned to inspect the blood establishments.

Inspection outcomes

Some suspensions of authorisations or closure- of blood establishments were reported in the replies to the survey. No data is available on the number of blood establishments that voluntarily ceased operation or were forced to cease operation for other reasons (e.g. economic). Poland reported the dismissal of one blood establishment director in 2013. Romania reported that four inspections were organised following SARE or the suspicion of SARE. For three of them, it was found that the procedures were compliant with the regulations. For one, administrative measures were imposed due to clerical errors. Four Member States reported having to impose penalties (BG, CZ, LT, SK). It was noted that there is a divergence in criteria for assessment, classification of deficiencies and eventual outcomes of inspections.

Comments

A move towards a system of risk-based assessment to prioritise establishments to be inspected has been cited as being effective by several Member States. Such systems would be preferred by many instead of, the current legislative requirement to inspect all blood establishments within at most a two-year interval.

There is a divergence in criteria for assessment, classification of deficiencies and some Member States called for developing more common definitions of deficiencies and outcomes of inspections.

2.2.4. Other inspections

Inspections and control measures of mobile and satellite collection sites

Difficulties with inspecting mobile and satellite collection sites every two years, as required by Article 8 of Directive 2002/98/EC, were raised by many Member States, both in the 2013 competent authorities meeting[2] and in response to this survey, due to the high number of existing sites and the definition of 'mobile site' not being adequately precise.

Some Member States, such as France, the United Kingdom and Belgium, have proposed a risk-based approach to define inspections intervals for these sites and a clarification of the blood establishment definition. France also proposed changes to Article 8 to include specifications regarding mobile site inspections.

[2] Meeting of the Competent Authorities on Blood and Blood Components 17 and 18 April 2013, http://ec.europa.eu/health/blood_tissues_organs/docs/blood_mi_20130417_en.pdf

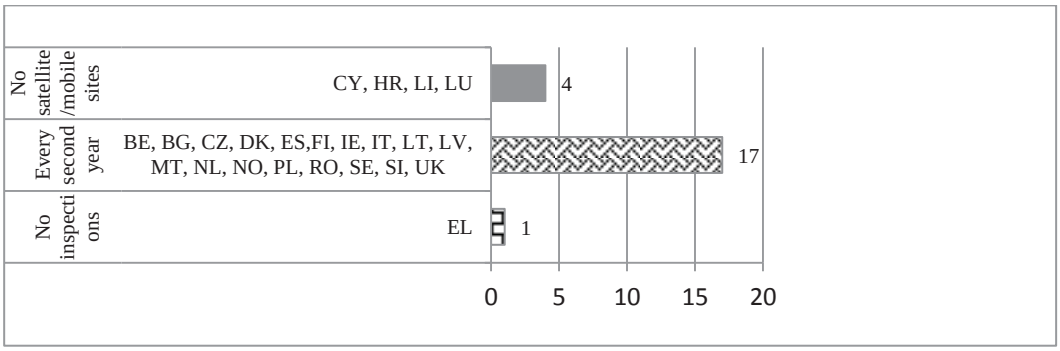

Fig. 13 - Inspection scheme of mobile and satellite sites

Inspection approaches for these sites are quite different between Member States. One Member State (Greece) reported having no inspections in place for these sites, while 21 Member States plus Norway reported following a variety of approaches for inspecting mobile/satellite sites:

- DK, HU, IE, LT, LV, RO, SI, plus NO reported that all mobile sites are inspected every two years although RO clarified that they only inspect fixed sites, not those sites where teams from a blood establishment go with their own equipment;
- In AT, at regional level, the sites are inspected based on a risk-based approach;
- In BE, satellite collection sites are inspected every two years. The mobile collection sites are inspected at a rate of two per province (there are 10 provinces in Belgium plus the region of Brussels);
- In BG, equipment and documentation are inspected on a regular basis during routine inspections as the mobile team's staff are considered part of blood establishment personnel. One blood establishment's satellite site for blood collection was inspected twice in a period of four years, as part of the blood establishment;
- CZ reported that mobile collection sites are inspected once every four years and satellite collection sites once every two years;
- DE reported that for satellite collection sites and mobile sites inspection intervals are generally equivalent to routine inspections of the related blood establishments, since the satellite collection sites and the mobile sites are considered to be part of the blood establishment;
- EE reported that satellite sites have separate authorisations and are inspected at least every two years as blood establishments. Mobile sites are inspected as part of a blood establishment; occasionally on-site inspections are carried out;
- ES satellite sites are inspected every two years and a sample of the total number of the mobile collection sites is inspected;
- FI has 18 satellite sites inspected every two years;
- In FR, the operation and management of the mobile collection site teams and equipment are inspected every two years, as part of the inspection of the reference blood establishment. The premises are inspected *as regularly as necessary* (less than ten inspected every year);
- IT reported that the sites are inspected every two years, but a risk-based approach will be introduced;

- NL reported that mobile sites are inspected randomly without specifying the frequency and intervals;
- PT reported that the intervals for inspecting those sites are yet to be defined by the new competent authority;
- SK reported that blood establishments are inspected every two years. Mobile site[s] can be included in this inspection, without clarifying if they are inspected;
- In the UK, mobile sites are inspected based on a risk-based sampling exercise during the inspection of their associated blood establishment.

Plasma establishment inspections

In 2012, 253 plasma establishments (a site for the collection of plasma) were inspected in 11 Member States plus Norway. CY, EE, HR, HU, IE, MT, PT, RO and SI reported not having sites for plasma collection. Bulgaria, Spain, Italy and Norway reported that they do not have establishments exclusively performing plasma collection. The United Kingdom reported 16 inspections performed in third countries, as plasma is not collected nationally. Four Member States did not respond.

Hospital Blood Bank Inspections

Hospital blood banks (HBB) are inspected in 23 Member States plus Liechtenstein and Norway.

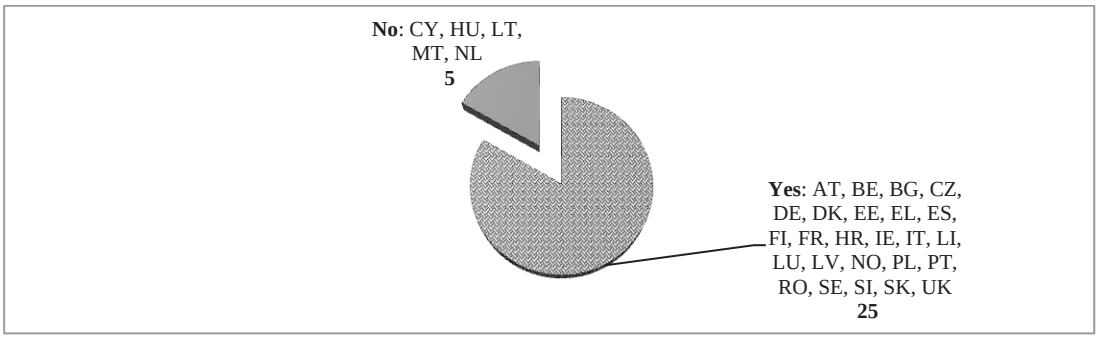

Fig. 14 – Hospital blood bank inspections

In 17 Member States plus Liechtenstein and Norway, the blood national competent authority is involved in the inspections of the HBBs. Ireland clarified that the Irish National Accreditation Board authorises the HBBs with the supervision of the blood competent authority.

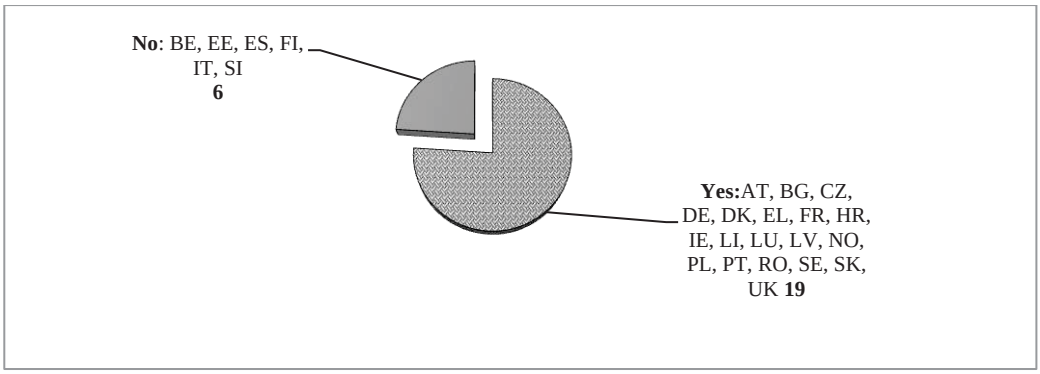

Fig. 15 – Hospital blood bank inspections with involvement of the blood competent authority/country

Comments

A significant divergence between national practices emerges as regards the inspection of the 731 mobile units and 534 satellite centres, where an important part of the blood (components) is collected.

2.3. Provisions for Blood Establishments

2.3.1. Responsible person

Under Article 9 of Directive 2002/98/EC, blood establishments shall designate a responsible person whose responsibilities and qualifications are defined in paragraphs 1 and 2 of this Article. All Member States plus LI and NO reported having a designated responsible person fulfilling the Article 9 (2) requirements in every blood establishment. In 19 Member States (BE, BG, CY,CZ, DK, EE, ES, FR, HR, IE, LI, LU, LV, NL, PL, RO, SE, SI, SK and UK) plus Norway, the responsible person's tasks are delegated to other qualified persons where necessary. The competent authorities check the qualifications of the responsible person during inspections.

Comments

All Member States reported having responsible persons in each blood establishment. The qualifications of the responsible person, and possibly his/her delegates, are verified during inspections. Member States reported the value of Joint Actions and the work of the Council of Europe (CoE) in clarifying common understanding and expectations towards responsible persons, their qualifications and possibilities of delegation, as these can vary between Member States.

2.4. Quality management

2.4.1. Quality System for blood establishments

As required by Article 11 (1) of Directive 2002/98/EC and Article 2 (1) of Directive 2005/62/EC, Member States shall take all measures to ensure that each blood establishment and hospital blood bank (Article 6) maintains a quality system based on good practices.

All Member States reported that blood establishments and hospital blood banks have a quality system which is verified and strengthened through the following measures:

- Inspections (AT, BE, BG, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, MT, NL, PL, PT, RO, SE, SI, SK, UK plus LI and NO);
- Audits (IE, LV, PL);
- Training courses (FR, HR, LV, RO).

2.4.2. Record keeping

Under Articles 13 and 14 (3) of Directive 2002/98/EC, Member States must ensure that blood establishments maintain records of the information required in Annexes II and IV. Moreover Articles 14 (3) of Directive 2002/98/EC and 4 of Directive 2005/61/EC require that blood establishments, hospital blood banks or facilities keep data to ensure full traceability for a minimum of 30 years in an appropriate and readable storage medium.

As reported, compliance with this requirement is verified through inspections and legal provisions to verify compliance:

- CY reported that requirements are fulfilled under the responsibility of the responsible person. Nonetheless it was not clear how this is checked by the competent authority;
- EL replied that *for BEs and HBBs without a computerised system, this requirement cannot be fully respected*; it is therefore not certain if these requirements are fulfilled in all Greek BEs and HBBs;
- ES mentioned specific computer systems;
- UK reported that this is ensured by IT systems, data retention policies and a disposal schedule.

The required mediums to store records are paper and electronic forms in 26 Member States, while only electronic forms are required in 2 Member States plus Norway. Liechtenstein requires only paper forms.

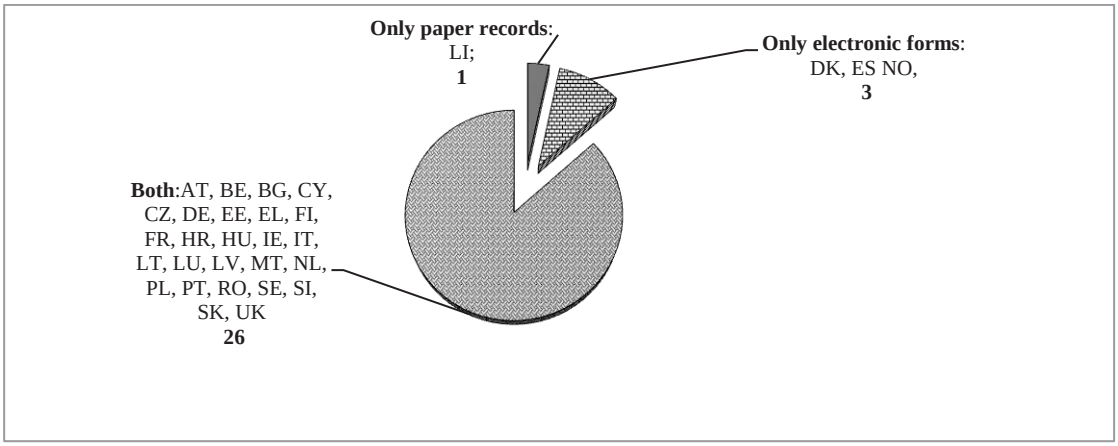

Figure 16 – Required data storage medium by Member State

All countries, except Romania and Norway, considered 30 years an adequate timeframe for data storage. Romania considered this period to be too long due to difficulties foreseen in ensuring archiving space and document management.

Comments

All Member States report to have quality systems in blood establishments, as well as in hospital blood banks. These are verified during inspections or audits. Member States mentioned the work of the Council of Europe (CoE), which organises regular training on quality management systems, to be helpful to keep these systems in line with legislation and state of the art practice in the sector.

While the 30 year data retention period is questioned by some Member States, this time window is in line with general data retention periods in the medical sector. Some Member States do, however, call for a clarification and limitation of what data should be retained.

2.5. Haemovigilance

2.5.1. Traceability - Donor identification system

Under Article 14 (1) of Directive 2002/98/EC, Member States must ensure that all blood and blood components, collected, tested, processed, stored, released and/or distributed on their territory can be traced from the donor to the recipient and vice versa. In this regard, Member

States are required to implement a donor identification system for each donation and single blood unit and component.

Twenty-seven Member States plus Norway reported that a donor identification system was implemented in their countries. There is one national coding system in 18 Member States plus Norway, and multiple systems in nine Member States. Liechtenstein has no system implemented, as they only have autologous pre-deposit donations. All Member States reported that the same rules on traceability apply to blood establishments as well as to hospital blood banks. Member States reported the following policies and donor identification systems:

- A national donor identification system is in place in CY, CZ, EE, EL, FI, FR, HR, HU, IE, IT, LU, MT, NL, NO, PL, RO, SE, SI, SK, UK;
- AT, BE, BG, DE, DK, ES, LT, LV, PT have more than one system implemented.

The donor identification systems used are: ISBT 128 (in 16 Member States plus Norway: AT, CY, DE, DK, EE, ES, FI, IE, LT, LV, MT, NL, PL, PT, SE, UK), Codabar (in 2 Member States: Hungary, Slovenia), Codabar plus ISBT 128 (IE) and Eurocode plus ISBT 128 (Germany). Spain reported that 76%, and Belgium that 96%, of blood establishments use the ISBT 128 system.

The use of international coding systems by Member States for labelling different blood components is listed in the following figure:

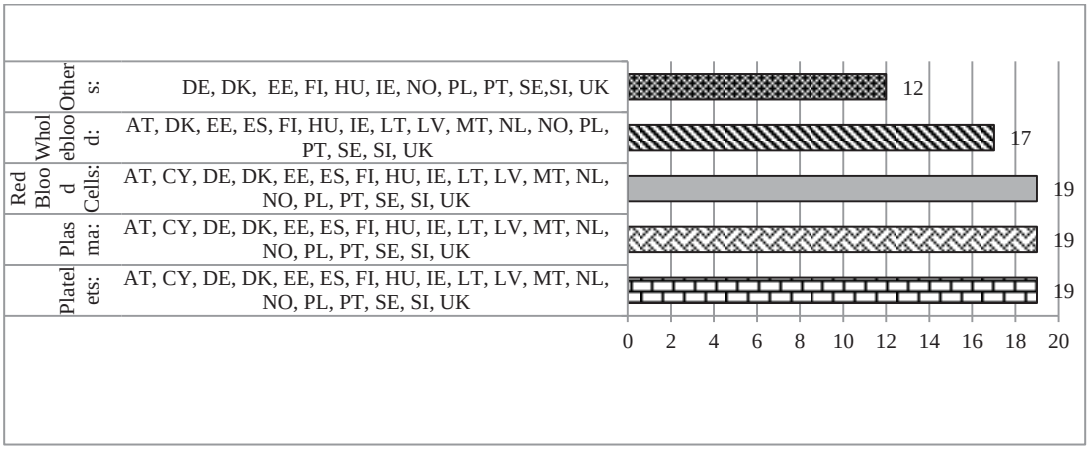

Fig. 17 - International coding systems used/component

Some Member States specified which are the "other" labelled components: granulocytes (DE, HU, IE, PL, SE, SI), cryoprecipitate (Estonia, Poland, United Kingdom), buffy coat (Norway, United Kingdom), neonatal components (Ireland, Poland). Denmark, Portugal and the United Kingdom reported that all blood components are labelled using international codes.

Comments

The great majority of Member States have implemented international standards for the identification and labelling of blood and blood components.

2.5.2. Notification of serious adverse events and reactions

Under Article 15(1), Member States must ensure the notification to the competent authority of any serious adverse events[3] which may influence the quality and safety of blood and blood

[3] According to Article 3(g) of Directive 2002/98/EC, 'Serious adverse event' shall mean any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and

components and which may be attributed to the collection, testing, processing, storage and distribution of blood and blood components, as well as serious adverse reactions[4] observed during or after transfusion which may be linked to the quality and safety of blood and blood components. The procedures for notifying serious adverse events and reactions are laid down in Commission Directive 2005/61/EC.

National vigilance system

All Member States except for Hungary reported having a national vigilance system in place.

In co-operation with Member States, templates, and practical guidance for their compilation, have been developed by the Commission for annual reporting of serious adverse events and reactions (Directive 2005/61/EC, Articles 5 and 6). This guidance is also used at national level in 24 Member States (AT, BE, CY, CZ, DK, EE, EL, ES, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK) plus Liechtenstein. Bulgaria and Norway reported using national regulations. In 24 Member States (AT, BE, CY, CZ, DK, EE, EL, ES, FI, HR, HU, IE, IT, LI, LT, LU, LV, MT, PL, PT, RO, SE, SI, SK) plus Liechtenstein, the European templates are also used at national level. BG, DE, FR, NL and NO use national templates.

In 21 Member States plus Liechtenstein and Norway, there is a dedicated vigilance officer at national level. Member States without an appointed officer gave different reasons for this. Germany explained that each competent authority has a responsible person and there is cooperation between the federal competent authority and the regional competent authorities of the *Laender*. In Estonia, the same specialist is responsible for haemovigilance, licensing and inspecting blood establishments. In the United Kingdom, there is a team of two haemovigilance officers.

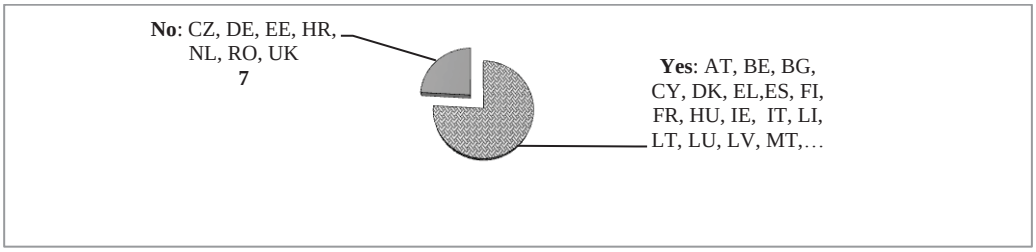

Fig. 18 – Vigilance officer in reporting countries

Blood establishments reporting SARE in 2012

In 2012, SARE reports were provided by 100% of blood establishments in 19 Member States plus Liechtenstein and Norway, 70-99% of blood establishments in eight Member States and 50-60% of blood establishments in one Member State.

blood components that might lead death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolong, hospitalisation or morbidity.

[4] According to Article 3(h) of Directive 2002/98/EC, 'Serious adverse reaction shall mean an unintended response in donor or in recipient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating for patients or which results in, or prolong, hospitalisation or morbidity.

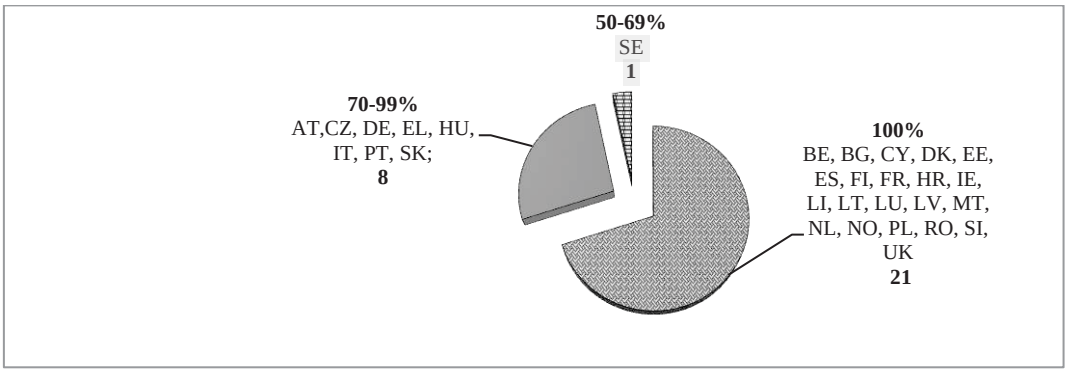

Fig. 18 – Percentage of reporting blood establishments/country

All countries, except United Kingdom and Cyprus, reported having a mandatory procedure for hospital blood banks when reporting SARE to the blood establishments which distributed the blood and blood components, as required by Article 5 (1) of Directive 2005/61/EC. In Cyprus, the hospital blood banks report directly to the Ministry of Health.

Root cause analysis of SARE

A root cause analysis of SARE is performed in 23 Member States (AT, BE, BG, DE, DK, EE, EL, ES, FI, FR, HR, HU, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK) plus Norway. Cyprus and Liechtenstein explained that they had not performed root cause analyses because no SARE cases had been reported so far. In Czech Republic, Spain and Sweden mentioned that root cause analyses are performed by blood establishments and hospital blood banks. In Ireland, root cause analyses are performed by the National Haemovigilance Office in association with the competent authority.

Feedback to blood establishments of SARE reported at EU level

Feedback to the blood establishments regarding SARE reported at EU level is given by 23 Member States (BE, BG, CY, CZ, DE, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK, UK) plus Norway. Spain and Norway waited for the publication of the European Commission summary report to share with their establishments. Denmark issue a national yearly

Recall procedures

Article 15(1) of Directive 2002/98/EC requires blood establishments to have an efficient and verifiable procedure to withdraw distributed blood and blood components associated with the notification of SARE. All Member States plus Liechtenstein and Norway reported to have this in place. In 2012, 1,867 recalls were reported by a total of 14 Member States. Austria and the United Kingdom reported that data was unavailable, Spain reported that data was only available at regional level and Italy reported that recall reporting is not mandatory.

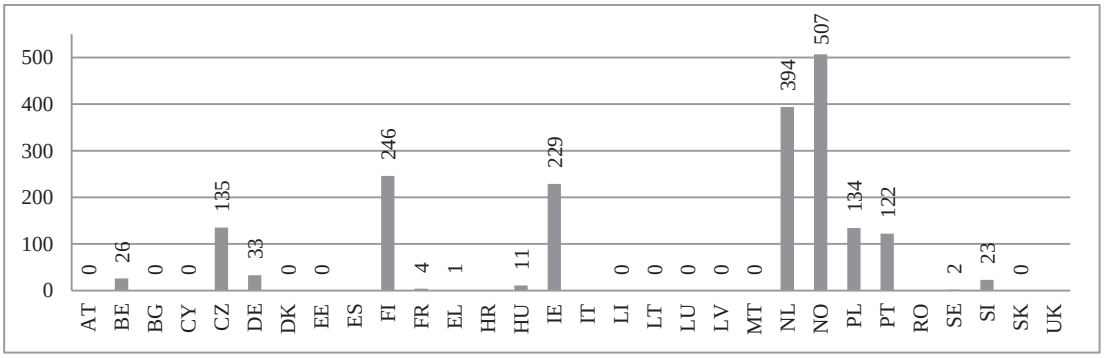

Fig. 20 – Number of recalls in 2012/country

Post donation information on donor health which could affect the quality and safety of blood and blood components was a common cause for recalls reported:

Country	Causes
BE	In 26 cases, microbiological testing of platelets had been negative at the time of distribution but the samples subsequently became positive resulting in recall.
CZ	135 (vast majority - look back procedure for plasma fractionation)
EL	1 unit in-date RBCs was recalled, in the case of whole blood platelets transfusion severe WNV encephalitis transmission. The FFP derived from the same blood unit was already transfused in to another patient (who remained WNV asymptomatic).
FI	246 recalls in 2012 because of defective product (3), reclamation (complaints?) (164), look back/trace back (9) or deviation in transport temperature (70); over 90% of which were red cells.
FR	4 recalls of blood derived medical products were performed as a precautionary measure following the onset of a CJD (sporadic form) in a donor.
HU	11 events related with donor. Lyme risk 4 cases, tuberculosis 1 case of acute leukaemia, all cases detected after blood collection. 2 minipools HCV contamination detected by PCR technique by plasma fractionation company, but the infections were not evident in the patients.
IE	159 (69.4%) recalls due to post donation information (including abnormal full blood count); 29 (13%) recalls due to suspected bacterial contamination; 33 (14.4%) recalls due to suspected adverse reaction to product; 8 (3.5%) repeated reactive virology test; 3 (1.3%) platelet aggregates; 2 (1%) air in line; 6 (2.6%) others.
NL	394 recalls mostly because of withdrawn donations and positive BactAlerts (bacterial contamination suspected)
PL	Storage – 66 Distribution – 13 Transport – 3 Other (no specify) – 52
PT	122 Total: positive bacterial - 91 blood components; post donation information - 21 blood components; TRALI - 5 blood components; HIV positive - 1 blood component; other - 4 blood component

Table 3- Reported causes for recalls

Rapid alerts and blood establishment notification by competent authorities

All Member States plus Norway and Liechtenstein reported having a system or procedure to notify blood establishments in case of a rapid alert either at national or at European level via the rapid alert system for blood. Member States were asked to provide information on their systems or procedures (Table 4).

Country	AT	BE	BG	CY	CZ
Alert System	Information by mail	Information note to the BEs by email	In July 2011 has been created team (directors and responsible persons from all big blood establishments) for crisis management associated with transmissible infections (WNVD) which reacts in case of a national rapid alert.	Information by fax, emails and via telephone to blood centre and blood banks	Information on web page of State Institute for Drug Control, and distributed via Medical Society
Country	**DE**	**DK**	**EE**	**EL**	**ES**
Alert System	PEI informs by e-mail the responsible regional CAs of the "Laender" and the graduated scheme officer/ qualified person. Graduated scheme officers are responsible to set up and manage a pharmacovigilance system and to collect and evaluate notifications on medicinal product risks and to co-ordinate the measures	A blood establishment contact list is available if it is necessary.	State Agency of Medicines(SAM) is responsible to notify all the BEs about the national rapid alert. All BEs have 24 hour phone number to be contacted by SAM .Information send by e mails as written confirmation.	Coordinating Haemovigilance Centre (Skae) of the Hellenic Center for Disease Control and Prevention is sending classified mails to BEs. A system similar to RAB is now under construction	NCA and the BEs' responsible person are in touch by e-mail and phone. A mail distribution list is continually updated. An alert system called e-Room, similar to the CIRCA BC platform under development
Country	**FI**	**FR**	**HR**	**HU**	**IE**
Alert System	The national rapid alert procedure secures the transmission of information e.g. between the Finnish Medicines Agency and blood establishments when urgent remedial or precautionary action is needed due to a serious public health threat.	Rapid alert system of the EU (CIRCA) for communication with the Commission and Member States - National emailing ,fax and phone calls - If necessary, a national crisis management team (CMT) is activated	Blood establishments are notified through network of CA's inspectors and responsible persons of blood establishments (by mail and fax).	The contact person - quality director- get the information from EU, countryside and it will be analysed with the clinical director of the service and coordinates the process.	Due to small number of BEs and BBs in Ireland, it is possible for the CA to communicate national rapid alerts via email to all relevant personnel and through use of CA website where required.
Country	**IT**	**LI**	**LT**	**LU**	**LV**
Alert System	Rapid alert is part of the web-based HV system, performed by automated launch of emails to involved parties.	Information by fax and phone	Information notified via emails and phone calls	Direct information from NCA to BE	Information not provided
Country	**MT**	**NL**	**NO**	**PL**	**PT**
Alert System	The CA Haemovigilance Unit is responsible for alerting and forwarding both National alerts to the Blood Establishment and other stakeholders establishments on relevant alerts at an EU level received through the CIRCABC system	Only one blood establishment in the Netherlands, contacted by CA regularly.	There is a standard operating procedure for notifying rapid alerts, and an updated mailing list of contact persons in all BEs.	Information on any new focus of infection is reported by the National IHR Focal Point or Main Sanitary Inspectorate to CA. CA informs BEs.	email communication send to the responsible persons of blood establishments
Country	**RO**	**SE**	**SI**	**SK**	**UK**
Alert System	Information sent by MoH or Centre for transmissible Diseases (depending on the case) to the NITH and from there to the BEs. If it is the case, BEs inform hospitals in their region.	Swedish National Board of Health and Welfare has a 24-hours service, receives all alerts and informs all CA. CAs inform responsible CA as BE/hospital blood banks by e mail and public website. A blood establishment contact list is available to the coordinators at IVO.	Ad hoc meeting on BTCS, the short description of alert and actions send to BE. In cases of SARE, CA is informed.	Information is reported to State Institute for Drug Control and Ministry of Health. Inspectors of State Institute for Drug Control conduct non-routine inspection and warn Head expert for Transfusion.	MHRA would issue alerts by email

Table 4 – Summary of rapid alerts systems and procedures/country

Alert notification to and from other national vigilance/alert systems

Member States were asked if the national blood system notifies, or receives alerts from, other national vigilance or alert systems (e.g., pharmaceuticals or tissues & cells). Cyprus, Estonia, and Latvia reported no notification to or from other national vigilance/alert systems. Slovakia reported not receiving alerts from other national vigilance/alert systems. In Liechtenstein, there is only one national vigilance/alert system. The systems with which information is exchanged by Member States are shown in Figure 21.

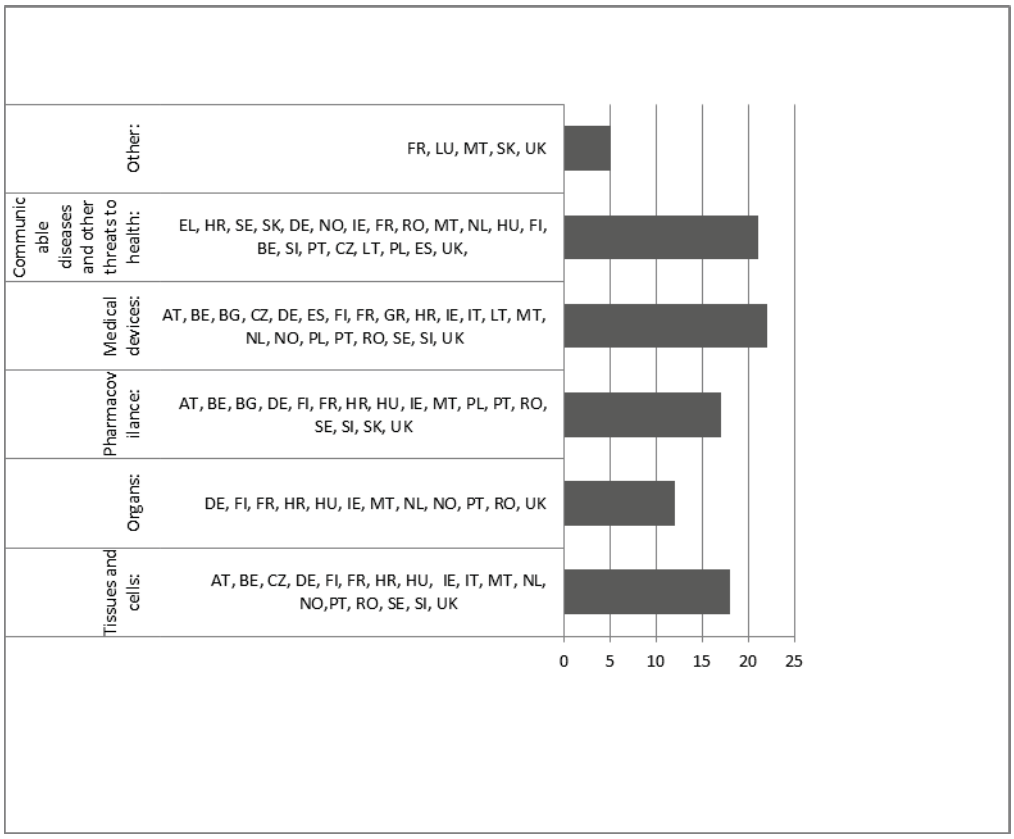

Fig. 21 – Alert notification to and from other national vigilance/alert systems

Additional questions on traceability and SAR/E reporting

Member States were asked for additional questions/ on traceability and SARE reporting. Poland suggested having a more precise and legally binding SAE definition: '*SAE – as only an event which is a real threat as result of improper component being issued for transfusion and SAE – as any event that might have endangered the recipient's health, even though identified and eliminated according to internal control procedures*'. Poland considered that the definition of "serious adverse events" should also include events that had taken place in a hospital laboratory, on a hospital ward or during the transfusion procedure.

Simplification of the imputability table related to serious adverse events was suggested as follows:

Transfusion-related imputability level:

- 0 - not assessable;
- 1 - no relation – there is evidence for attributing the adverse reaction to alternative causes, and;
- 2 - relation assessed – evidence includes results of diagnostic tests.

Comments

The relatively large number of blood establishments that do not report SARE requires particular attention. The number of non-reporters leads to the conclusion that annual SARE reporting activities are an underestimate of the real number of SARE, and national efforts should be further scaled up.

During the annual presentations of SARE data during the competent authority meetings, national authorities have expressed their interest in further developing the root cause analyses of SARE, which can lead to valuable lessons learned for professionals and possible reductions in SARE numbers. There was a call for common definitions to further harmonise the SARE reporting exercise. Additional questions were brought up on how to involve hospitals in SARE reporting and how to involve local actors in root cause analyses. Competent authorities in this respect welcome the work by the CoE work on guidance and training.

Competent authorities also highlight that the current legislation requires reporting of serious adverse reactions in recipients only; even a donor death is not reportable (Directive 2002/98/EC, Article 15). This is despite the definition of a serious adverse reaction in the same Directive (Article 3) that gives equal importance to adverse reactions in donors and in recipients. Many consider that donor protection is to be strengthened through strong legal protection given to living donors, in line with the requirements in the field of organs laid down in Directive 2010/53/EC (Article 15).

The national link to the EU rapid alert system for blood and blood components (RAB), set up in 2013, is now well established.

2.5.3. Import/export

Member State import rules and regulations

Under Article 21, Member States shall ensure that imported blood and blood components intended for use or distribution in the Union are tested in conformity with the Directive's requirements. In addition, Member Sates shall ensure there is a quality system or equivalent in the stages preceding import (Article 2(3) of Directive 2005/62/EC), as well as a traceability system or equivalent as required under Directive 2005/61/EC.

Twenty-two Member States (BE, BG, CZ, DE, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, RO, SE, SI and SK) plus Liechtenstein and Norway reported having rules in place for authorisation and control of blood and blood components for transfusion, coming from other (EU and third) countries. These rules define the conditions under which such import can take place, or in some cases prohibit such imports. Austria and Denmark reported they have no rules or conditions. Cyprus, Spain and Portugal replied that blood components are not imported for transfusion.

The existence of rules to authorise and control import of blood and blood components for fractionation was reported by 17 Member States (AT, BE, BG, CZ, DE, EL, ES, FI, FR, HU, IT, LU, LV, PL, RO, SE and UK).

Importation of blood components for transfusion

Twenty Member States (BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SI, SK) plus Norway reported having data regarding blood components imported for transfusion from third countries (outside the EU). However, only Greece and Ireland reported the import from third countries in 2012: 25,200 red cell concentrates from the Swiss Red Cross Blood Centre to Greece and two red cell concentrates from the USA to Ireland.

Importation of plasma for fractionation

Regarding plasma imported for fractionation, 15 Member States (BG, CY, CZ, DE, EE, FI, FR, HR, LT, LU, NL, PT, RO, SE, SI,) plus Norway reported having data on plasma imported for fractionation from third countries. See Annex 2 for information reported on plasma fractionation facilities in Member States. Thirteen Member States (AT, CZ, DK, EE, IE, LT, LU, LV, MT, NL, PT, SI, SK) plus Liechtenstein and Norway do not report having data on imported plasma for fractionation or they do not import it. The national standards in place for verifying the equivalent quality and safety of blood components imported from third countries are listed Figure 22.

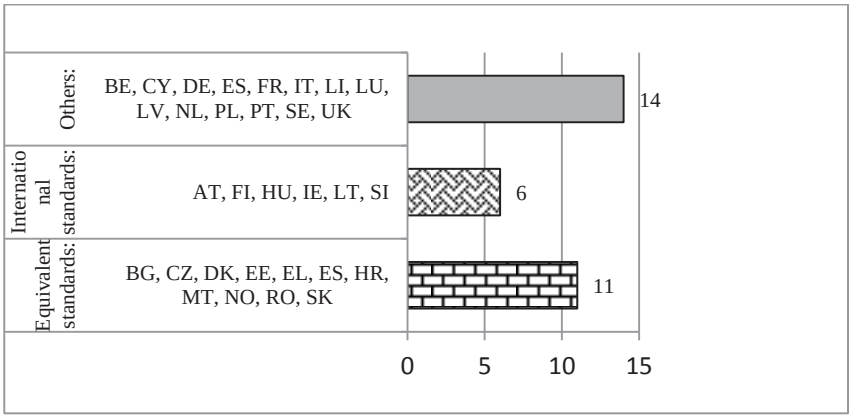

Fig. 22 – Procedures to verify equivalent standards of quality and safety of imported blood components/country

Regarding "others", Belgium and the United Kingdom mentioned inspections as the verification method applied. Germany, France, Italy and the United Kingdom reported that equivalent standards to national standards are required. In Sweden, compliance with the Plasma Master File is a requirement in addition to equivalent standards of the Directive 2002/98/EC. Latvia reported that import is not allowed.

Testing requirements for import of blood and blood components from third countries going beyond the minimum requirements provided in Annex IV to Directive 2002/98/EC are applied by 15 Member States (BE, CZ, DE, EL, ES, FR, HR, IE, IT, LI, NL, PL, PT, RO, SI, SK) plus Liechtenstein. These include the tests shown in Figure 23.

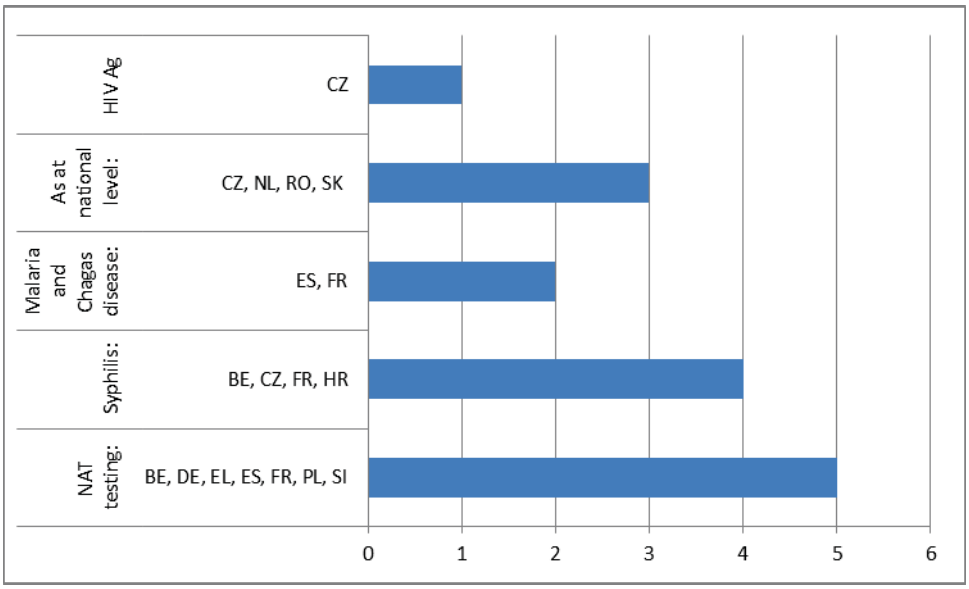

Fig. 23 - Additional tests required for import/country

Ireland reported "*possibly NAT and perhaps West Nile virus testing*" and considered that the issue needs to be discussed with the European blood establishments and ECDC.

Export

In 2012, only Finland, France and Italy reported export of blood components for transfusion from their Member State to third countries (outside the EU):

FI	2 units red blood cells, leucocyte depleted in additive solution	Norway
FR	200 units of therapeutic lyophilized plasma	USA
IT	126 red blood cell units	Congo, Paediatric Hospital of Kimbondo, for humanitarian aid
	70 red blood cell units	Republic of San Marino according to bilateral agreement.

Table 5- Report on exported blood components/country

A majority of Member States reported that they have data on the export of plasma for fractionation in third countries or in other EU Member States. Just six Member States reported data on the export of plasma for fractionation:

DE	3,399,419 L	Third countries (not specified)
DK	214,576 (60,9 metric tons)	Switzerland
EE	34,196 'doses' of plasma	Countries not specified
SK	3063 L	Ukraine

Table 6- Reported data on exported plasma for fractionation/country

Member States reported the following rules for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries:

- CY, EL, ES, FR, HR, HU, IE, MT, NL, PT and UK do not export blood components for fractionation;
- BG limits export to humanitarian aid and production of drugs for their national needs;
- NL clarified that plasma is only collected for fractionation in the country and is not exported;
- AT referred to GMP Annex 14[5];
- DE, DK, RO and SK referred to national laws;
- CZ reported that requirements to export depend on the partner and export is under a MoH export licence;
- In FI and NO, there are no special rules for the export of blood and blood components for fractionation;
- In IT, national plasma can only be sent to EU Member States for contract fractionation purposes. This is authorised and controlled by the competent authority (the National

[5] The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 14. Manufacture of Medicinal Products Derived from Human Blood or Plasma; http://ec.europa.eu/health/files/eudralex/vol-4/annex14_rev30-03_2011_en.pdf

Medicines Agency (Agenzia Italiana del Farmaco - AIFA). Commercialisation is strictly prohibited;

- LI has authorised blood collection by the Austrian Red Cross, section Vorarlberg;
- LT reported following the requirements of the blood Directives and European Pharmacopoeia (Ph. Eur.) monographs on human plasma-derived products;
- LV requires a manufacturing licence for the manufacture of medicinal products in another Member State;
- SI reported that a contract and quality assurance agreement is required;
- All BEs in SE, that are releasing plasma for fractionation abroad, are inspected and authorised according the same national legislation as applies for use of the plasma in Sweden.

Member States reported the following rules for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries:

- Blood components are not exported for transfusion in AT, CY, EL, ES, HR, HU, LI, LU, MT, PT, SE, UK;
- Export is limited to emergency situations in BG, IE, DK and SI which allows export to neighbouring countries for immunised patients or for humanitarian assistance;
- In FI, LT, NO, and PL there are no specific rules;
- In FR, there is a legislative rule for export of blood components, but no mandatory authorisation procedure. Export is carried out by the civil National Blood Service (EFS), which notifies the competent authority (ANSM);
- IT reported a national legally binding specific procedure to export blood components for transfusion, which must fulfil national quality and safety requirements and be authorised by the Ministry of Health;
- NL reported that only authorised blood establishments could export blood or components for transfusion. The Military Blood Bank supplies the Dutch troops in third countries;
- RO and SK referred to national provisions which have to be followed.

Comments

While it is clear that there is limited movement of blood and blood components for transfusion between Member States and to and from third countries, it is difficult to draw conclusions on the volumes of plasma for fractionation that are imported or exported in the absence of a harmonised data collection system. There is a not always clear distinction between import/export from/to third countries and distribution from/to other EU Member States.

2.5.4. Shortages and surplus of blood and blood components

In this survey, regular shortages of blood components for transfusion were reported by six Member States:

- BG reported red cell and platelet shortages once per year, most commonly seasonally, often after long summer holidays, less frequently there is a shortage of a particular blood group;

- Shortages of red cells and platelets were reported by CY and SE;
- EL reported red cell and platelet shortages during summer holidays, intensified by WNV outbreaks;
- HU reported shortages of platelets, plasma, red blood cells and whole blood;
- PT reported having a shortage of red cells during the first semester of 2012, which does not occur frequently.

A surplus of blood and blood components was reported by five Member States: platelets, plasma and red blood cells reported by Germany, red blood cells by Italy, plasma by Lithuania, Romania and Sweden. In Romania and Italy, surplus plasma is discarded. In Sweden it is sold to pharmaceutical companies.

BG, CY, EL and HU expressed interest in concluding bilateral agreements with other Member States and in establishing short-term/ad-hoc mechanisms for addressing shortages, while Italy, Liechtenstein and Romania expressed interest in such agreements to address blood component surpluses. Greece has taken the lead on an initiative to draft a model for such agreements within the group of national competent authorities.

Comments

The existence of national surpluses, shortages and cross-border donations suggests the potential benefits of closer collaboration between Member States.

2.5.5. Cross-border movement of Donors

Thirteen Member States (EL, SK, EE, DE, IE, FR, NL, HU, SI, LU, CZ, PL, UK) reported that they have cross-border movement of donors to/from their countries. Fifteen other Member States (AT, HR, IT, DK, SE, LV, CY, RO, MT, FI, BE, PT, LT, BG, ES) plus Liechtenstein and Norway reported that they do not observe this practice.

Comments

Close to half of the Member States report cross-border movements of donors, making donation outside their country of origin/residence. Due to its relationship to the compensation or incentives offered to donors, this topic is covered more extensively in the Staff Working Document on the implementation of the principle of voluntary unpaid donation[6].

2.6. Quality and safety of blood and blood components

2.6.1. Provision of information to prospective donors

Under Article 16 of Directive 2002/98/EC, Member States must ensure that blood establishments provide prospective donors of blood or blood components with the information set out in Part A of Annex II to Directive 2004/33/EC. All 28 Member States plus Norway and Liechtenstein replied that they have measures in place to ensure only trained personnel provide the required information to donors. Twenty-seven Member States plus Norway and Liechtenstein mentioned that the information for donors is standardised at national/regional level to ensure the requirements of Article 2 of Directive 2004/33/EC are fulfilled. Eight Member States (CY, FR, IE, IT, RO, SI, SK, UK) plus Liechtenstein indicated other measures.

[6] Note that in the survey for the VUD report also AT and CY reported cross-border movements, while CZ, DE, FR, EL, IE did not report these movements there.

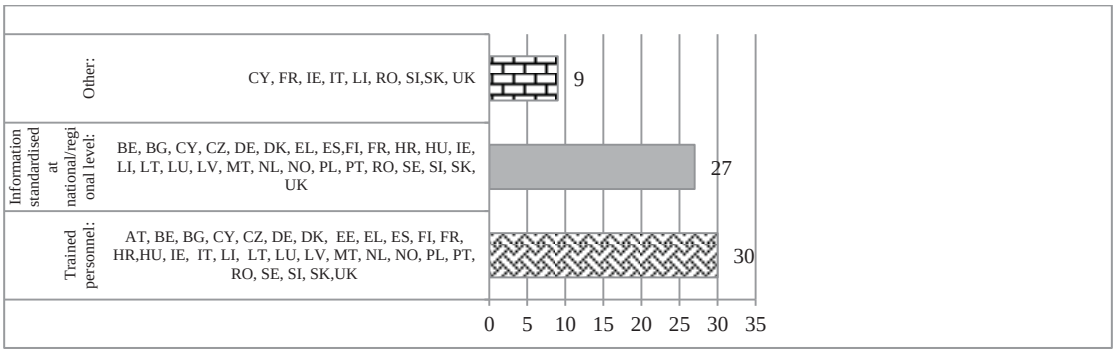

Fig. 24 – How Member States ensure that the required information is provided to blood donors

The blood directives do not require the existence of a system for self-exclusion by a donor. Nevertheless, 19 Member States reported to have such a system in place, including post-donation cards with a bar code (Belgium); a section with questions for self-exclusion in the blood establishment website (Ireland), information in the pre-donation material (Czech Republic, France, Italy); phone calls (Netherlands, Slovenia) and boxes available for posting self-exclusion forms (Slovakia).

Given the widespread adoption of self-exclusion systems, which often lead to effective recalls of donated blood (components), competent authorities suggested that it might be valuable to reflect on measures to improve further adoption of these systems by EU Member States.

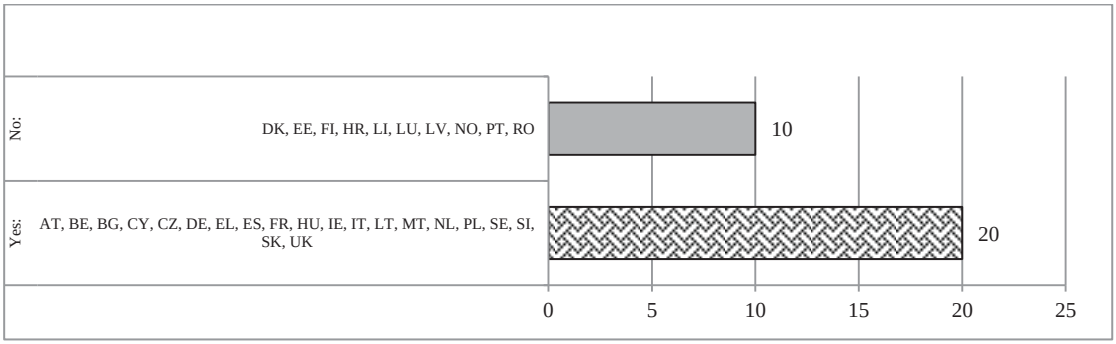

Fig. 25 – Donor self-exclusion system in place

Comments

All Member States reported having measures to inform prospective donors through interview by trained staff. Many Member States report good experiences with donor self-exclusion systems which are one of the main triggers for recalls.

2.6.2. Information required from blood donors and examination of blood donors

Blood donor information is collected through a personal interview by a healthcare professional, who may or may not be a medical doctor, through a standardised questionnaire, in 22 Member States. In some Member States, there is a mixed situation, as shown in the following figures.

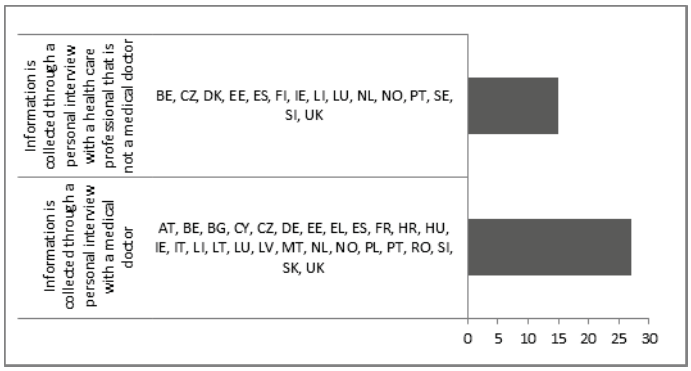

Fig. 26 – Healthcare professional obtaining donor information/country

There have been numerous discussions in the competent authority meetings related to the differences in the questions asked on the national, regional or local forms. An exercise comparing questions and streamlining national questionnaires was suggested for consideration.

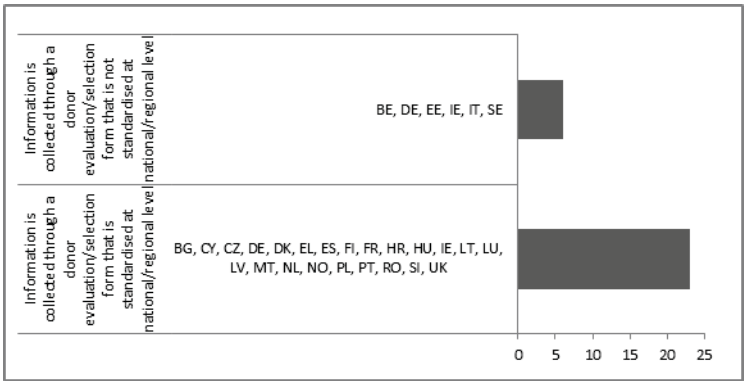

Fig. 27 – Use of standardised form to collect blood donor information/country

Germany specified that a national standardised form to collect blood donor information does exist but blood establishments may also use forms not standardised at the national level, as long as requirements as set by national law (i.e. Transfusion law) and relevant guidelines (e.g. haemotherapy guidelines) are taken into account.

Comments

The personal donor interview by a healthcare professional is an essential step to help ensure that a planned donation is safe for the donor as well as for the future recipient(s). While the questionnaires are standardised within many Member States, they do however vary between Member States.

2.6.3. Eligibility criteria for donors of whole blood and blood components

Article 18 of Directive 2002/98/EC requires that the evaluation of blood and blood component donors should be assured by blood establishments in compliance with criteria defined in the Annex III to Directive 2004/33/EC.

Relevance of eligibility criteria

In response to the question on the most relevant acceptance/deferral criteria provided in Annex III, nine Member States (AT, BE, EE, FR, LV, NL, PL, PT, SK) plus Norway and Liechtenstein consider all criteria equally relevant.

The United Kingdom considered that the criteria as a minimum standard are too broad, i.e. not specific enough.

The criteria associated with higher risk of disease transmission, and pre-donation haemoglobin levels were considered the criteria most relevant to protect recipients and donors, respectively.

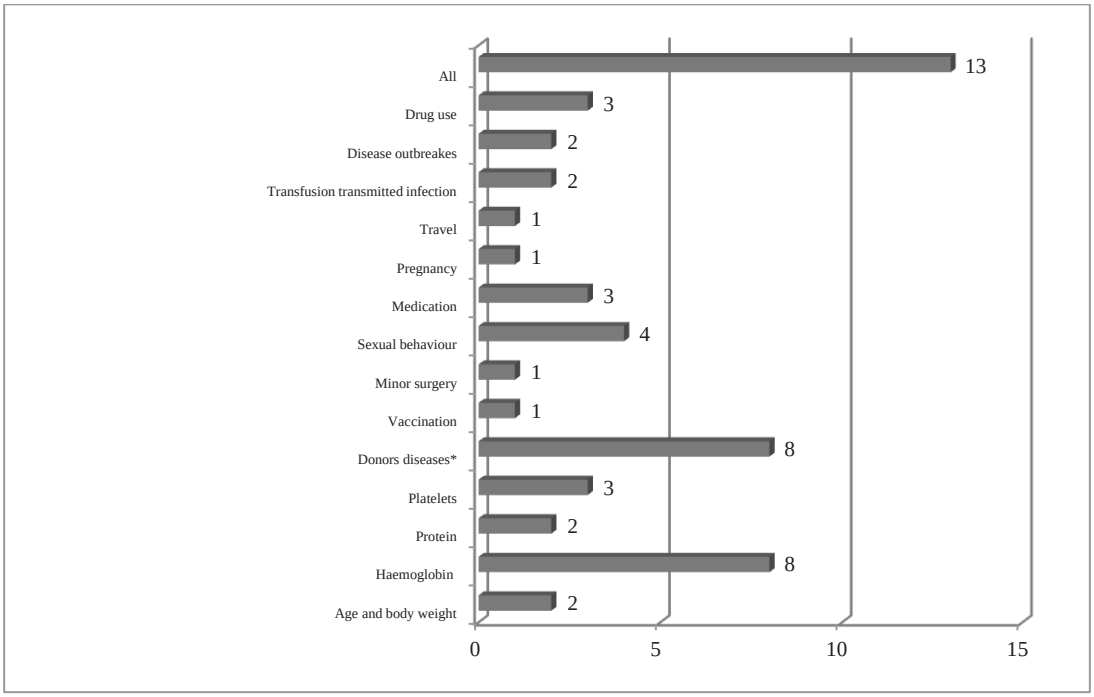

Fig. 28 – The most relevant eligibility/deferral criteria

Difficulties in implementing and verifying the eligibility criteria

Sexual behaviour was considered by 19 Member States the most difficult or the least reliable criterion to implement while Germany, Poland and Norway expressed no difficulties in verifying the eligibility criteria.

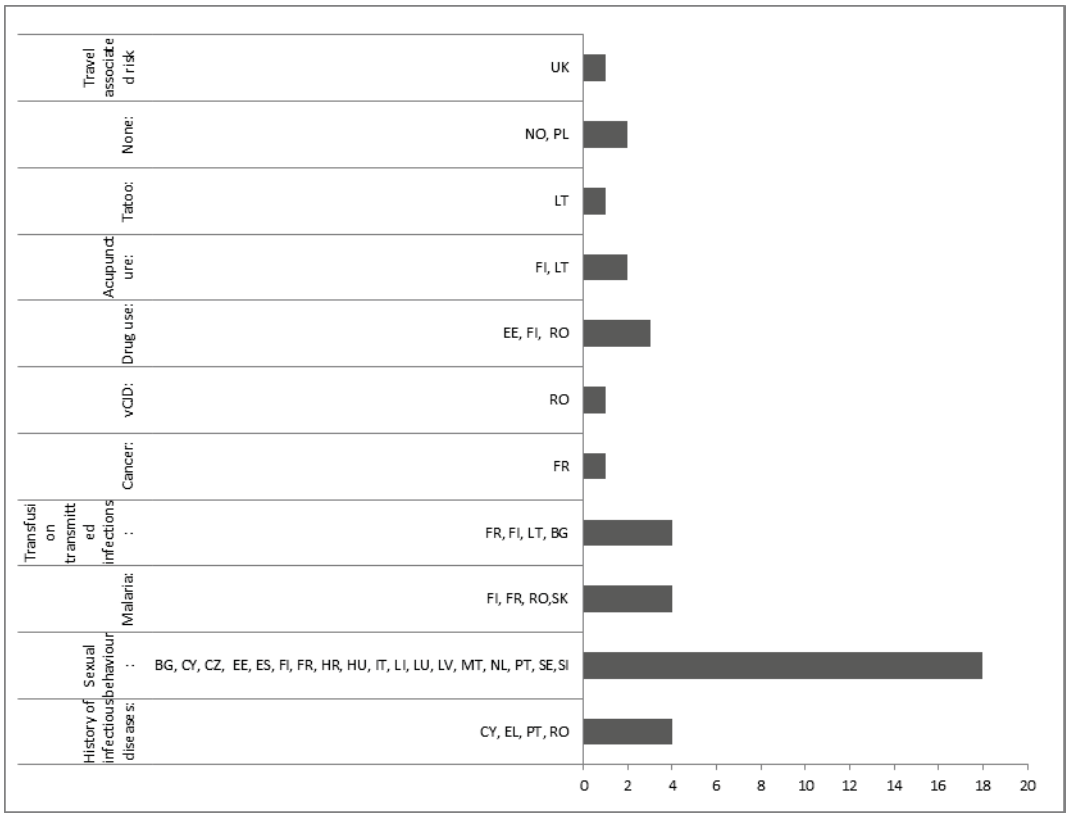

Fig. 29 – The most difficult criteria to implement/verify

Changes in eligibility criteria

Asked about the need to change the current age acceptance criteria considering an ageing EU population, seven Member States answered as follows:

- In BE, in 2012, the age of acceptance was raised from 65 to 71;
- In CY, donors older than 65 are accepted if a good health medical certificate is provided;
- DE proposed that upper age limits should be decided by the physician in charge of donor selection when deciding on deferral or admission for donation;
- FI has proposed that an annual permission for 66-70 year old donors could be given by a qualified healthcare professional (by a physician) to maintain self-sufficiency in Finland. The Finnish Medicines Agency (Fimea) proposed a revision of donor age limits based on a risk assessment regarding donors and recipients, and a survey of the practice of annual permission for donors over 65 years old in EU countries;[7]
- In LU, since August 2012, the maximum age is 70 years;
- NL replied that the size of the donor population could be increased if the age criteria were replaced with medical condition criteria;
- In PL, a lower age limit is being considered if it does not conflict with other Polish regulations. Persons over 65 can donate blood if there are no contraindications.

[7] Meeting of the Competent Authorities on Blood and Blood Components 6 and 7 November 2013.Summary Report; http://ec.europa.eu/health/blood_tissues_organs/docs/blood_mi_20131106_en.pdf

Fourteen Member States considered that other eligibility criteria as laid down in Annex III to Directive 2004/33/EC need to be changed:

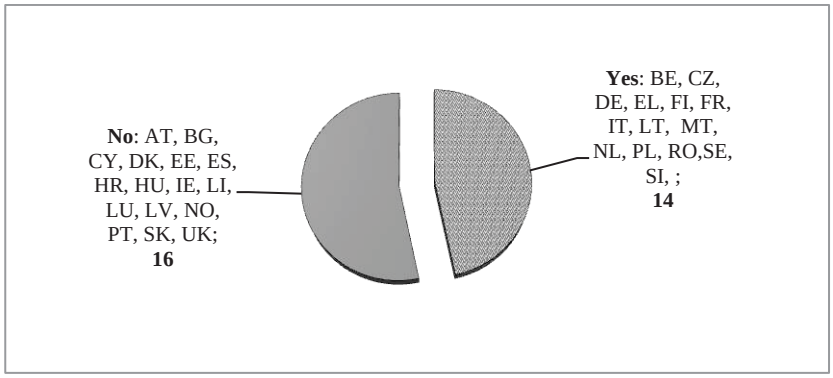

Fig. 30 – Member State opinions regarding the need to change donor eligibility criteria

Belgium proposed a change to the 28 day West Nile virus (WNV) deferral period[8] (28 days after leaving an area with ongoing transmission of WNV to humans) by accepting donations when a molecular genomic test is negative or if the blood component is treated with a pathogen inactivation method (validated for inactivation of WNV). This has been partly addressed in a recent amendment in the implementing legislation[9] and development of a related preparedness plan by ECDC. Moreover, Belgium proposed that for particular epidemiological situations (e.g. disease outbreaks)[10] notification should be done by the competent authority of the Member States concerned to the European Commission, with a view to EU-level action.

Finland proposed a survey of EU Member State practices and a risk assessment of the impacts of raising upper age limits on both donors and recipients. In addition, they proposed discussion on the following changes:

- Minor dental treatment[11] - *no deferral;*
- Malignancy with complete recovery[12] - *temporary deferral; permanent only for haematological malignancies*;
- Endoscopic examination performed in EU[13]- *no deferral*;
- Acupuncture performed with sterile single-use needles[14] - *no deferral;*
- Malaria[15] - *criteria for deferral should be re-assessed.*

France also proposed revisions of:

- The West Nile virus (and arbovirus) deferral period (*analysis of the appropriateness of a deferral period of 120 days*), genomic testing and definition of West Nile Virus "affected area" as adopted by ECDC[16];

[8] Point 2.2.1 of Annex III to Directive 2004/33/EC
[9] Directive 2014/110/EU amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations
[10] Point 2.3 of Annex III to Directive 2004/33/EC
[11] Point 2.2.2 of Annex III to Directive 2004/33/EC
[12] Point 2.1 of Annex III to Directive 2004/33/EC
[13] Point 2.2.2 of Annex III to Directive 2004/33/EC
[14] Point 2.2.2 of Annex III to Directive 2004/33/EC
[15] Point 2.2.1 of Annex III to Directive 2004/33/EC
[16] West Nile virus risk assessment tool, ECDC TECHNICAL REPORT -, 2013

- The minimum level of donor haemoglobin: *Member States may however adopt requirements for minimum haemoglobin levels down to 120 g/l for females and 130 g/l for males on the basis of the results of studies carried out on their specific population;*
- Chikungunya and dengue: Analysis of the opportunity *to introduce clinical criteria* for donors at risk of exposure;
- *Analysis of risk and the measures* to be taken regarding donors who have travelled.

Croatia proposed an *extension and more specific* point 2.3 of 2004/33/EC for particular epidemiological situations in affected areas (e.g. WNV, Malaria, Dengue, HEV).

Italy proposed changes on hepatitis B[17]: *except for HBsAg-negative persons who are "demonstrated to be immune", it should be clarified what is intended by "demonstrated to be immune", considering that persons testing anti-HBs positive with (or even without) anti-HBc may test HBV DNA positive, thus resulting in OBI (Occult HBV Infection) carriers.*

Lithuania proposed that the behaviours at risk of acquiring infectious diseases[18] that could be transmitted by blood *should be listed*.

Malta proposed a change on haemoglobin levels in general.

Changes proposed by the Netherlands included:

- That if *HBV-NAT screening is performed, HBsAg screening can be cancelled*;
- *WNV-NAT instead of temporary deferral* after visit to affected area;
- *An update* on criteria for Malaria, Q-fever.

Poland proposed the following changes:

- Donors under *17 years of age may donate* blood in exceptional circumstances (for instance: Donation of HLA–compatible blood components for family members);
- Donor weight and haemoglobin concentration *definition in case of two unit red cell apheresis*;
- Coagulopathy and bleeding tendency *should be clarified*;
- "metabolic disease" and endocrine disorders (e.g. hypothyroidism) *should be mentioned separately*;
- Diabetes *should be mentioned under donors on oral medication*;
- Body temperature criteria *should be included*;
- Borreliosis (Lyme disease) *should be included and deferral for chronic Q disease should be more precise*;
- An update on criteria for Malaria and West Nile virus;
- Point 2.2.2, in right column of the first row *should be revised* to include HIV and hepatitis B, and in the left column to include hepatitis B carriers, hepatitis C and HIV;[19]
- *Deferral period extension* after hepatitis B vaccination;[20]

[17] Point 2.1 of Annex III to Directive 2004/33/EC
[18] Point 2.2.2 of Annex III to Directive 2004/33/EC
[19] Point 2.2.2 of Annex III to Directive 2004/33/EC

- *Precise deferral period* following "exposure" to tick born encephalitis and after recovery from tick born encephalitis;[21]
- *Guidelines* for deferral during breastfeeding;
- *Coherence and precision* on permanent and temporary deferral regarding "persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood" ;[22]
- *Discussion and recommendations* on accepting donations from persons detained in juvenile correctional institutions (homes).

The following changes were proposed by Romania:

- Additional t*emporary deferral* criteria: leucocytosis (leucocytes over 11000/mmc-12000);
- *Evaluation of iron status* at least in particular situation in donors having borderline Hb value, based on physician decision.

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

Assessment of sexual behaviours implying risk

According to Annex III to Directive 2004/33/EC persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood and blood components or derivatives should be permanently deferred for allogeneic blood donation. 18 Member States plus Norway and Liechtenstein reported existing national guidelines for the assessment of risk associated with sexual behaviour.

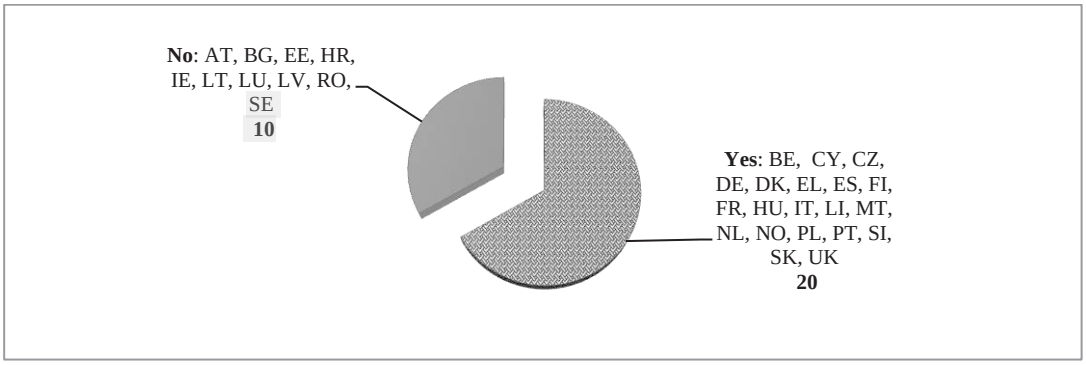

Fig. 31 – Assessment of risk associated with sexual behaviour

The main exclusion criteria for sexual risk behaviour listed by the reporting countries were men having sex with men, being paid for sex with drugs or money, having sex with someone who injects drugs or is paid for sex, having sex with someone who is from an area of high prevalence of HIV, having multiple sexual partners or a new partner.

Assessment of variant Creutzfeldt Jacob disease (vCJD)

Annex III to Directive 2004/33/EC foresees precautionary measures regarding vCJD. Seventeen Member States plus Norway and Liechtenstein reported existing national guidelines to assess vCJD risk.

[20] Point 2.2.3 of Annex III to Directive 2004/33/EC
[21] Point 2.2.3 of Annex III to Directive 2004/33/EC
[22] Point 2.1 of Annex III to Directive 2004/33/EC and Point 2.2.2 of Annex III to Directive 2004/33/EC

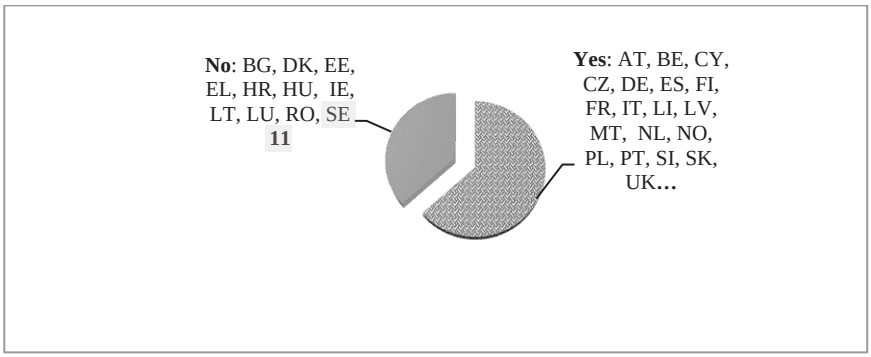

Figure 32 – variant Creutzfeldt Jacob disease (vCJD) precautionary measures

Main causes leading to deferrals

Twenty-one Member States reported having a centralised system to collect data on blood donor deferral (either a national IT system or annual reports).

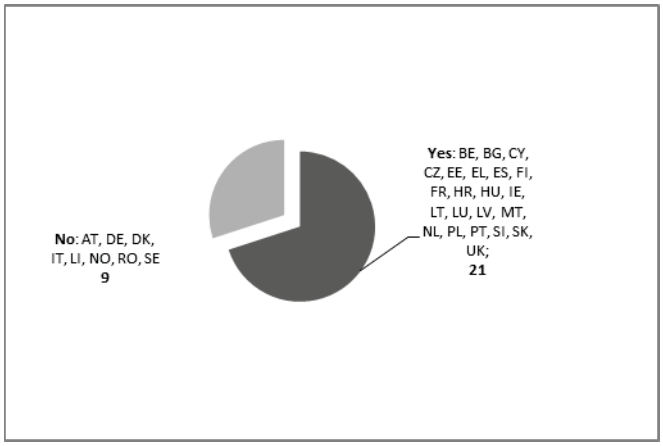

Figure 33 – Centralised system regarding blood donor deferral data

The main causes leading to deferrals reported by Member States that collect this data nationally were: low haemoglobin levels, risk of transmission of infectious diseases, risk behaviours, travel, medication and other medical reasons. The "other medical reasons" included abnormal blood pressure (CY, HR, LT, MT, SI and UK).

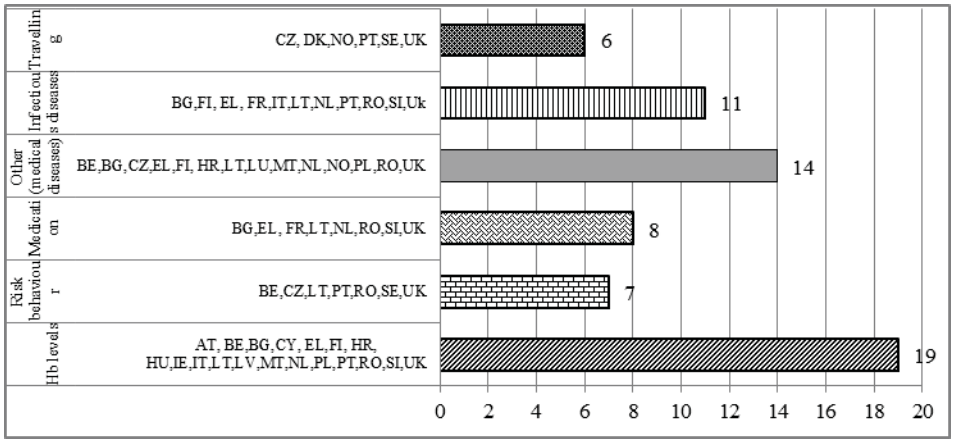

Fig. 34 - Main causes leading to deferrals/country

Temporary derogations during a potential crisis

In 2009, in view of a potential H1N1 pandemic, Commission Directive 2009/135/EC was adopted to allow Member States to invoke temporary derogations to accept donors with lower haemoglobin levels, to ensure blood supply during times of potential crisis. Those temporary derogations were considered the most efficient measure to maintain blood supply in case of future crises by 22 Member States (BE, BG, CY, CZ, DK, EE, EL, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, SI, SK, UK) plus Norway and Liechtenstein. Temporary derogations were applied by eight Member States (BE, BG, CY, EL, LU, LV, SK, UK).

As additional measures, only Finland suggested that the donor upper age limit could be raised and that the competent authorities should be empowered to decide on temporary derogations. Germany explained that the situation may be very different for some types of crises such as severe disasters.

Overall, such temporary measures were considered useful.

Comments

The main causes for donor deferral are the risk of transmission of infectious diseases, low haemoglobin levels, risk behaviours, travel history and other medical reasons, such as high blood pressure. Other eligibility criteria relate to age limits, to temporary deferrals in case of crises and to the assessment of risk associated with sexual behaviour. Several Member States also emphasised the need for more donor protection measures.

2.6.4. Testing of Donations

Under Directive 2002/98/EC, every blood and blood component donation should be tested by qualified laboratories, which have been accredited, designated, authorised or licensed (Article 5, (1)) in conformity with the requirements of Annex IV (Article 21, (1)).

Laboratory inspections

In compliance with Article 5(1) of Directive 2002/98/EC, 27 Member States plus Norway and Liechtenstein inspect laboratories to ensure that the tests required for donors are carried out only by qualified laboratories that have been accredited, designated, authorised or licensed. The methods by which competent authorities ensure compliance with this requirement are shown in the figure below:

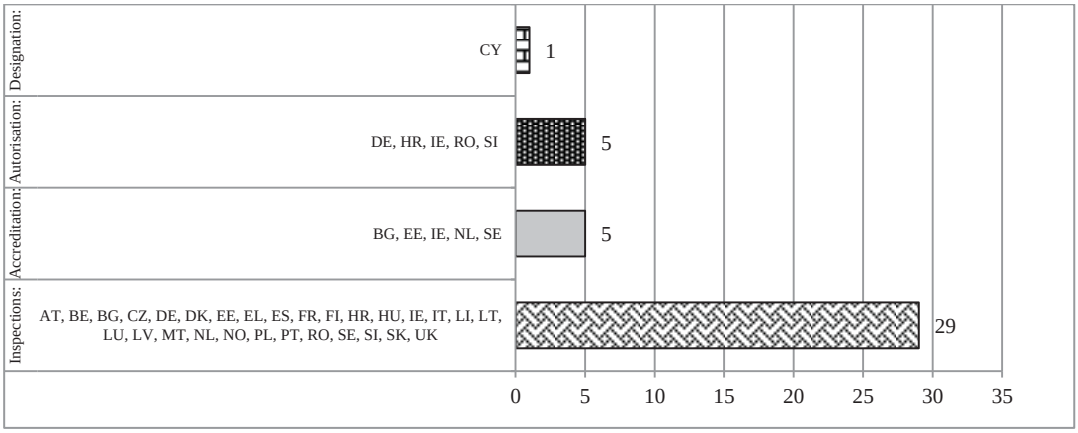

Fig. 35 - Competent authorities' actions to comply with Article 5(1)

Cyprus reported that all laboratories performing tests for donors are designated by the Ministry of Health. However, these laboratories are not inspected as an inspection system is not in place. In Finland, one blood establishment has activities relating to the testing of human

blood and blood components. However, some activities relating to donor testing may be performed externally (i.e. rare tests for donors) under a written contract which is checked routinely during blood establishment inspections, though the testing activities might not be inspected on-site every two years. Poland and Slovakia reported that laboratories are audited as well as blood establishments.

Nucleic acid amplification testing (NAT)

The competent authorities were also asked to provide data/information regarding use of NAT technology for routine testing of blood or blood components. NAT is not required by Annex IV to Directive 2002/98/EC, but it is used in some Member States to test donor blood samples.

Twenty Member States (AT, BE, DE, DK, EE, EL, ES, FI, FR, HR, IE, IT, LT, LU, LV, NL, PL, PT, SI, UK) reported the use of NAT technology for routine testing of every donation. In most countries it is used for HIV, hepatitis B and C although in some of these Member States (Germany and France) it is not mandatory to use it for hepatitis B. It is also used much less frequently for West Nile virus (WNV), hepatitis A and Parvovirus B19 testing.

NAT technology is not used in SE, SK, CY, RO, MT, HU, CZ, BG, plus Liechtenstein and Norway. The reasons mentioned for this were financial constraints (BG, CY, CZ, MT, NO, RO, SK), minimal benefits (CZ, MT, NO, SK) and lack of a legal obligation (Sweden and Liechtenstein). In Greece and Italy, NAT for WNV is only used seasonally (in the summer period), to ensure safety of the blood supply within the affected areas.

In Germany, NAT is mandatory as routine screening for HIV-1 (10.000mIU/ml) and HCV- (5.000 IU/ml), and for confirmatory testing for HIV-1, HCV, HBV. NAT for HBV, HAV and Parvovirus B19 is not mandatory, but used for routine screening by many blood establishments, mainly those also delivering plasma for fractionation.

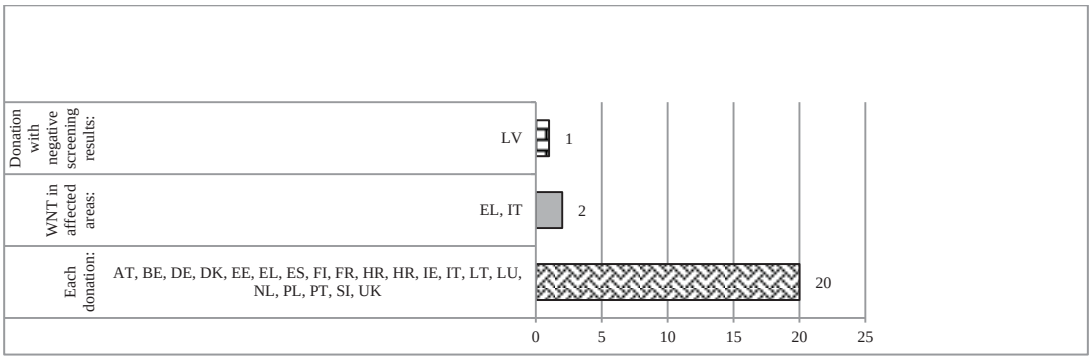

Fig. 36 – Circumstances of NAT use/country

A centralised system to collect positive/abnormal test results was reported by 27 Member States (BE, BG, BI, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK) and Norway. The number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV, hepatitis B, C and other agents were provided (see Annex 3).

During meetings of the competent authorities, it was suggested that gathering nationally centralised test results and comparing them at EU level would be beneficial.

Additional tests performed on a routine basis

All countries except Spain, Liechtenstein and Latvia reported having additional tests to those required in Annex IV to Directive 2002/98/EC. See the previous point for NAT tests for Hepatitis B, C and HIV.

Country	AT	BE	BG	CY	CZ
Additional tests	For whole blood donations: unspecific immune reaction marker (Neopterin, CRP)	Syphilis testing and NAT for HIV1, HBV and HCV.	Syphilis and irregular antibodies. They are mandatory under national legislation for each whole blood donation.	Syphilis (Treponema pallidum)	HIV p24 antigen, syphilis antibodies
Country	**DE**	**DK**	**EE**	**EL**	**ES**
Additional tests	Mandatory for whole blood donations and apheresis donations for transfusion are " Blood grouping: " Rh details (C,c,D,E,e), Kell criterion, serum blood group antibodies on the occasion of first and second whole blood donation. Infectious disease markers: " Anti-HBc antibodies " HCV Genom (NAT) " HIV-1 Genom (NAT) " Anti-Treponema pallidum antibodies	ID NAT for HIV; HBV and HCV	Some of them are mandatory. HBV NAT test is not mandatory, but all the BE-s are using it in addition to HBsAg.	No additional tests reported	No additional tests reported
Country	**FI**	**FR**	**HR**	**HU**	**IE**
Additional tests	NAT for HIV-1–, HCV- and HBV are mandatory for whole blood donations. B19-DNA and HAV-RNA tests are done but not mandatory for whole blood donations	Screening tests for all donations: HIV NAT, HCV NAT, HBV NAT, Anti-HTLV I/II, Syphilis. NAT for HBV is not mandatory. Screening test for Malaria, Chagas disease: If necessary. Screening test for hepatitis E virus NAT since December 2012 for FFP-SD NAT (pool of 96 samples), - by the CTSA in the earlier of 2013 for plasma lyophilized pools.	HIV 1p24 antigen, HCV core, TP antibody (Syphilis)	anti-HBc, TP antibody (Syphilis)	NAT PCR performed on all allogeneic donations but not mandatory
Country	**IT**	**LI**	**LT**	**LU**	**LV**
Additional tests	NAT testing for HBV, HCV and HIV at each donation. HCV NAT mandatory since 2002, HBV and HIV NAT since 2008	No additional tests reported	HIV NAT, HBV NAT and HCV NAT	Law only says that additional tests can be required	No additional tests reported
Country	**MT**	**NL**	**NO**	**PL**	**PT**
Additional tests	Anti HBc testing is performed	Not mandatory.	Ant- HBc when > 6 months since last donation	All donations are tested for HBV DNA, RNA HCV and RNA HIV (mandatory).	NAT for HIV, HCV and HBV; EiA IgM and IgG testing for Syphilis - All blood donations EiA HTLV 1 e HTLV 2 - First Time donations Malaria
Country	**RO**	**SE**	**SI**	**SK**	**UK**
Additional tests	Yes, MoH Order no. 1226/2007 updated by Order 650/2012	anti-HTLV- I o II Treponema Pallidum	Test for syphilis is required: not required for autologous donations.	anti- HB core (total) and ALT are mandatory	Syphilis, HTLV, and HCV

Table 7 – Additional tests/country

Member States were asked about additional tests for plasma donations but reported no additional information. Additional tests required by Member States are usually justified for local reasons, e.g. the increased prevalence of certain infectious diseases. These criteria might however also limit the sharing of blood and blood components between Member States.

Members States authorities therefore expressed interest in having a transparent perspective on the additional tests implemented in each of the Member States.

Additional information on testing

Some Member States provided additional information on testing:

- BG reported that testing laboratories, as a part of blood establishments, participate in the Proficiency Testing Scheme organised by EDQM. The national system for external control of transmissible infections for testing laboratories in blood establishments is organised by the National Centre of Infectious and Parasitic Diseases (NCIPD);
- HR: An international accreditation system for testing laboratories is foreseen to be implemented in renewed legislation;
- IT: European Proficiency Testing Studies, as already performed by EDQM, should be enhanced;
- UK: All labs perform NEQAS (Scotland) (an external quality control program).

Changes in basic testing requirements

Eight Member States (CY, DE, EL, HR, IT, LT, NL, RO) considered changes are needed to the mandatory testing requirements for donations as specified in Annex IV to Directive 2002/98/EC:

- CY and RO proposed including testing for syphilis as a minimum requirement;
- DE replied that a general answer cannot be given as it depends on national strategies, e.g. in relation to the specific epidemiology of a given country, the use of pathogen-inactivated blood components etc;
- EL, HR, IT and LT proposed mandatory NAT;
- IT proposed that WNV NAT should be regulated as an option to screen donors living in affected areas and to screen potentially exposed donors;
- An additional sentence was proposed by NL: "Additional tests *or alternative combinations of tests* may be required for ..." This will allow the listed tests to be omitted if another test or combination of tests makes the listed test redundant.

Several of the testing requirements have been subject to discussion in the bi-annual competent authority meetings. 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.

It was noted in the discussions at 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 and their introduction can have a major impact on the local availability of blood and blood components. Testing can therefore not be considered as the single pillar for safety of blood and blood components but must be combined with deferral criteria and, where appropriate, inactivation techniques. It is through a combination of these strategies that safety risks are reduced to a minimum.

Techniques for pathogen reduction/inactivation

Techniques for pathogen reduction/inactivation are used in 16 Member States (AT, BE, CZ, DE, EL, ES, FR, IT, LT, LU, NL, NO, PL, PT, SE, SI, UK) plus Norway. Methylene blue,

amotosalen (riboflavin), and solvent detergent are examples of pathogen reduction/inactivation techniques used, as summarised in Table 8.

Country	AT	BE	CZ	DE	
Pathogen inactivation techniques	Plasma (Methylene blue / Intercept / Mirasol) Platelets, RBCs (Radiation)	Plasma for transfusion: pathogen inactivation mandatory techniques used - methylene blue, solvent detergent, amotosalen. Platelets: pathogen inactivation techniques used- amotosalen, (riboflavin)	Platelets: very few units (dozens), amotosoralen	a) Therapeutic frozen MB plasma: methylene blue and light followed by absorption of methylene blue and its photo derivatives by blueflex filter. b) Therapeutic frozen SD plasma: plasma pooled and tested according to Ph.Eur. monograph Human Plasma for Fractionation; treatment with solvent and detergent and removal of these additives according to Ph.Eur. monograph Human Plasma (pooled and treated for virus inactivation c) Therapeutic frozen Intercept Plasma: plasma obtained from whole blood or apheresis donations treated with amotosalen-HCl and UVA b) Intercept-PC: platelet concentrates from pooled buffy coats or from apheresis donations suspended in plasma and additive solution, treated with amotosalen-HCl and UVA.	
Country	**EL**	**ES**	**FR**	**IT**	
Pathogen inactivation techniques	Photo-inactivation of Plasma with Methylene blue	Methylene-blue inactivation for plasma (transfusion)	Amotosalen with UVA light exposure used for Platelets (platelets apheresis leucocyte-depleted and platelets recovered pooled leucocyte-depleted) pathogen. For plasma fresh-frozen leucocyte-depleted pathogen reduction/inactivation: Solvent-detergent, Amotosalen with light exposure.	Blood Component pathogen reduction/inactivation is not mandatory. Pathogen inactivation techniques are applied to a minor percentage of fresh frozen plasma for transfusion (riboflavin/UV, amotosalen/UVA, methylene blue, solvent detergent) and platelets (riboflavin/UV, amotosalen/UVA). Two specific full Health Technology Assessment studies, respectively on FFP and PLT pathogen inactivation, are in progress at the National Blood Centre, in order to make adequate data and information available for eventual national regulatory decision-making.	
Country	**LT**	**LU**	**NL**	**NO**	**PL**
Pathogen inactivation techniques	Mirasol technology is used for approx. 3 % of platelets.	Only for FFP, solvent detergent plasma is used	Irradiation: plasma Washing: all products Solvent Detergent: plasma	Solvent Detergent for all plasma units. Pathogen Reduction of 11 % of platelet concentrates (Intercept and Mirasol)	Mirasol PRT for platelets and plasma for clinical use and Macopharma Macotronic system for plasma for clinical use.
Country	**PT**	**SE**	**SI**	**UK**	
Pathogen inactivation techniques	Inactivation of pathogens by Amotosalen UVA (Intercept) in 1 BE	Some of the blood establishments in Sweden are using pathogen inactivation techniques for platelets but it is not mandatory and the blood establishment itself has to consider if they want to use that technology.	Amotosoralen + UV radiation (Intracept) for Platelets	Methylene blue treatment of plasma (England, Northern Ireland)	

Table 8 - Reduction /inactivation techniques used/country

Pathogen inactivation techniques are mainly used for plasma and not for other blood components. It was noted in the discussions at the competent authority meetings that, while the theoretical value of pathogen inactivation techniques can be high, the effective value depends largely on the implementation and validation of these techniques. Pathogen inactivation techniques can therefore not be considered as the single pillar for safety of blood

and blood components but are to be combined with deferral criteria and testing. It is through a combination of these strategies that safety risks are reduced to a minimum.

Comments

In all Member States tests are performed by laboratories authorised by the blood competent authority or other competent authorities. Competent authorities also recognise the role of international accreditation programmes for these laboratories.

While the EU legislation requires minimum testing for Hepatitis B, C and HIV (1/2), Member States reported additional routine tests mainly for syphilis, malaria, hepatitis A, hepatitis E and Parvovirus B19.

Introduction of mandatory NAT testing for HIV and hepatitis, and where appropriate pathogen inactivation techniques, were highlighted as important issues that need further reflection, particularly regarding cost-benefit assessments. In that respect, a general point mentioned was the need for a common assessment mechanism to understand the impact of changes in deferral criteria, testing or other measures on safety, quality, cost and supply. The role of common assessments by ECDC and the Commission was recognised, e.g. the development of a preparedness plan to address the seasonal outbreaks of West Nile Virus in some Southern EU countries.

Competent authorities reiterated also the value of consolidating nationally centralised test result data.

2.6.5. Storage, transport and distribution conditions

The storage, transport and distribution conditions of blood and blood components in blood establishments and in hospital blood banks must comply with Article 22 of Directive 2002/98/EC, and Article 5 and Annex IV to Directive 2004/33/EC. To comply with these requirements, 23 Member States plus NO reported existing legislation and regulations:

- CY reported existing national guidelines;
- HR, LI and NL mentioned their blood establishments' standard operating procedures (SOPs);
- ES reported existing specific computer systems;
- The reply from HU was unclear as it only mentioned refrigerator validation by the quality assurance department;
- 13 Member States (BE, EL, FI, FR, IE, IT, MT, NL, NO, PL, PT, RO, SE and UK) plus NO ensure the compliance with these requirements by inspections;
- LU reported that quality management is ensured by SOPs;
- LV reported control measures as visits to blood establishments and hospital blood banks and audits of documentation.

Comments

Many Member States report that they verify compliance with these EU provisions during inspection. Standard operating procedures, computer systems and audits were also mentioned as tools to verify or strengthen compliance.

2.6.6. More stringent measures

More stringent measures to ensure safety and quality, with respect to those foreseen under the Directive, were introduced or were maintained by 10 Member States.

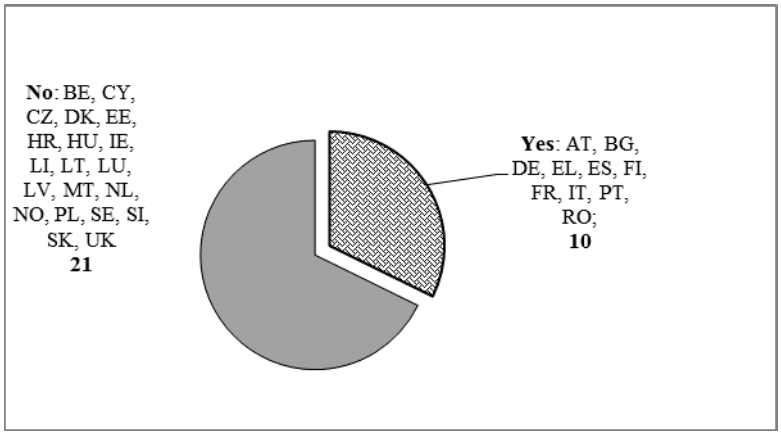

Fig. 37 - More stringent measures/country

These measures included:

- NAT testing for hepatitis B (HBV NAT), hepatitis C (HCV NAT), and HIV 1/2 (HIV 1 NAT) for whole blood and apheresis donations;
- NAT testing for WNV (EL);
- Dengue fever testing (PT);
- Pathogen inactivation techniques of plasma (EL);
- Requiring the responsible person to be a licensed physician, specialist in transfusion medicine or equivalent discipline, with at least 5 years of post-graduate full-time service in a blood establishment (IT);
- Additional eligibility/deferral criteria (RO);
- Mandatory inspection for hospital blood banks (RO);
- Registration and reporting of all incidents and adverse reactions, including the activity performed at clinical service level (RO);
- Penalties applicable to violations occurring at the clinical level - before, during or after transfusion, import or export of blood or blood components (BG).

Comments

Member States implement additional national safety and quality measures, in some cases because of increased risk e.g. the increased local prevalence of a certain disease.

2.7. Exchange of information, reports and penalties

2.7.1. Penalties

Under Article 27 of Directive 2002/98/EC Member States must lay down rules on penalties applicable to infringements of the national provisions, and take all measures necessary to ensure that they are implemented and notified to the Commission.

Twenty-five Member States have adopted national provisions laying down rules on penalties for infringements.

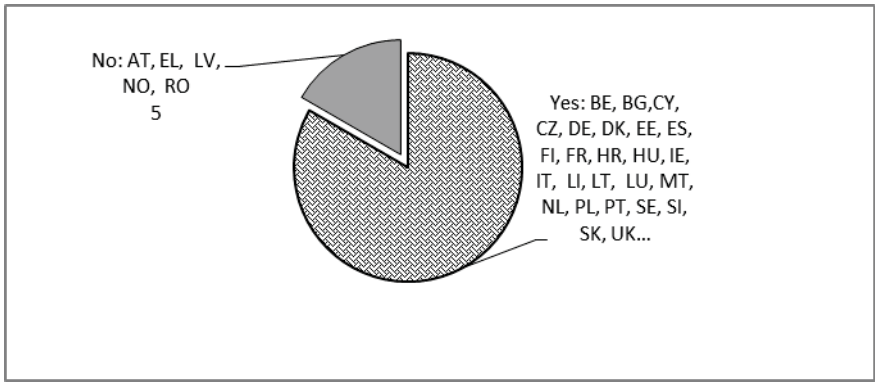

Fig. 38 – Member States adopting rules on penalties applicable to infringements of the national provisions

Four Member States reported to have imposed penalties: BG, CZ, LT and SK. The main reasons were related to the clinical use of blood and blood components (Bulgaria - five financial penalties), the change of legal entity of blood establishments which was not announced in advance (Czech Republic - one financial penalty), non-compliance with testing documentation requirements (Lithaunia - one licence revoked), and major shortcomings which were not eliminated after inspection (Slovakia – one authorisation suspension).

The penalties foreseen in national legislations, 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 where blood (components) are exchanged, it was suggested that further collaboration and coordination could be envisaged, potentially in a dedicated EU initiative related to inspections and authorisations.

2.7.2. Difficulties in transposition or implementation

Asked about difficulties they may have encountered when transposing or implementing the EU Blood Directives, Member States reported the following challenges:

- Financial constraints for implementing quality procedures, resistance to change, insufficient staff at the competent authority, blood centres and hospital blood banks (CY);
- The time-frame of 30 years for data storage (EL);
- Lack of resources (PT);
- Progressive shortage of medical staff in blood establishments leading to overlapping of functions, non-compliant facilities and lack of a national IT system (RO); and
- Challenges associated with verification of the requirements for donation and testing of blood components imported for uses other than transfusion.

Comments

Member States mentioned that general reporting requirements were considered heavy and called for a reduction in the frequency of these requirements (currently foreseen every 3 years). Also restrictions in resources and financial constraints, both at blood establishments and at competent authorities, were mentioned as complicating factors in the implementation of the legislation.

Annex 1: Individual country responses to the survey on the implementation of the EU Blood and Blood Components Directives conducted in 2013 and based on 2012 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):	+435055536435
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)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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 Federal Office for the Safety in Health Care (BASG) / AGES was set up in January 2006 and is responsible for marketing authorisation of medicinal products in Austria and assessment of medicinal products 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: Institut Marketing Authorisation on Medicinal Products & Lifecycle Management (Head: Dr. Christa Wirthumer-Hoche) Institute Assessment & Analysis (Head: Dr. Gerhard Beck) Institute Surveillance (Head: DDr. Alexander Hönel) Head of the Austrian Medicines and Medical Devices Agency: Dipl.-Ing. Dr. Christa Wirthumer-Hoche
1.5. 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

1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	45
2.1.2. How many of the BEs are satellite sites?	no information available
2.1.3. How many of the BEs are mobile sites?	no information available
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	no information available
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	no information available
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	no information available
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	250303
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	500
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	NA
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	Max. 700 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	13.471
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	NA
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	NA
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	24
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	2
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	included position in donor evaluation form
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	included position in donor evaluation form, contact by phone numbers, information provided during the interview
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	all criteria which are of relevance reagrding the product quality
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	all criteria which are not of direct relevance reagrding the product quality
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No

2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	see outcome of EDQM working group
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	haemoglobin levels
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	No
2.2.11.1. If no, what other deferral criteria would you suggest for derogation? Would you have other suggestions on the usefulness and set-up of such temporary derogations?	No information available
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	By inspection
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	for blood donations every single donation
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	for whole blood donations: unspecific immune reaction marker (Neopterin, CRP)
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	mandatory
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	No
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Plasma (Methylenblue / Intercept / Mirasol) Platelets, RBCs (Radiation)
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	By inspections
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	QM-System has to follow the principles defined in Guideline 2002/98/EG, Article 29 h, laid down in national legislation (QS-VO-Blut).

3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	By inspections
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	QM-System has to follow the principles defined in Guideline 2002/98/EG, Article 29 h, laid down in national legislation (QS-VO-Blut).
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	QM-System has to follow the principles defined in Guideline 2002/98/EG, Article 29 h, laid down in national legislation (QS-VO-Blut).
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	national legislation (Blutspenderverordnung, BGBl. II Nr. 100/1999)
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	No
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	45
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	BASG / AGES
4.6. How many laboratories performing donor testing are active within your country?	26
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	BASG / AGES
4.8. How many hospital blood banks are active within your country?	170
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	Baxter, Vienna / Octapharma, Vienna
4.10.2. If yes, please state the responsible authority within your country.	BASG / AGES
5. Inspections (Art 8 Directive 2002/98/EC)	

5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	BASG / AGES
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	4
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Pharmaceuticals (including plasma derivatives) Advanced therapies
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	once in two years (45 BE - including plasma establishments))
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	9 in 2012
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	none
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	none
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	none
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	based on PIC/S / EMA Compilation of Community Procedures template
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	all
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	on risk based approach on regional level
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	satisfactory
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	satisfactory
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	satisfactory
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	NA
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	NA
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	NA
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	11
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes

5.9.1. If yes, please describe.	No difference
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	No difference
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	depends, as it is not mandatory
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	2
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	by inspections
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By inspections
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	there is a haemovigilance officer who assesses the haemovigilance reports from the BE and clinical units
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	It is requested by law
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	it depends on the case. For example if it could have implications for other patients or donors or products

6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	No
6.2.8.2. If no, why not.	currently there is no summary report of the Commission available
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	none/ not available
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Information by email
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Information by email
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Pharmacovilance Medical devices
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	tissue and cells, medical devices
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	no
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	None
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	see GMP Annex 14
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	International standards
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	see GMP Annex 14
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	NA.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in	No

your MS?	
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	financial penalties up to 7270 € or up to 36 340€ depending on type of violation
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	BMG
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Mosquito identification system (Allerberger / ECDC)
8.5. Which other communicable diseases are of relevance to you?	NA
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Ärztegesetz (BGBl. I Nr. 169/1998)
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	NA
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	NA

A.1.2. Survey response Belgium

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Federal agency for medicines and health products FAMHP
1.1.2. Address of NCA 1:	Eurostation building, block 2 place Victor Horta, 40/40 1060 Brussels Belgium
1.1.3. Telephone (central access point):	00 32 2 524 80 00
1.1.4. E-mail (central access point):	welcome@fagg-afmps.be
1.1.5. Website:	www.fagg-afmps.be
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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 Federal Agency for Medicines and Health Products (FAMHP) (Law of 20/07/2006), a federal agency of public interest, is the competent authority in terms of quality, safety and efficacy of drugs and health Products. Our activities are divided into three branches (DG) also called "pillars". PILLAR 1 "DG PRE authorization" 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
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	/
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	6
2.1.2. How many of the BEs are satellite sites?	0
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	297.833
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	246.062
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	51.771
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	538.336
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	Maximum 500ml (4time/year)
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	104.545
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	Maximum 650ml/ collect (2l/month, 15l /year)
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	13.471
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	350ml

2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	6.078
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	6
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	6
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is not standardised at national/regional level
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	By inspection of the Blood establishment
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	post-donations card with bar code
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	The criteria are all relevant. Consider modification of the criteria according to the development of scientific knowledge.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	In the case of temporary deferral criteria for donors of allogeneic donations, a date of confirmed cured is not always easy to know. So the medical doctor who is at the collection, has the responsibility to accept or reject the donor.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	Point 2.2.1."West Nile Virus (WNV) (*): 28 days after leaving an area with ongoing transmission of WNV to humans": proposal to add: "may be accepted if a molecular genomic test is negative at each donation or if the blood component is treated with a pathogen inactivation method (validated for inactivation of WNV). Point 3.2. Deferral for particular epidemiological situations :" Particular epidemiological situations (e.g. disease outbreaks). Deferral consistent with the epidemiological situation (These deferrals should be notified by the competent authority to the European Commission with a view to Community action)": Proposal of modification: :" Particular epidemiological situations (e.g. disease outbreaks). Deferral consistent with the epidemiological situation (disease outbreaks in a MS should be notified by the competent authority of the MS concerned to the European Commission with a view to Community action)":
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Sexual transmissible disease New partner Changing partners Paid sex MSM Sexual partner with sexual transmissible disease or using IV drugs now or in the past
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	In Belgium, last year the current age of acceptance has been changed from 65 to the age of 71 year.
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Too low hemoglobin: 30.746 deferred donor s for a total of 674.916 donations Donor risk (sexual multipartner, IV drug, tattoo, piercing,…): 21.711 defer red donors Other medical or not- medical reasons: 32.229 deferred donor s
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes

2.2.9.1. If yes, please specify.	Activity report
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	84538
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	By inspection
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	every donation
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Syphilis testing and NAT for HIV1, HBV and HCV.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Syphilis testing and NAT for HIV1, HBV and HCV.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	10
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	60
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	18
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis : 46
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	no
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Plasma for transfusion: pathogen inactivation mandatory: techniques used : methylen blue, amotosalen Platelets: pathogen inactivation techniques used: amotosalen, (riboflavin)
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	the delegation of tasks are under the responsability of the responsible person
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	By inspection
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes

3.2.4.1. If yes, please specify.	under the responsability of the BE
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	By inspection
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	on a readable and appropriate support.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	By inspection
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	By inspection
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Not mandatory
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	6 : authorisation by 5 july 2004
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	The FAMHP, federal agency of medicines and health products.
4.6. How many laboratories performing donor testing are active within your country?	6 - Each blood establishment must to have his laboratory to performing donor testing.
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Regional competence
4.8. How many hospital blood banks are active within your country?	111
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	C.A.F. – D.C.F. cvba sprl De Tyraslaan 109 – BE 1120 NEDER-OVER-HEEMBEEK Dhr. R. F. TIEBOUT, Directeur-Generaal
4.10.2. If yes, please state the responsible authority within your country.	Federal agency for medicines and health products FAMHP
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge	DG Inspection of FAMHP

of inspections.	
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	5
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	One general system-oriented inspection every two years
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	All the satellite sites, every two years
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	44
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	No problem
5.5.3. How many BE have been inspected at least twice in the last 3 years?	6
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Satellite collection sites: every two years Mobile collection sites: 2 per province. There are 10 provinces in Belgium + the region of Brussels
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	104
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	10
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	0
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	10
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	A hospital blood bank is a hospital function. Hospitals are inspected by the regional authorities.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	No

5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	usefull information
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	3
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	FAMHP
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By inspection
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	A web based template is used and an electronic word document is used as backup.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	A web based template is used and an electronic word document is used as backup
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	all
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	By distribution of information notes to the BEs.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	Platelet concentrates - not pathogen inactivated – are systematically tested for the presence of microbiological agents. They are distributed negative to date. In 26 cases the microbiological testing became positive after distribution of the platelets and a recall was started.
6.2.11. Do you have in place a system/procedure to notify BEs in	Yes

case of a national rapid alert?	
6.2.11.1. If yes, please give a short description of the system/procedure.	Information note to the BEs
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Information note to the BEs
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Via medical device vigilance system.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	For importation, the BEs need to verify that the foreign establishment has a quality system, a traceability system and a notification system answering the requirements of the Belgian legislation.(Art 3 quarter, art 4bis §5 and art 13 quarter RD 4 April 1996 Preparation, conservation, delivery of blood)
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Art 2 Law 5 jul y1994 Blood : Le sang ou les dérivés du sang ne peuvent être prélevés, préparés, importés, conservés, distribués, dispensés, délivrés et utilisés que conformément aux conditions imposées par la présente loi et par les arrêtés pris par le Roi en exécution de celle-ci. Le sang destine exclusivement à la préparation de dérivés stables du sang exclusivement réservés à l'exportation, peut être prélevé en dehors de la Belgique et importé en Belgique dans les conditions et avec les garanties fixées soit par la législation du pays auquel ils sont destinés soit par le Roi; les dérivés de sang destinés exclusivement à la préparation de dérivés stables ayant la même destination peuvent être préparés et importés dans les mêmes conditions et avec les mêmes garanties, à condition qu'ils soient préparés au départ d'un sang prélevé en dehors de la Belgique dans ces conditions et avec ces garanties.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	by inspection
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	Syphilis testing an NAT HIV1, HBV and HCV
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Art 2 Law 5 jul y1994 Blood : Le sang destine exclusivement à la préparation de dérivés stables du sang exclusivement réservés à l'exportation, peut être prélevé en dehors de la Belgique et importé en Belgique dans les conditions et avec les garanties fixées soit par la législation du pays auquel ils sont destinés soit par le Roi; les dérivés de sang destinés exclusivement à la préparation de dérivés stables ayant la même destination peuvent être préparés et importés dans les mêmes conditions et avec les mêmes garanties, à condition

	qu'ils soient préparés au départ d'un sang prélevé en dehors de la Belgique dans ces conditions et avec ces garanties.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Blood and blood components must comply with the requirements of the Belgian law.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	0
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Information note to the BEs
8.5. Which other communicable diseases are of relevance to you?	Any other outbreack of communicable diseases in the world.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Provided the collection, processing and application are carried out in the same (operating) room. Examples : hemodilution, blood salvage techniques, preparation of PRP.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	According to our views, the collection of blood or blood components from patients in hospitals and intended for the preparation of ATMPs or magistral preparations (serum eye drops)do not fall under the scope of directive 2002/98/EC. Also in our opinion, blood or blood components collected from patients in hospitals and used for the preparation of components intended for autologous application, other than transfusion purposes, fall under the scope of Directive 2004/23/EC and not under the scope of Directive 2002/98/EC.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	When stable derivatives are produced on an industrial scale using large pools (> 300 liter) of blood/blood components as starting materials.

A.1.3. Survey response Bulgaria

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Bulgarian Drug Agency (BDA)
1.1.2. Address of NCA 1:	8 Damyan Gruev,Str. 1303 Sofia Bulgaria
1.1.3. Telephone (central access point):	tel: + 359 2 8903555
1.1.4. E-mail (central access point):	bda@bda.bg
1.1.5. Website:	www.bda.bg
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives)
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	Note: The Ministry of Health is the legislative body responsible for changes in “Law for blood, blood donation and blood transfusion” according to variations in Bulgarian or European legislation in this area. Furthermore, it is responsible for blood establishments’s accreditation. Accreditation is carried out according to the "Health Establishments Law" Art. 86 by the Accreditation Council, which is a specialized accreditation body to the Minister of Health.
1.2. National Competent Authority 2?	No
1.4. 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.).	According to the “Law for blood, blood donation and blood transfusion” Art.38 : The Executive Director of the Bulgarian Drug Agency shall function as a competent authority. Executive Director of the Bulgarian Drug Agency shall execute direct control through officials determined by him. In 2007 the department of “Control of blood transfusion system” was established. The main tasks of this structure are: Annual inspections of each blood establishment. Routine inspections in hospitals which are performing transfusion of blood and blood products as a part of their medical activities. Inspections (event-related) shall be conducted in each case of a serious incident or adverse reactions or in doubt of a serious incident or serious adverse reaction. Laying down rules on the reporting of adverse reactions. Maintain register of adverse reactions and events. ŸHaemovigilance - supervision of the traceability of the unit of blood or blood component from the donor to the recipient and vice versa. ŸInforms the blood establishments about received by RAS /rapid alert system/ information connected to transmissible diseases and vice versa. Prepares a SARE report until 30 th of June to the European Commission every year. Publishes an annual reports on the agency website as a part of the BDA annual report and sends report to the Ministry of Health about activities as a competent authority. Prepares a report to the Ministry of Health every three years about all activities in the hemotransfusion area – transposition, inspections etc. Translated version of this report shall be sent to EC by Ministry of Health. Department “ Control of blood transfusion system”- staff (personnel): A director (involved in the inspection activities too) 2 chief inspectors (one of them is a vigilance officer- maintains the register of adverse reactions and events) 1 senior inspector 1 inspector (junior) 3 experts – their main tasks are the evaluation of documentation for marketing authorization, the extension and renewal or modification of the marketing authorizations for medicinal products derived from human blood or plasma but they are also involved in the inspections as a part of inspection team if necessary. Department “Control of blood transfusion system” does not have its own budjet – it uses part of Bulgarian Drug Agency’s budjet. The Department as part of BDA is independent from the transfusion system, but it is part of the Ministry of Health.
1.5. 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
1.6. Could you please describe the competence/mandate of the	No Regional Competent Authority(ies) in the country.

Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	Stand – alone :6 ;Hospital – based : 23 Total : 29 Note: 6 BEs carry out all the activities (e.g. testing for transmissible diseases and processing). 23 hospital based BEs carry out part of the activities (e.g. blood collection, storage and issue blood components to hospitals)
2.1.2. How many of the BEs are satellite sites?	0. No BEs that are satellite sites in itself. One BE has additional satellite site for blood collection as part of its structure.
2.1.3. How many of the BEs are mobile sites?	0. No BEs that are mobile sites in itself. Every BE has montly plan for blood collection using mobile team. The mobile team's staff is part of BE personell.
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	122 779
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	43 245
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	34 595
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	167 851
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 +/- 10 %
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	232
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	500
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	2 714
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	200
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	No other donations by apheresis in 2012.
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	6 laboratories in big stand – alone BEs. The laboratories are included in their structure.
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	The same 6 laboratories in big stand – alone BEs. No special laboratories for testing plasma donations.
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Donor evaluation/selection form standardised at national level and donation form are uploaded.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	During thematic inspections documentation, connected to the blood donation is detailed checked.. Each blood donation has unique number (included in bar code) and all forms that must be filled in by the donor can be checked for donor's signature. We check whether donor screening questionaire is completed and signed by the donor and by physician - authorized interviewer and whether informed consent form is signed by the donor. The completeness of donation form about unique personal data that allow to identify the donor and

	testing results, donor register (that every BE maintain as a electronic and paper records), SOPs for the donor selection process, personnel training records etc. are other documentations inspected by CA during inspections. When some of the test results for transmissible diseases are confirmed as possitive we have special procedure in place. The representative of Blood establishment (from transmissible diseases testing laboratory) contacts obligatory with family doctor (GP) of the donor using special form, called "Notifiction Letter". This document require GP to inform personally blood donor about testing results.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	We don't have special self-exclusion form but the questionaire is designed to be understandable for the general public. Moreover all donors are obligatory informed by physician (that is authorised interviewer) for option to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort.
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Having in regard that main task of all parts (including CA) and activities in the blood transfusion chain is the quality and safety of blood and blood components collected and transfused, the most relevant deferral criteria are these connected to transmissible infectious diseases.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	The deferral criteria in point 2.2.2 - in fact a risky sexual behaviour, which puts persons at risk or at high risk of acquiring severe infectious diseases that can be transmitted by blood. Difficulties are connected to a balance between responsibilities for protection of health of donors and recipients in the area of blood transfusion and the respect the Charter of Fundamental Rights of the EU, including the prohibition of any discrimination based on sexual orientation.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	The risk behaviours having an impact on blood donor management are: - persons engaging in male-to-male sexual acts; - sex workers (persons who receive money or equivalent goods/services in exchange for sexual services) because of high risk for acquiring HIV and other sexually transmitted transfusion-relevant infections.
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	1. Medication – about 50 % 2. Low haemoglobin levels in donor's blood – about 15 % 3. Low body weight – about 15% 4. Serious active, chronic, or relapsing diseases – about 10 % 5. Transmissible infectious diseases – about 10% Note: This information was provided by National Center of Transfusion Hematology that collect information about reasons for donors deferral from all BEs in the country.
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	According to the "Law for blood, blood donation and blood transfusion" Art.36: National Center of Transfusion Hematology shall establish and maintain a register of the first level in accordance with the requirements of Regulation № 29 of 19 July 2004 (on the conditions and order to draw up, processing, storage and provision of information from register under Art. 36 of "Law for blood, blood donation and blood transfusion" and the form of documents in hemotransfusion chain). The register included information about the donors: personal data of the donor (name, surname, ID number,

	home address, phone); data from clinical examination and laboratory tests; causes and duration of deferral etc. Each BE shall send at regular basis this information about donors to the National Center of Transfusion Hematology.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	16 718 deferrals
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	In Regulation № 9 / 25 April 2006 establishing medical standard of a transfusion haematology are listed basic characteristics of the locations where transfusion haematology can be practised (Section III). Laboratories for immuno-haematologic testing of donated blood and laboratories for screening of each unit of donated blood for markers of transmissible infections are part of BEs. No laboratories outside BEs that can test donated blood. Laboratories testing donated blood as a part of Blood Establishments are accredited by the Accreditation Council, which is a specialized accreditation body to the Minister of Health according to the "Health Establishments Law" Art. 86. All laboratories at BEs are inspected at regular basis each year by CA.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	In the end of 2012 was set up working group for evaluation the possibilities to implement NAT testing in BEs. The working group included representatives from Ministry of Health, Blood Establishments, National manufacture of medicines from plasma and Bulgarian Drug Agency as a competent authority. The final report was sent to Ministry of Health in February 2013 with proposal to implement NAT testing as a pilot project in one BE (National Center of Transfusion Hematology-Sofia) but because of shortage of money the project was stopped. The main barrier to implement NAT testing is financial.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	According to Regulation № 18 of 10 June 2004 on the conditions and procedure for the diagnosis, processing and storage of blood and blood components and quality of blood from import. Issued by the Ministry of Health in force from 06.07.2004; SG. 58 of 6 July 2004, each donated blood unit is to be tested for: blood groups ABO, RhD, irregular antibodies and for markers of infections Anti-HIV-1 Anti-HIV-2 HIV-Ag HBs-Ag Anti-HCV HCV-Ag Syphilis The additional tests performed on a routine basis are tests for Syphilis and irregular antibodies. They are mandatory under national legislation for each whole blood donation.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	The donation of plasma is carried out in the same place where the donation of whole blood takes place - the blood estabishments. There are no special plasma collecting facilities. Each donated plasma unit is to be tested for the same markers of transmissible infections as whole blood donation.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	5 confirmed cases

3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	851 confirmed cases
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	86 confirmed cases
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	217 confirmed cases for Syphilis
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	The testing laboratories, as a part of blood establishments, participate in Proficiency Testing Scheme organized by EDQM. The national system for external control of transmissible infections for testing laboratories in blood establishments is organized by National Center of Infectious and Parasitic Diseases (NCIPD).
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Delegation of responsibilities is given only to individual who is trained for the task. The delegation is obligatory in written form. According to "Rules of procedure of the Blood Establishments" Art.16a, competent authority must be notified within 7 days for delegation of responsibilities.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	According to Regulation № 9 / 25 April 2006 establishing medical standard of a transfusion haematology all BEs should establish a procedure for selection of well-qualified personnel with appropriate education, training and experience. As a part of quality system, personnel qualification and training are checked by NCA at regular basis during routine inspections. Subject to inspections are policy, SOPs, job descriptions, annual training program for staff, personal development plans, certificates from a training of personnel, training records and documented competency assessments. Furthermore one of the basic rules of blood transfusion system written in "Law of blood, blood donation and blood transfusion" Article 22.(1)" The persons engaged in collecting, diagnostic, processing and storage of blood and blood components shall pass a compulsory training course at least once in two years."
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	BEs already established a quality system. It contain descriptions of at least the following processes: - quality management, quality assurance, continuous quality improvement, change control and validation processes; - personnel and organization; - premises and equipment; - documentation; - blood and blood components; - testing and processing of blood and blood components; - storage, issuing and distribution of blood and blood components; - quality monitoring; - quality control; - deviations, complaints, adverse events or reactions, withdrawal of blood, corrective and preventive measures; - self-inspections, audits and quality improvement; - contract management.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	The quality system of BEs is documented. Part of the maintained documentation is listed in SMF (Site Master File - similar to SMF for producers of blood and blood components derived medicines adapted for Blood Establishments according EuBIS project.) which is sent every year by BEs to competent authority. NCA checks quality system documents for updates and reviews during in site inspections and desk-based checks of the mandatory documentation. All official reporting forms are indicated in Regulation № 29 of 19

	July 2004 on the conditions and order to draw up, processing, storage and provision of information from register under Art. 36 of "Law for blood, blood donation and blood transfusion" and the form of documents in hemotransfusion chain. Issued by the Ministry of Health.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Records are kept using both paper records and computerized system.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Storing conditions of blood components are described in Regulation № 18 of 10 June 2004 on the conditions and procedure for the diagnosis, processing and storage of blood and blood components and quality of blood from import and Regulation № 9 establishing medical standard of a transfusion haematology . All storage, distribution and transportation activities are validated and documented (SOPs) , covering special requirements as devices for temperature control with recording capabilities, additional alarm system to the freezers and refrigerators, reserve power source, enough storage space etc.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Each blood donation has unique number (bar coded). A system of donation numbers is used to uniquely identify each donation. The unique personal data of the donor is kept in register of BE and only staff members have access to this information using required registration procedure. The staff involved in this process, sign declaration for data protection. The third parties have not information about donor (including hospitals for inpatient care, transfusing blood and blood components and manufacturers of drugs, derived from plasma). BEs issue blood and blood components units only as a unique number to hospitals for inpatient care.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	A bar code based system is mandatory and is used during all processes – from donation to transfusion of blood and blood components.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	European blood Directives and recommendations of Council of Europe Guide are basic documents implemented in National legislation connected to blood transfusion system- Regulation № 9 / 25 April 2006 establishing medical standard of a transfusion haematology and Regulation № 18 of 10 June 2004 on the conditions and procedure for the diagnosis, processing and storage of blood and blood components and quality of blood from import.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	All BEs are accredited and authorized. One of the big BEs was accredited and authorized in 2008. The others big BEs were accredited and authorized in 2009. Hospital – based, small BEs were accredited and authorized as part of hospitals where they are based.
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No

4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Laboratories for immunohaematologic testing of donated blood and laboratories for screening of each unit of donated blood for markers of transmissible infections are part of BEs. No laboratories outside BEs that can test donated blood. Laboratories testing donated blood as a part of Blood Establishments are accredited by the Accreditation Council, which is a specialized accreditation body to the Minister of Health according to the "Health Establishments Law" Art. 86.
4.6. How many laboratories performing donor testing are active within your country?	6 laboratories in 6 big stand-alone BEs.
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Hospital blood banks pass accreditation as part of hospitals, where they are located by the Accreditation Council, which is a specialized accreditation body to the Minister of Health according to the "Health Establishments Law" Art. 88. Authorisation and oversight of hospital blood banks is done by NCA for blood – Bulgarian Drug Agency.
4.8. How many hospital blood banks are active within your country?	In 2012 they were 28 (five years ago number was 56).
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	We have one plasma fractionation facility in the country. Bul Bio - National Center of Infectious and Parasitic Diseases Ltd. (BB-NCIPD Ltd.) Address: Bulgaria, Sofia, 26 Yanko Sakazov Blvd. Zip 1504 BB-NCIPD Ltd. is a public company and belongs to the Ministry of Health of Bulgaria. The production nomenclature of BB-NCIPD Ltd. covers more than 600 medicines, divided in two main groups: human medicines and in-vitro diagnostic medicine products. The medicinal products derived from human blood or plasma which BB-NCIPD Ltd. is producing are albumins and immunoglobulins. They are intended only for national market and use in the country.
4.10.2. If yes, please state the responsible authority within your country.	Bul Bio- NCIPD Ltd. as every manufacturer of medicinal products in the country is controlled by Bulgarian Drug Agency - Control of medicinal products Department / Manufacturing Control Division.
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	According to the “Law for blood, blood donation and blood transfusion” Art.38 : The Executive Director of the Bulgarian Drug Agency shall function as a competent authority. Executive Director of the Bulgarian Drug Agency shall execute direct control through officials determined by him. Department “ Control of blood transfusion system” of the CA is in charge of inspections .
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	5 full time inspectors. Note: CAs inspectors perform inspections not only in BEs, but also in hospital blood banks and hospitals which are performing transfusion of blood and blood products as a part of their medical activities.
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Pharmaceuticals (including plasma derivatives) Others
5.2.1.1. If others, please specify.	The only overlap with the inspection scheme are pharmaceutical inspections (medicinal products derived from human blood or plasma). They are done by Qualified Person of Bul Bio-NCIPD Ltd. (a national plasma fractionation facility) according Directive 2001/83/EC. The QP inspect only 6 big BEs that give plasma for fractionation.
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	53 inspections
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	6 inspections

5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	29 inspections
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	2 inspections (suspicion on SARE) but cases were not confirmed.
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	30 routine inspections in hospitals which are performing transfusion of blood and blood products as a part of their medical activities. 5 non routine (following SARE) inspections in hospitals which are performing transfusion of blood and blood products as a part of their medical activities. Total number of inspections in 2012: 59 routine inspections 29 of them in BEs and 30 in hospitals 7 non routine inspections 2 of them in BEs and 5 in hospitals
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	NCA uses risk based approach in the planning of inspections, having in regard the complexity of the site, its processes and products as well as the criticality of the products or services provided by the structure. The complexity and criticality usually remain fairly constant regardless of the compliance status of the site and this is the reason BEs to be inspected every year.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	NCA perform every year inspections to all BEs in the country. This is obligatory according to the "Law for blood, blood donation and blood transfusion" Art.39 (2) (Amended, SG No. 65/2006) "The inspections shall take place at least once a year. Inspections shall be conducted in each case of a serious incident or unwanted event or in doubt of a serious incidents or serious unwanted events."
5.5.3. How many BE have been inspected at least twice in the last 3 years?	All 29 BEs in the country were inspected every year in this period.
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Every BE has montly plan for blood collection using mobile team. The mobile team's staff is part of BE personell. The equipment and documentation (SOPs, job descriptions, work instructions, transport and cleaning records etc.) are inspected at regular basis during routine inspections. One BE has additional satellite site for blood collection as part of its structure and this structure was inspected twice in period of 4 years.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	In 2012 were performed thematic inspections of one of the most critical processes – labeling of blood components. The labeling of blood components is carried out only by big BEs. No shortcomings were observed.
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	In 2012 were performed routine inspections in all BEs. The minor shortcomings were noted in some hospital based BEs. The shortcomings were connected with premises (facilities). They needed to be repaired. CAPA were done in time limit.
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	In 2012 there were no major shortcomings were observed during inspections.
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	In 2012 there were no inspection in BE followed by suspension of its authorization.
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	In 2012 there were no inspection in BEs followed by closure of the blood establishment.
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	No other significant outcome of the inspections carried out in the BEs in 2012.
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	The donation of plasma is carried out in the same place where the donation of whole blood takes place - the blood estabishments. There are no special plasma collecting facilities.
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own	Yes

territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	According to the "Law for blood, blood donation and blood transfusion", NCA perform inspections not only in BEs, but also in hospital blood banks and hospitals which are performing transfusion of blood and blood products as a part of their medical activities. Usually blood banks are based in big hospitals that actively perform transfusion of blood components.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	Blood banks are responsible for : Supply of blood and blood components for particular patient and storage until transfusion; Immunohematological tests of patients and selection or reselection of blood and blood components for patient; Distribution of blood and blood components to wards in hospital. Optimal use of blood components in wards of the hospital and haemovigilance. Blood banks do not have permission to collect blood from blood donors. They receive analyzed and tested blood and blood components from BEs. The blood banks are subject to inspection as all other structures operating pursuant to the "Law for blood, blood donation and blood transfusion".
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	NCA uses national legislation - Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology" and Regulation № 18 of 10 June 2004" on the conditions and procedure for the diagnosis, processing and storage of blood and blood components and quality of blood from import" and many other regulations but recommendations of Council of Europe Guide is basic document implemented in national legislation, connected to blood transfusion system.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	NCA for blood – Bulgarian Drug Agency. According to Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology" "Healthcare facilities providing services under "Law for blood, blood donation and blood transfusion" ensure the traceability of blood and blood components through accurate identification procedures, record keeping and appropriate procedures for labelling and reporting of any serious adverse reactions and/or serious events to the competent authority."
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	During inspections of BEs, electronic register which keeps the unique personal data of the donors is checked for secure IT and long-term archiving areas for appropriate environmental control. Cross check between paper records and electronic ones is done.

6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	The system includes BEs, blood banks, hospitals which are performing transfusion of blood and blood products as a part of their medical activities and NCA. Procedures and requirements are described in Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology" Section V. Haemovigilance.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	No
6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	Healthcare professionals performing transfusion and observing adverse reactions in patients with imputability level 1, 2 and 3 should immediately report such events by filling in the form contained in Annex No. 18 of Regulation 29 of 2004. (template uploaded) BEs send a rapid notification to BDA in the format presented, containing data about the reporting establishment, the date on which the serious adverse event occurred and the reasons that caused the accident. (template uploaded) BEs submits to BDA on an annual basis a complete report on all serious adverse events by using the form presented. (template uploaded) The templates for SAE are indicated in the Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology".
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	No
6.2.3.1. If no, please specify what guidelines you use? If possible, please upload the template.	NCA uses at national level Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology". We can not upload the template.
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Blood banks are responsible for optimal use of blood components in wards of the hospital and haemovigilance. They receive analyzed and tested blood and blood components from BEs. In a case of SAR or SAE obligatory send report to the BEs which distributed the blood and blood components and to NCA for blood-BDA, according to the “Law for blood, blood donation and blood transfusion” Article 42. (1) “Persons engaged in collecting, diagnostics, processing, transfusion and storage of blood or blood components, shall immediately inform the Bulgarian Drug Agency of all serious incidents or unwantedreactions or suspicion for serious incidents or unwanted reactions, taken place.” and Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology".
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	NCA maintains register of adverse reactions and events according to the “Law for blood, blood donation and blood transfusion” - Article 40. (3) (New, SG No. 65/2006) “The Bulgarian Drug Agency creates and holds a register of the serious incidents and serious unwanted events, linked to the collection and use of blood and blood components.” All reported cases of SAR/E are included in the register of SAR/E but adverse reactions in patients with imputability level 1- Possible, 2- Likely, Probable and 3- Certain are obligatory subject to root cause analyses. Moreover according to the “Law for blood, blood donation and blood transfusion” – Article 42. (2) “The

	executive director of the Bulgarian Drug Agency through authorised persons shall analyze and summarize the information about the serious incidents and the serious unwanted reactions and shall take measures for preventing them.”
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	The whole official information, received from European Commission DG SANCO or other authorized European institutions are sent to all big BEs. The big (regional) BEs shall sent information to small, hospital based BEs in their region.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	In 2012 there were no recalls related to safety and quality of blood/blood components were issued in the country.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	In July 2011 has been created team for crisis management associated with transmissible infections (in fact with WNVD). This team includes directors and responsible persons from all big blood establishments. The same structure will react in case of a national rapid alert.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Information received via the RAS is translated and sent to the big (regional) BEs. When alerts affect neighbouring countries (Rumania, Greece) information is sent directly to small, hospital based BEs which are located near to the border with affected country. Information usually include measures to be taken to prevent spread of disease mentioned in an alert.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Pharmacovilance Medical devices
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	NCA receive alerts from national alert systems maintained by Medical devices and Pharmacovigilance structures as part of BDA.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	The rules and conditions for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries are clearly indicated in the “Law for blood, blood donation and blood transfusion” - Article 8. (1) Blood and blood components shall only be imported in the territory of this country with the permission of the Minister of Health or a Deputy Minister authorized by the Minister in case of emergencies where the available quantities of blood and blood components in the country are not sufficient for the protection of people's health. (2) The import under Paragraph 1 above shall be allowed in case the blood and blood components have been diagnosticated, processed, labelled and provided by an institution legally recognised by the respective state and shall be accompanied by documentation making possible the identification of every unit of blood or blood components and by information about laboratory testing performed and about the methods of diagnostics and processing. (3) The requirements, which the quality of blood and blood components under Paragraph 1 above should meet, shall be determined by the Regulation under Paragraph 2 of Article 20 of this Act. Detailed description of the requirements for the importation of blood and

	blood components are listed in Regulation № 18 of 10 June 2004" on the conditions and procedure for the diagnosis, processing and storage of blood and blood components and quality of blood from import" Chapter Six. Quality of imported blood.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	This rules and conditions are the same as those for import of blood and blood components for transfusion from EU Member States or third countries.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	In 2012 there were no blood components imported for transfusion from third countries (outside the EU).
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	In 2012 there were no plasma imported for fractionation from third countries (outside the EU).
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	The export rules are laid down in the "Law for blood, blood donation and blood transfusion" Article 7. (1) Blood and blood components shall only be exported beyond the territory of this country by a decision of the Council of Ministers, where they are meant for: 1. rendering humanitarian aid; 2. production of drugs for this country's needs. (2) The Minister of Health shall organise the export of blood and blood components in the cases under item 2 of Paragraph 1 above.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	The export rules are laid down in the "Law for blood, blood donation and blood transfusion" Article 7. (1) Blood and blood components shall only be exported beyond the territory of this country by a decision of the Council of Ministers, where they are meant for: 1. rendering humanitarian aid; 2. production of drugs for this country's needs. (2) The Minister of Health shall organise the export of blood and blood components in the cases under item 2 of Paragraph 1 above.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	In 2012 there were no blood components exported for fractionation from our country to third countries (outside the EU).
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	In 2012 there were no blood components exported for transfusion from our country to third countries (outside the EU).
7.11. Is there a regular shortage of blood or blood components in your MS?	Yes
7.11.1. If yes, how often (per year) is there a shortage of blood or blood components in your MS?	Once per year. Although this is not a rule but the most common deficiency of blood is observed seasonally. Often after a big summer holydays. Less frequently and no each year there is a shortage of a particular blood group.
7.11.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Red Blood Cells
7.11.3. If yes, would you be interested in concluding bilateral agreements with other MS in order to address the shortage?	Yes
7.11.4. If yes, would you be interested in establishing short-term/ad-hoc mechanisms for addressing the shortage?	Yes

7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	Yes
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	The penalties are imposed for violations of the Regulation № 9 / 25 April 2006 "establishing medical standard of a transfusion haematology" in the part related to the clinical use of blood and blood components: Section IV. Clinical use of blood and blood components (e.g. lack of required documentation - transfusion without informed consent in writing from the patient and lack of evidences for performed bedside tests).
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	5 penalties were imposed in 2012
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	Monetary penalties were imposed.
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	The Directive lays down the rules on penalties, applicable to infringements of the provisions directed to processes in BEs and hospital blood banks affecting quality and safety of blood and blood components. The national legislation includes additional penalties applicable to violations occurring at the clinical sphere - before, during or after transfusion, import or export of blood or blood components etc.
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	No significant difficulties were encountered in the transposition and implementation of the Blood Directives.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	In July 2011 has been created team for crisis management associated with WNVD, included responsible persons from all blood establishments. Concerning confirmed cases of WNV for 2012 in neighbouring countries (Rumania, Greece) , Bulgarian Drug Agency as the Competent authority with regard to the activities of blood establishments and blood banks for collection,testing, processing, storage and distribution of human blood and blood components, consider the set- up of the following measures as indispensable: 1.Strengthen surveillance of donor selection through extensive clinical examination and interviews, and especially for the residents and visitors of the affected areas and areas with high risk of mosquito bites- rivers, lakes, reservoirs. 2.Increasing awareness of the staff in blood establishments and blood banks and especially in the regions along Danube river and West border region along Struma river. 3.The donors will be required to inform Blood Establishmets and blood banks, if within a period of 15 days after donation he/she found the appearance of a febrile episodes or skin rush. 4.Temporary deferral of potential donors doubtful for disease for 28 days after leaving the areas with high risk of mosquito bites - rivers, lakes, reservoirs or flu-like symptoms pass away. (for the period between June and October). The measures will be in force between June and October 2013.
8.5. Which other communicable diseases are of relevance to you?	Malaria ; Dengue
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich	No

plasma) to fall under the EU blood legislation within your country?	
8.6.1. If no, which is the applicable legal framework and the competent national authority?	NCA for blood is not responsible for bed-side techniques of collection, processing and application of blood or blood components. The final product of bed-side techniques is not collected and prepared in BEs, according to specific quality standards, Moreover "Law for blood, blood donation and blood transfusion" do not apply to stem cells. The bed-side techniques of collection, processing and application of blood or blood components are under legislation of medical standarts to the different medical specialties that use them. Some of them, when it comes to applying the blood cells that undergo changes could be attributed to Regulation № 1394/2007 on advanced therapy medicinal products in Member States as a hospital exemptions because they are prepared on a non-routine basis in a hospitals under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No other techniques used in the country that we have doubts whether they fall under the scope of Directive 2002/98/EC.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	NCA do not consider that any process in preparation of blood components can change their natural origin. The techniques used can only make blood components more safely. Whole blood and blood components are not active substances in the meaning of pharmaceutical legislation. The comparisons are irrelevant. Whole blood and blood components shall remain under scope of Blood 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
1.1.5. Website:	http://www.zdravlje.hr/
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Tissues and cells Human organs
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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.).	Ministry of Health is a central state administration body. Activities are financed from the state budget. Additionally, for the costs of authorization BE are paying fee. Two units share responsibility for blood. 1. Health Protection Directorate 1.1. Service for Blood, Tissues and Cells Inspection (1 head of 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) Uredba o unutarnjem ustrojstvu (trenutno važeća)
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	NA
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	9
2.1.2. How many of the BEs are satellite sites?	0
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	67774
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	58089
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	11670
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	179305
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml +/- 50 ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	0
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	NA
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	2646
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	280-300 ml
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	118
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	9 are performing serology testing, 1 is performing NAT

2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	0
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Form in attachment
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	There is legal requirement for the documenting and reporting information to the donor. Those issues are regularly checked during inspections.
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Infectious diseases Intravenous or intramuscular drug use Sexual behaviour Those criteria are the greatest threat to the public health.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Sexual behaviour
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	MSM promiscuity paid sex sex with persons in risk groups
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Main causes leading to deferrals: low haemoglobin level, high/low blood pressure, endocrine diseases, respiratory diseases, other reasons. Reduced hemoglobin 41.7 %, Heart and blood vessels disease 2,8 %, Hyper and hypotonia 17.7 %, Neurological Diseases 1.1 %, Respiratory Diseases 3,3 %, Digestive tract Diseases 3,4 %, Genitourinary Diseases 0.9 %, Skin and subcutaneous tissue 2.2 %, Endocrine pain., malnutrition and immunity 3.4 %, Mental illness 0.9 %, Infectious and parasitic diseases 1.5 %, Injuries and poisoning 1.2 %, Vaccines 0.9 %, Menses, pregnancy, childbirth, lactation and abortion 1 %, Risk behavior 0.5 %, Collapse before giving blood 0.1 %, Cancellation before giving blood 0.2 %, Surgery 3 %, Malignant diseases 0.3 %, Alcoholism 0.6 %, Other 13.1 %
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	National referral centre - Croatian Institute for Transfusion Medicine is collecting and processing data.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	29248
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	There is legal requirement for laboratories to be authorized. Laboratories are regularly inspected.

3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	Individual donor testing for every donation
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	HIV 1p24 antigen, HCV core, TP antibody (Syphilis)
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Yes (considering that plasma in total is recovered plasma)
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Addition of obligatory NAT testing.
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	7
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	14
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	6
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis 8
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	International accreditation systems for testing laboratories is foreseen to be implemented in renewed legislation.
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	In the most BEs responsibilities for collection, processing, testing and quality assurance are delegated to other qualified persons.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Authorisation requirement Inspections Regular evaluation of personnel Mandatory trainings
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	BEs' QS includes: quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance, errors, complaints and self-inspection. HBB: do not all have QS established (because of lack of personnel)
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Authorisation requirement Inspections Regular evaluation of personnel Mandatory trainings
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	both, paper records and electronic forms
3.2.7. Is there a system in place to ensure that storage, transport and	Yes

distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	
3.2.7.1. If yes, please specify.	There is implemented quality system (separated refrigerators or space in cooling chambers, SOPs for storage order) and IT system including labelling system insuring protection of mix-up, storage temperature is monitored in BE and HBB automatically, but during transportation is purely maintained (no cooling devices).
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	National IT system is implemented allowing only authorised personnel to access the data. During the production and further there is no connection between donor and product.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Yes
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	Well accepted, foreseen to be mandatory in the next revision of the legislation.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	9
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Ministry of Health
4.6. How many laboratories performing donor testing are active within your country?	9
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	It is not obligatory for Hospital blood banks to be authorised. For oversight is responsible Ministry of Health.
4.8. How many hospital blood banks are active within your country?	33
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Service for blood, tissues and cells inspection
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	1 head of Service and 2 inspectors
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Advanced therapies

5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	5
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	2
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	5
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	2
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	0
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	NA
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	There were no inspections with such result.
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	Corrective measures imposed
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	Corrective measures imposed
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	There were no inspections with such result
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	There were no inspections with such result
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	There were no inspections with such result
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	Requirements for HBBs are described in Ordinance on personnel, premises and technical equipment for health care providers. Requirements are in concordance with blood Directives.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	Ministry of Health’s Service for blood, tissues and cells inspection is responsible for inspection of HBBs.
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	Well accepted, foreseen to be mandatory in the next revision of the legislation.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of	4

these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Ministry of Health
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	all
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By inspection
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	BE and hospital blood banks must without delay, by phone, fax or e-mail inform Croatian Institute for Transfusion Medicine and Ministry of Health about SARE. For that situation they have to use SARE template defined in Ordinance.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	Lack of the personnel
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Hospital blood banks must without delay, by phone, fax or e-mail inform Croatian Institute for Transfusion Medicine and Ministry of Health about SARE.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	In all SARE
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	BEs are informed on SARE through the network consists of CA's inspectors and responsible persons of BE.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	Data are available only for CITM (in attachment)
6.2.11. Do you have in place a system/procedure to notify BEs in	Yes

case of a national rapid alert?	
6.2.11.1. If yes, please give a short description of the system/procedure.	In case of RA BE are notified through network of CA's inspectors and responsible persons of BE (by mail and fax).
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	In case of RA BE are notified through network of CA's inspectors and responsible persons of BE (by mail and fax).
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Organs Tissues and cells
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Blood and blood components may not be exported or imported from or into the Republic of Croatia. Under exceptional circumstances, however, in the event of natural disasters and other extraordinary situations, or where justified by medical emergencies, the Minister may approve an export or import of blood and blood products.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	NA
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	Syphilis
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Import and export is not allowed
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Import and export is not allowed
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0

7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	No penalties were imposed
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	No penalties were imposed
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	No penalties were imposed
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Expenses of the implementation of IT and requirements for equipment. Separation of BEs from HBBs. Reconstruction of the facilities to meet criteria of Directives (still in progress)
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Croatian Institute for Transfusion Medicine is informed about all new data of WNV outbreaks and they gave guidance to BE for donor eligibility.
8.5. Which other communicable diseases are of relevance to you?	No
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Act on Health Care, CA is Ministry of Health
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Allogeneic apheresis of granulocytes.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Processes which change original function of the blood component in the product (f.e. activating platelets for orthopaedic use).

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:	"GEORGIO" 1 PRODROMOU Str.& 17 HILONOS Str. 1448 NICOSIA CYPRUS
1.1.3. Telephone (central access point):	0035722605736
1.1.5. Website:	www.moh.gov.cy
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance

	Other
1.1.7.1. If other, please specify.	Public Health and Health Care
1.2. National Competent Authority 2?	No
1.4. 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.).	Deparments of the Ministry of Health: 1. Medical and Public Health Services 2. Nursing Services.3. Pharmaceutical Services 4. Dental Services 5. Mental Health Services 6. State General Laboratory At the central level there are various administrative units for the fulfilment of the obligations of the Ministry of Health as for example: Purchasing and Supply Section, European Coordination Section, Health Monitoring Unit One, Computerisation, Health Promotion and Disease Prevention and Legislation. Another unit is being the Blood Center, the budget of which is part of the overall annual budget of the Ministry of Health dependence on goverment (wedges,staff, devices etc).
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	There is no Regional Competent Authority. All the district blood banks are directly under the responsibility of the Ministry of Health
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1 Blood Center and 4 blood banks Blood Banks Blood Banks
2.1.2. How many of the BEs are satellite sites?	none
2.1.3. How many of the BEs are mobile sites?	none
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	48,121
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	7148 Data collected oby the BC and 1 BB
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	7106
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	57,847
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	1507
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	360-480ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	272
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	200-250ml
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	261
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	4
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	4
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	Some of the Volunteers (doctors, chemists, nurses) of the Cyprus Coordinating body of Blood Donations and Awareness provide the national standarised information. Also information is provided by

	flyers
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	questionnaire
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	By written documentation on the blood donors questionnaire. Also after the testing when there is an upnormal result is documented.There is a responsible person from employees specificaly the person who is in charge for blood donations (doctor) who has the responsibility to settle via telephone an interview with the blood donor. When blood donor comes to the inerview is informe for the results.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	awareness campaign, lectures, leaflets
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Low Haemoglobin level is the most frequent reason for blood donation deferral.Most likely due to the high percentage of thalassaemia carriers in the country. Other frequent reason for deferral is the low blood pressure. Also medication reception especially b-blockers
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Communicable diseases and sexual behavior as you depend on the honesty of the blood donor. Though because of the small size of the country such as cases are limited.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Absence of steady partner
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	Persons who are older than 65 years old in a good health condition and submit by their doctor a medical certificate
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Low Hb levels and Blood Pressure abnormalities
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	The Blood Center and the blood banks are keeping data (P/C, manual) and sending to the CA the data upon request
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	8062
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	All the laboratories that carry out the tests for donors are public and hospital based They all designated by the Ministry of Health (Rebublic of Cyprus)

3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	High cost
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Syphilis (Treponema pallidum) is included in Blood Donation Law 1997 (regulations article 31 No 322)
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Yes as plasma donation is regulated and covered from the same National Blood Donation law.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Syphilis (Treponema pallidum)
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	8
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	19
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	19
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis (Treponema pallidum): 42
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	no comment
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Long time experience to blood banks prior to the adoption of article 9(3)
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Appropriately qualify personnel is selected and an ongoing in service training
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	There is an ongoing process of assuring the maintenance of high quality based on the principles of good practice as described in Article 10 and 6
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	These documentation is readily available upon request by CA
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	ICT and manually records are been kept
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	CA prepared quidelines according to the Directive 2002/98, Article

	22 and Article 29(e) and to the Directive 2005/62 regarding starage,distributionand transport conditions. These quidelines were distributed to all of the Public Blood Banks and Blood Center and to all Hospitals/Clinics of the private sector on the 2 of May 2012
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	We define two only persons from the stuff (to each blood bank and Blood Center) who are responsible for keeping blood donors data. Also on the ICT data a password is in use which only these two persons have access
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	No
3.2.9.2. If no, why not?	Blood center and blood banks use manually the labelling. The cost is prohibiting factor for the acquisition of this system
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	Important and very useful element for the every day activities in Blood Center and Blood Banks
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Designation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Other
4.2.1. If other, please specify.	Relevant documentation submited upon request
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	One BC 08/12/2006
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Ministry of Health
4.6. How many laboratories performing donor testing are active within your country?	4
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Ministry of Health
4.8. How many hospital blood banks are active within your country?	6
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	No
5.1.3. If no, please explain why not.	Only recently four professionals had been trained by EU funded project as inspectors
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	none
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	none
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	none

5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	none
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	none
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	none
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	N/A
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	N/A
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	N/A
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	N/A
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	N/A
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	N/A
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	N/A
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	N/A
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	useful
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Ministry of Health
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	for all
6.1.4. Do you apply an international coding system for blood	Yes

components?	
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	In each blood bank and Blood Center there is a store room for keeping these records. Only few people have the key
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	At the level of Minstry of Health there is a person who is responsible to collect the data from all the blood banks, blood center and private hospitals
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	No
6.2.6.2. If no, how do you ensure that SAR/E are reported from Hospital Blood Banks to BEs?	they do not reported to BEs but directly to the Ministry of Health
6.2.7. Do you perform root cause analyses of the SARE?	No
6.2.7.2. If no, why not?	because for the moment we do not observe serious SARE cases
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Each blood bank and the Blood Center are informe immediatetly by fax, letters and emails when a SAR recorded at EU level
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	No recalls until now
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	by sending fax, emails and via telephone we informe blood center and blood banks in a rapid alert case
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	the same as 6.2.11.1
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	No
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	No
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No

7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	The recommedations of directive 2002/98 but we do not import blood and blood components from other EU MS or third countries
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	As in 7.1
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	N/A
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	N/A
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	N/A
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	Yes
7.11.1. If yes, how often (per year) is there a shortage of blood or blood components in your MS?	Three times yearly especially on Christams, Easter and summer Holidays
7.11.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Red Blood Cells
7.11.3. If yes, would you be interested in concluding bilateral agreements with other MS in order to address the shortage?	Yes
7.11.4. If yes, would you be interested in establishing short-term/ad-hoc mechanisms for addressing the shortage?	Yes
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What	Finance problems to implement quality procedures, resistance to change, not enough staff at the CA level and at the Blood Center and

specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Blood Banks
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	28 days deferrral of blood donors who traveled to the countries with the outbreaks of WNV
8.5. Which other communicable diseases are of relevance to you?	Malaria
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	Yes
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Factor VIII, Albumin, haemacell, fibrinogen

A.1.6. Survey response Czech Republic

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health
1.1.2. Address of NCA 1:	Palackého nám 2, 128 20 Prague Czech Republic
1.1.3. Telephone (central access point):	+420-224 971 111
1.1.4. E-mail (central access point):	mzcr@mzcr.cz
1.1.5. Website:	www.mzcr.cz
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices Other
1.1.6.1. If other, please specify.	health care
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Other
1.1.7.1. If other, please specify.	regulation, legislation
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	State Institute for Drug Control
1.2.2. Address of NCA 2:	Šrobárova 48, 100 41 Prague, Czech Republic
1.2.3. Telephone (central access point):	+420 272185111
1.2.4. E-mail (central access point):	posta@sukl.cz
1.2.5. Website:	www.sukl.cz
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance Other
1.2.6.1. If other, please specify.	price / cost regulation
1.3. National Competent Authority 3?	No
1.4. 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.).	Ministry of Health: govermental institution. Blood components and plasma for fractionation are managed within Dpt. of Pharmacy. There is also special dpt. dealing with EU affairs. State Institute for Drug Control: independent institution. Blood components and plasma for fractionation (together with cells and tissues) are managed within Clinical Practice and Surveillance over Biolog. Material Processing - Inspection Division. Haemovigilance is managed within Dpt. of Pharmacovigilance. There is also special dpt. dealing with price regulation.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	no Regional Competent Authorities
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	74
2.1.2. How many of the BEs are satellite sites?	12
2.1.3. How many of the BEs are mobile sites?	9
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	272 152
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	227 175
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	49 252
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries,	Exact data are not available. There is small scale cross-border

plasma/blood donations, estimated magnitude, explaining factors, …).	movement of plasma donors from CZ to Austria or Germany.
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	418 954
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml (standard)
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	617 617
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	800 ml (average)
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	exact figures are not available, total No. of aphereses (excl. plasmapheresis, incl. platelets, red cells and/or multicomponent) is 18 271
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	"volume" is not available (and not regulated). Standard collection is 2x 10^11 platelets
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	exact figures are not available, total No. of aphereses (excl. plasmapheresis, incl. platelets, red cells and/or multicomponent) is 18 271
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	52, donor testing is performed only by some BEs
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	donor testing is performed by BEs if they perform plasmapheresis (see above) plus 2 laboratories for specialized plasma centers
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	reqiurements are set in the CZ Decree (MoH 143/2008 Coll.) and controlled during inspections
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	reqiurements are set in the CZ Decree (MoH 143/2008 Coll.): the donor signs in the Questionnaire, that he/she has red "information", answered all questions to his / her best knowledge and reconsidered his/her responsibility (incl. possibility of self-exclusion)
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	infection risk (harmonization within EU is important)
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	sexual behavior (there is a little reason for permanent exclusion for behavioral risk ! One should keep in mind that "behaviour can be changed")
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	sexual behavior (there is a little reason for permanent exclusion for behavioral risk ! One should keep in mind that "behaviour can be changed")
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	MSM, sexual intercourse with a person with AIDS/HIV pozit., sex. intercourse for money or drugs, sex. intercourse with inj. drug adict, sex. intercourse with prostitute, frequent changes of casual sex. partners
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current	No

age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	- epidemiological: travelling to risk area (malaria, WNV...), exposition to "bloody" medical procedures / piercing / tatoo, thick bite - medical: low blood count, low ferritin, elevated leukocytes
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	there is a National Registry of donor found to be pozitive for HIV, HBV and/or HCV markers
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	150
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	testing site in declared in the BEs licence, requirements are checked during inspections
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	cost / benefit considerations
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	HIV p24 antigen, syphilis antibodies
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	yes
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	9
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	30
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	111
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	syphilis: 30
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	no
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	platelets: very few units (dozens), amotosoralen
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes

3.2.2.1. If yes, please specify.	legislation allows to delegate tasks to other persons, but in practice it is not used
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	the requirement is stated in the decree (MoH 143/2008 Coll.) and checked during the inspections
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	the requirement is set in the decree (MoH 143/2008 Coll.) and checked during the inspection
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	the requirement is set in the decree (MoH 143/2008 Coll.) and checked during the inspection
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	combination of printed documments and electonic copies. The requirements are set in the decree (MoH 143/2008 Coll.) and checked during the inspection
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	the requirements are set in the decree (MoH 143/2008 Coll.) and checked during the inspection
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	all manufactured products are labeled with unique numerical code (according to the "standard for labeling of blood components"). No data allowing identification of a donor are given to any BEs partner
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Yes
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	in general - good
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	85 (1.8.2013)
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	State Institute for Drug Control
4.6. How many laboratories performing donor testing are active within your country?	52 (within BEs)
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	blood banks are not authorised but they are checked by State Institute
4.8. How many hospital blood banks are active within your country?	120 (68 run their services within authorised BE)
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1),	No

14, 15, 22 and 24 of Directive 2002/98/EC?	
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	State Institute for Drug Control, Inspection Division, Clinical Practice and Surveillance over Biolog.Material Processing
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	1,5
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Others
5.2.1.1. If others, please specify.	Good Clinical Practice
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	45 inspections of BEs, 21 inspections of BBs in 2012
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	5 inspections of BEs in 2012
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	45 inspections of BEs in 2012
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	2
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	basic inspection intervals have been established in compliance with the requirements set forth by Decree. The interval may be shortened based on the degree of risk based on the results of the previous inspection. Where the evaluation achieved is “satisfactory”, the interval may be shortened to 12 – 24 months. Where the evaluation achieved is “not satisfactory”, the interval for follow-up inspections shall always be 12 months or less.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	internal reasons
5.5.3. How many BE have been inspected at least twice in the last 3 years?	40
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	mobile collection sites inspected 1x/4Y satellite collection sites 1x/2Y
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	inspection report
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	inspection report
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	inspection report
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	inspection report, number of cases: 0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	inspection report, number of cases: 0

5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	NA
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	5
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	No
5.8.1. If no, please explain.	only GMP inspectors for blood establishments (State Institute for Drug Control) has approx. 320 officials.
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	blood banks are not licence holders but there is a duty to annonce their activities. Blood banks are inspected once a 4 years.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	blood banks are not licence holders but there is a duty to annonce their activities. Blood banks are inspected once a 4 years.
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	in general - good
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	No
5.11.2. If no, why not?	internal reasons
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Ministry of Health (legal requirements), State Institute for Drug Control (in site inspections)
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	whole blood, red blood cells, platelets, plasma, kryoprotein, kryoprotein-depleted plasma, granulocytes
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	the requirement is set in the law (Act 378/2007 Coll.) and decree (MoH 143/2008 Coll.) and checked during the inspections
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	blood establishments and blood banks are obliged to send immediate and annual hemovigilance reports. NCA statistically evaluates data, fills SARE template and sends it to EC
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	No
6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	it is obligatory to use "template" published as an Annex of Decree No 143/2008 Coll. (this template is not, in our oppinion, very convenient and does not comply with practical requirements)
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes

6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	internal reasons
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	please see 6.2.1.1
6.2.7. Do you perform root cause analyses of the SARE?	No
6.2.7.2. If no, why not?	internal reasons (it is done by BE / BB)
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	results are presented to BTS medical community
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	135 (vast majority - lookback procedure for plasma fractionation)
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	web page State Institute for Drug Control, information is in paralell distributed via Medical Society
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	web page State Institute for Drug Control, information is in paralell distributed via Medical Society
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	all kinds of alerts are directed to the same institutions (MoH, State Institute for Drug Control). If relevant, they are send to partners / responsible bodies involved
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	no
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	reguirements are set in the law (Act 378/2007 Coll.), in addition an individual licence from MoH is necessary
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	reguirements are set in the law (Act 378/2007 Coll.), in addition an individual licence from MoH is necessary. As far as there is no fractionating capacity in the CZ, these rules are not applicable
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	to fullfill CZ legal requirements (incl. HIV Ag, syphilis)
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes

7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	requirements depend on the partner, "export licence" from MoH is necessary
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	requirements depend on the partner, "export licence" from MoH is necessary
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	Yes
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	administrative failures - change of legal entity of blood establishments was not announced in advance.
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	1
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	financial penalty
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	to define clearly the scope (as regards use of blood and it´s components for "non-transfusion" purposes, eg. topical use etc...)
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	donors travelling into "countries in risk" during summer season are deferred for 4 weeks
8.5. Which other communicable diseases are of relevance to you?	none of special concern
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	currently in discussion
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Yes: eye drops with autologous plasma, autologous fibrin glue and sealants etc.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would	pooling more then10 donations

fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	

A.1.7. Survey response Denmark

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Sundhedsstyrelsen (Danish Health and Medicines Authority)
1.1.2. Address of NCA 1:	Axel Heides Gade 1 DK 2300 Copenhagen S, Denmark
1.1.3. Telephone (central access point):	+45 72 22 74 00
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)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	Development and implementation of national legislation, formulation of national health policies, etc.
1.2. National Competent Authority 2?	No
1.4. 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.).	In Denmark, The Danish Health and Medicines Authority is the supreme authority in healthcare and regulatory control of medicines. We assist and advise the Ministry of Health as well as other authorities with the administration af healthcare services and inform Danish citizens on health issues. It is also our responsability to ensure the availability of effective and safe medicines, medical devices and new terapies 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 advise 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 responsability for education, authorisation, registration and supervision of healthcare professionals. There are approximately 700 employees devided between 10 departments and with resides at 4 addresses.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Regional Competent Authorities are not present in Denmark
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	5 (in Denmark the blood establishment is an integrated part of the hospital system
2.1.2. How many of the BEs are satellite sites?	58
2.1.3. How many of the BEs are mobile sites?	6
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	154,350
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	This data is not available for our office
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	This data is not available for our office
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	293,765
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml ± 45 ml
2.1.10. For plasma donations by apheresis, could you please provide	3,086

the number of plasma donations in 2012 (01/01-31/12/2012).	
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	600 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	1,232
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	irrelevant, no of plts is relevant
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	0
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	5
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	5
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Not available in English. Appendix 1 (Bilag 1) in attached national regulation (BEK nr 366 af 23/04/2012)
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	By inspections (is there a system/spot checks)
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Criteria concerning HIV and hepatitis
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Criteria regarding diseases that are very rare in Denmark (it is not possible to ask about everything)
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	male homosexual practice; prostitution (permanent deferral); women who have had sex with bisexual male, sexual contact with i.v. drug user, sex with person who shares or have shared injection needles with others, sex with person treated for hemophilia before 1988, sex with person from areas where HIV or HTLV infection is widespread in the general population (Africa South of Sahara, India, South East Asia, South America), sex with HIV positive,sex with prostitute (4 months deferral),
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Travelling Medication
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively	No

applied by BEs in your country?	
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	By inspections (systems and spot checks)
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	ID NAT 100 %
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	ID NAT for HIV; HBV and HCV
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	It is mandatory
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	0
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	5
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	4
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Not applicable
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Delegation only to qualified and trained personel
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Inspections (systems and spot checks)
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	The quality system follows requirements in the Directive
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Inspections (systems and spot checks)
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	IT systems
3.2.7. Is there a system in place to ensure that storage, transport and	Yes

distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	
3.2.7.1. If yes, please specify.	The system follows requirements in the Directive
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	All data is stored in state of the art blood bank IT systems (ProSang and Blodflödet) with protected and controlled access (user name and password). The function of these IT systems are inspected by the Danish Health and Medicines Authority in connection with the biannual inspection of blood establishments demanded in the Danish and European legislation .
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	No, but ISBT 128 is 100 % implemented
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	The guideline is followed in generel
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	5
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Sundhedsstyrelsen (Danish Health and Medicines Authority)
4.6. How many laboratories performing donor testing are active within your country?	5
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Sundhedsstyrelsen (Danish Health and Medicines Authority)
4.8. How many hospital blood banks are active within your country?	See section 2.1
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Sundhedsstyrelsen (Danish Health and Medicines Authority)
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	3
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Pharmaceuticals (including plasma derivatives) Medical devices
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	Every second year
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0

5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	11
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	80 %
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Every second year
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	We do not classify shortcommings as minor nor major
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	We do not classify shortcommings as minor nor major
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	They are in generel in complience
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	10
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	The system is implemented in the NCAs quality system
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	We only have hospital blood banks in Denmark
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	The guide is very usable
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	No
5.11.2. If no, why not?	Do to lack of ressources
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member	Sundhedsstyrelsen (Danish Health and Medicines Authority)

State?	
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	All components
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Only electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Inspetions (systems for backup and storage, spot checks)
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	In accordance with Executive Orders forms are available from our website http://laegemiddelstyrelsen.dk/en/service-menu/product-areas/blood-and-blood-products (in Danish only). The forms are in accordance with the Directives
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	In accordance with Executive Orders forms are available from our website http://laegemiddelstyrelsen.dk/en/service-menu/product-areas/blood-and-blood-products (in Danish only). The forms are in accordance with the Directives
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	All cases
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	No
6.2.8.2. If no, why not.	No we only issue a national yearly report on the blood product area
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	0
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	We have a contact list to the BE and contact them if it is necessary.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes

6.2.12.1. If yes, please give a short description of the system/procedure.	See section 6.2.11.1
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Same CA
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	No rules. DK is self sufficient and has during the last 20 years imported less than 20 RBC units - all from EU/EEC member states and all for specific immunized patients.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	No import
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	The rules are described in the Danish Blood Law
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Export allowed to neighbouring countries in case of emergencies or immunized patients
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	214.576 (60,9 metric tons); Switzerland
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties?	Not applicable

Please describe.	
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	Not applicable
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	Not applicable
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	The danish comments to a potential revision of the directive was sent to Stefaan.VAN-DER-SPIEGEL@ec.europa.eu on 02-01-2013.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Travel deferral rules
8.5. Which other communicable diseases are of relevance to you?	None
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Sundhedsloven (Danish National Health Act), Medical Devices Act Sundhedsstyrelsen (Danish Health and Medicines Authority)
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	We follow the EU-directive criteria for medicinal products

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 7374140
1.1.4. E-mail (central access point):	info@ravimiamet.ee
1.1.5. Website:	http://ravimiamet.ee/en
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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.).	State Agency of Medicines (SAM) is a governmental body under the Ministry of Social Affairs. There is 6 departments in SAM. Department of Biologicals is responsible for the blood (and blood components), cells, tissues, organs and advance therapy medicinal products. There are 3 employees in the Department of Biologicals - head of department and 2 specialists. There have been major changes in staff during last two years. Therefore specialist nr 1 has 1,8 years of experience, specialist nr 2 has 7 months of experience and head of the department has only 2 months of experience. In addition one GMP inspector from the Department of Inspection participates the inspections made to the cell, tissue and organ handlers or blood establishments.
1.5. 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)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	There are no Regional Competent Authorities in Estonia.
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	5
2.1.2. How many of the BEs are satellite sites?	1
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	35869
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	28353
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	7516
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Some donors has moved abroad. Therefore during the look-back procedures it can be sometimes hard to reach the donor (for exaple if additional testing is needed).
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	58120
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	1028
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	650
2.1.12. For platelet donations by apheresis, could you please provide	105

the number of platelet donations in 2012 (01/01-31/12/2012).	
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	393
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	804
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	5
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	5
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is not standardised at national/regional level
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	It is regulated by law. All information given to and received from the donors (including donor evaluation form) and all test results must be stored at least 15 years. All relevant abnormal findings must be reported back to the donor (including counseling) by the blood establishment.
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	It is hard to highligh a single criteria, because all aspects that can affect either donor or a recipient are relevant.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	All criterias concerning donor behavior are hard to verify.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Blood establishments have created donor selection questionnaires that include questions about the occasional sex partners (in return for money or drugs), having sex with men (for the male donors), having sex with a man who has had sex with man (for female donors)
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Unfortunately we do not have an overview about all deferrals because blood establishments are not reporting every case. Blood establishments report cases that concern repeated donors' positive test results for the infectious diseases.
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	We are collectig deferrals of repeated donors that are associated with the look-back procedures.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	26 (for repeated donors)
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes

3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Requirements for the laboratories that carry out testing of donors blood are established in legislation. During licensing and inspections of BE-s laboratories are regularly checked.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	Each donation is tested for the HIV, HBV and HCV markers using NAT testing.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Some of them are mandatory. HBV NAT test is not mandatory, but all the BE-s are using it in addition to HBsAg.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Some of them are mandatory. HBV NAT test is not mandatory, but all the BE-s are using it in addition to HBsAg.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	6 (confirmed positive cases for repeated and first time donors)
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	13 (confirmed positive cases for repeated and first time donors)
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	32 (confirmed positive cases for repeated and first time donors)
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Positive test results for syphilis - 15 (confirmed positive cases for repeated and first time donors)
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Tasks can be delegated to the person who is nominated as a replacement person of responsible person. The requirements for the replacement person are set out in legislation.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Qualification and training of personnel is controlled during licensing of BE (for some employees) and during inspections. All BE-s must establish training program for each employee.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	It is regulated by law.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	It is regulated by law and checked during the inspections.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	It is regulated by law and checked during the inspections.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in	Yes

Directive 2002/98, Annex IV, and Directive 2005/62/EC?	
3.2.7.1. If yes, please specify.	Requiremets are set out in law.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Donor codes are used to identify the donors. Donor name and the code can be related only by the BE-s.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Yes
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	-
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	5 (14.08.2013)
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Estonian Accreditation Centre. Laboratories that are part of the BE-s are controlled by SAM.
4.6. How many laboratories performing donor testing are active within your country?	5
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Health Board
4.8. How many hospital blood banks are active within your country?	24
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	State Agency of Medicines (SAM), Department of Biologicals is responsible for the ispections of BEs.
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	1
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Advanced therapies
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	24
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	34
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	0

5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	1
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	All reports send by the BE-s about serious adverese reactions and serious adverse events are regularly analysed. Results are used to spot out errors that need intervention by CA. In case of major changes (new test systems, new machines) BEs notify CA. Based on that CA makes a decision about the need for inspection.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	3
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Satellite sites are inspected as BE-s. Mobile sites are inspected occasionally.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Inspection focused on biovigilance system. BE improved the the way of reporting serious adverse events and reactions.
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	BE improved the vigilance system.
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	-
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	-
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	-
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	Only one inspection was made during 2012 to the BEs because the inspector responsible for the BEs left and the training of the new inspector was needed before the inspections.
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	No plasma establishments in Estonia
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	Health Board is responsible for inspecting hospital blood banks.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	It helps to prepare for the inspections. It is also very useful for the new inspectors just starting their jobs. It gives a good overview about general systems in BE.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	3
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on	Yes

the results and control measures of your inspections?	
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	State Agency of Medicines
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	For all the blood components
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT system
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Cryoprecipitate
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	It is regulated by law and controlled during inspections.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	BEs are reporting SAR and SAE to the Sate Agency of Medicines (SAM).
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	There is no separate vigilance officer in SAM. Biovigilance is a task for the specialist who is also responsible for the licencing and inspecting BEs.
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	System is regulated by legislation. Hospital blood banks must inform concerned BEs of any serious adverse reactions. The template form for reporting is also set out in law.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	For all SARE reports BEs also send the investigation reports. If during the evaluation of these investigation reports (by CA) it seems that there may be also other aspects that need to be addressed, root cause analysis are done. Usually BEs are asked to send more information or asked to also study some other aspects.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	If there are SARE at EU level that can also affect Estonian BEs, SAM gives feedback to the BEs

6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	0
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	SAM is responsible to notify all the BEs about the national rapid alert. All BEs have provided SAM with the 24 hour phone number that can be used in urgent situations. Also e-mails are used to send a written confirmation about the situation.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Again SAM is responsible to notifay all the BEs about the national rapid alert. All BEs have provided SAM with the 24 hour phone number that can be used in urgent situations. Also e-mails are used to send a written confirmation about the situation.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	No
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	SAM also receives alerts via vigilande systems for tissues, cells and organs.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Blood and blood components are considered to be medicines, requiring special authorisation for transport and export/import to/from the European Economic Area (EEA) and third countries. Therefore State Agency of Medicines is notified about every import/export activities.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	There is no fractionation facilities in Estonia.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	No import of blood components for transfusion from third countries during 2012.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	No fractionation facilities in Estonia.
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Fractionation facilities are making their own inspections to the BEs before they sign a contract.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	All the export events must be notifyied to the SAM. Export and of blood and blood components used for medical purposes outside the European Economic Area requires an application for import/export special authorisation.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes

7.9.1. If yes, please provide this data by country of destination.	Octapharma - 26 997 doses of plasma Biotest AG - 7199 doses of plasma
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	No components were exported for transfusion from Estonia during 2012.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	-
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	-
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	-
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	-
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	BEs are using 28 days deferral for the donors that have visited countries affected by WNV. Testing of WNV in not routinely used.
8.5. Which other communicable diseases are of relevance to you?	Donors are routinely tested for syphilis.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	National compentent authority is Health Board.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	-
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	-

A.1.9. Survey response Finland

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	The Finnish Medicines Agency (Fimea)
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
1.1.5. Website:	http://www.fimea.fi
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	The National Supervisory Authority for Welfare and Health (Valvira)
1.2.2. Address of NCA 2:	P.O. Box 210, FI-00531 Helsinki, Finland
1.2.3. Telephone (central access point):	+358 29 520 9111
1.2.4. E-mail (central access point):	kirjaamo@valvira.fi
1.2.5. Website:	http://www.valvira.fi/
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Other
1.2.6.1. If other, please specify.	The National Supervisory Authority for Welfare and Health (Valvira) and the six Regional State Administrative Agencies supervise hospital blood banks as a part of other healthcare service providers in Finland.
1.3. National Competent Authority 3?	No
1.4. 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 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 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. In addition, the organisation is supported by a process of internal services. The Supervision and licenses -process includes the Inspectorate unit and the Laboratory unit. The Inspectorate is responsible for authorisation and inspection of blood establishments, and for haemovigilance functions. About 20 inspectors/experts are working in the Inspectorate. One senior inspector is responsible for the authorisation and inspection of blood establishments, and for haemovigilance actions. In addition, the Assessment of medicinal products -process provides medical expertise at need (mostly in haemovigilance). Legal expertise is provided by the process of internal services. The National Supervisory Authority for Welfare and Health (Valvira) is a centralised body operating under the Ministry of Social Affairs and Health. Valvira's purpose is to supervise and provide guidance i.e. to healthcare service providers, and to manage related licensing activities. Valvira guides the six Regional State Administrative Agencies and local authorities in the areas of health and social care, alcohol administration and environmental health. Valvira's aim is to foster similar guidance, licensing and supervision practices on every regional and local level. Valvira and the Regional State Administrative Agencies carry out their supervisory duties on the basis of jointly agreed supervision programmes. Valvira and the Regional State Administrative Agencies are responsible for supervision of hospital blood banks as a part of other healthcare service providers.
1.5. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies).	Other

(more than 1 answer possible)	
1.5.1. If other, please specify.	The National Supervisory Authority for Welfare and Health (Valvira) and the six Regional State Administrative Agencies supervise hospital blood banks as a part of other healthcare service providers in Finland.
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Supervision of BEs is centralised to the Finnish Medicines Agency. Supervision of hospital blood banks is decentralised: Valvira's purpose is to supervise and provide guidance i.e. to healthcare service providers, and to manage related licensing activities. Valvira guides the six Regional State Administrative Agencies and local authorities in the areas of health and social care, alcohol administration and environmental health. Valvira's aim is to foster similar guidance, licensing and supervision practices on every regional and local level. Valvira and the Regional State Administrative Agencies carry out their supervisory duties on the basis of jointly agreed supervision programmes. Valvira and the Regional State Administrative Agencies are responsible for supervision of hospital blood banks.
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1
2.1.2. How many of the BEs are satellite sites?	There is only one blood establishment in Finland. The only blood establishment has 17 satellite sites (18 sites in total).
2.1.3. How many of the BEs are mobile sites?	The only BE has 6 sites that have mobile unit(s).
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	144226
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	126914
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	16649
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	246434
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	460
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	4127
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	750
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	438
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	360
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	0
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	1
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	1
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at

	regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Attached a copy of the donor evaluation form.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	The donor evaluation/selection forms (paper) and testing procedures are documented and standardized. The BE informs the donor about any abnormal findings. Before the donor evaluation/selection, the donor reads an appropriate information package given by the BE. The package informs that any relevant abnormal findings are reported to the donor. All the procedures need to be described in SOPs.
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Body weight and hemoglobin. Permanent def. criteria: all criteria based on serious chronic medical conditions (except cured malignant diseases), criteria based on transfusion transmissible infections, and IV drug use. Temporary def. criteria: all criteria based on infections, criteria based on exposure to risk of acquiring a transfusion transmitted infection : mucosal splash etc., transfusion of blood, tissue or cell etc., tattoo or body piercing, persons whose behavior or activity... (E.g. new sex partner, sex with sex-worker, sex-tourism), all criteria based on vaccination, pregnancy, minor surgery, medication, deferral for particular epidemiological situations.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Sexual risk behavior, IV drug use, xenotransplant recipients, risk of malaria (e.g. endemic area), and acupuncture (by qualified practitioner).
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	The Finnish Medicines Agency (Fimea) proposes the Commission to start discussions concerning the age limits of donors. Fimea's view is that it would be useful to make a risk assessment of the age limits of donors (from the donors' and recipients' point of views) and to make a survey on practices with the annul permission for donors over 65 years old in the EU countries. We also suggest to start discussions related to changes to the following deferral criteria: Minor dental treatment (no deferral), Malignancy with complete recovery (temporary deferral; permanent only for haematological malignancies), Endoscopic examination performed in EU (no defeferral), and Acupuncture performed with sterile single-use needles (no deferral). In addition, the EU criteria for malaria deferral should be re-assessed.
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	New sex partner, sex with sex-worker, sex-tourism, MSM sex, sex with IV drug user.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	The only Finnish BE has strongly expressed us their concern on the issue of self-sufficiency in blood and blood components in Finland. Referring to their collected data related to donor adverse events for donors age 65+, the BE has proposed that the annual permission for 66-70 years old donors could be given by a qualified healthcare professional (by a physician only if necessary) to maintain the self-sufficiency in Finland. The Finnish Medicines Agency (Fimea) proposes the Commission to start a discussions concerning the age limits of donors. Fimea's view is that it would be useful to make a risk assessment of the age limits of donors (from the donors' and recipients' point of views) and to make a survey on practices with the annul permission for donors over 65 years old in the EU countries.
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor	Main causes leading to deferrals, and the frequency of them: Total number of deferrals: 28 794. Of them 24 700 temporary and 4 094

deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	permanent. Leading temporary def: Low Hb (6107), medical conditions (4 671), risk for transfusion transmissible infection (4 626), infections (2 755), risk for malaria/other tropical or epidemic infection (2 200), surgery (1 978). Leading permanent def: Low Hb (1016), chronic medical conditions (2 199), risk for transfusion transmissible infection (263).
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	Deferrals codes are registered in electronic donor register. Statistic of deferral codes is made by an electronic rapport system.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	Number of deferrals recorded in 2012: Total number of deferrals: 28 794. Of them 24 700 temporary and 4 094 permanent.
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	No
2.2.11.1. If no, what other deferral criteria would you suggest for derogation? Would you have other suggestions on the usefulness and set-up of such temporary derogations?	A set-up of some other temporary derogations would also be useful, i.e. also upper age limit could be raised. In urgent crisis, it would be useful that the national CAs could make these decisions.
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	The donor testing is centralised in Finland. The required tests are carried only by a qualified laboratory.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	HBV NAT, HCV NAT and HIV-1 NAT tests are mandatory in Finland.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	HIV-1–RNA, HCV-RNA and HBV-DNA tests are mandatory for whole blood donations in Finland. B19-DNA and HAV-RNA tests are done but not mandatory for whole blood donations in Finland.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	NAT tests (HBV, HCV, and HIV-1) are mandatory in Finland.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	1
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	2
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	15
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis (TrpAb): 51 (this antibody test was implemented in 2012, previous screening with cardiolipin). Parvo (B19): 46. Mal-Ab: 44 (number of tested donors 424)
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes

3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	The BEs (all the satellite sites of the only BE) are inspected by the Finnish Medicines Agency on a regular basis. The National Supervisory Authority for Welfare and Health (Valvira) and the six Regional State Administrative Agencies are responsible for the supervision of hospital blood banks.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	A quality system requirement for BEs and hospital blood banks is set by the Blood Service Act (197/2005) and our national regulations. The Finnish Medicines Agency does not authorise a BE which does not have an appropriate qualitys system.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	The requirements for BEs and hospital blood banks are set by the Blood Service Act (197/2005) and our national regulations. The Finnish Medicines Agency does not authorise a BE which does not fullfil these requirements. The BEs (all the satellite sites of the only BE) are inspected by the Finnish Medicines Agency on a regular basis.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	The requirement is set by the Blood Service Act (197/2005). The records are kept for a minimum of 15 years (i.e. donor information leaflets and donor testing results are kept in electronic format).
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	The requirements of the Directives have been transposed to the Blood Service Act (197/2005) and the Finnish Medicines Agency's regulations (1/2008 and 2/2008). The BEs (all the satellite sites of the only BE) are inspected by the Finnish Medicines Agency on a regular basis.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	These personal data requirements have been transposed to the Blood Service Act (197/2005) and the Finnish Medicines Agency's regulations (1/2008 and 2/2008). All the personal data of donors should be protected. The BEs (all the satellite sites of the only BE) are inspected by the Finnish Medicines Agency on a regular basis.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	It is not mandatory.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	The Guide is really useful.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	1
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories	The Regional State Administrative Agencies.

performing donor testing?	
4.6. How many laboratories performing donor testing are active within your country?	1
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	The National Supervisory Authority for Welfare and Health (Valvira) and the Regional State Administrative Agencies.
4.8. How many hospital blood banks are active within your country?	41
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	The Finnish Medicines Agency (Fimea), Supervision and licences -process, Inspectorate -unit.
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	One and a half
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Pharmaceuticals (including plasma derivatives) Advanced therapies
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	9
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	9
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	Inspections can be made after receiving a notification of serious adverse reaction or event. Inspectors spend more days in critical sites. The critical sites can be inspected more frequently than normally (2 years inverval). Sites undertaking substantial changes can be inspected before the approval.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	There is only one blood establishment in Finland. The BE has 18 sites. The BE has only one quality system and authorisation (a satellite organisation).
5.5.3. How many BE have been inspected at least twice in the last 3 years?	18
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	There is only one blood establishment in Finland. The BE has 18 sites. All satellite collection sites and sites that has mobile blood service units are inspected in every two years.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0
5.6.2. What was the outcome of the inspections carried out in the	9

BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	0
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	No other outcomes.
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	2
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	The National Supervisory Authority for Welfare and Health and the six Regional State Administrative Agencies are responsible for supervision (including ispections) of hospital blood banks as a part of other healthcare service providers.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	The guide is very useful.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Blood establishments: The Finnish Medicines Agency. Hospital blood banks: The National Supervisory Authority for Welfare and Health and the six Regional State Administrative Agencies.
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	For all of them.
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	The blood establishments are inspected on a regular basis.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes

6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Facilities (hospital blood banks / healthcare units) where transfusion occurs have procedures in place to retain the record of transfusions and to notify blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood and blood components. Blood establishments notify to the Finnish Medicines Agency any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Facilities (hospital blood banks / healthcare units) where transfusion occurs have procedures in place to retain the record of transfusions and to notify blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood and blood components.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	Blood establishments are required to perform a root cause analysis in every case (if possible).
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	The blood establishment is asked for further information of the SARE if needed.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	246 recalls in 2012 because of defective product (3), reclamation (164), look back/traceback (9) or deviation in transport temperature (70); over 90% of which were red cells.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	The national rapid alert procedure for blood and blood components in place secures the transmission of information e.g. between the Finnish Medicines Agency and blood establishments when urgent remedial or precautionary action is needed due to a serious public health threat. Such threats include e.g. quality and/or safety defect notifications (recalls, preventive measures, advice, etc.) from other related healthcare sectors (e.g. medical devices, and tissues and cells) with potential consequences on the quality and safety of blood and blood components intended for human application, or development of rapid/significant epidemiological situations (e.g. disease outbreaks) which may have cross-border implications in the field of blood and blood components intended for human

	application.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	The rapid alert system for blood and blood components in place secures the transmission of information e.g. between the Finnish Medicines Agency and blood establishments when urgent remedial or precautionary action is needed due to a serious public health threat (e.g. if a rapid alert from CIRCA-BC concerns Finland). Such threats include e.g. quality and/or safety defect notifications (recalls, preventive measures, advice, etc.) from other related healthcare sectors (e.g. medical devices, and tissues and cells) with potential consequences on the quality and safety of blood and blood components intended for human application, or development of rapid/significant epidemiological situations (e.g. disease outbreaks) which may have cross-border implications in the field of blood and blood components intended for human application.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	The Finnish Medicines Agency (Fimea) is a competent authority also for tissues and cells, and organs. The National Supervisory Authority for Welfare and Health (Valvira) informs Fimea when urgent remedial or precautionary action is needed due to medical device rapid alerts.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	A blood establishment can import blood and blood components for transfusion from EU Member States if it is authorised by the blood establishment licence, and the quality, safety and traceability requirements for blood and blood components set by the Blood Service Act (197/2005) are fulfilled. Import of blood and blood components for transfusion from third countries requires Fimea's authorisation. Blood and blood components from third countries must fulfill the same quality, safety and traceability requirements set by the Blood Service Act (197/2005).
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Rules and conditions set by the Blood Service Act (197/2005) apply also for the import of blood and blood components for fractionation.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	International standards
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	There were no blood or blood components for transfusion imported from third countries in 2012.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes

7.6.1. If yes, please provide this data by country of origin.	There were no blood or blood components imported for fractionation from third countries in 2012.
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	There is no special rules for the export of blood and blood components for fractionation to EU Member States or third countries. Blood establishments must have standard operating procedures for the act of delivery (distribution) of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products, and for the issuing of blood or blood components for transfusion. The requirements are set by the Blood Service Act (197/2005) and Fimea's regulations 1/2008 and 2/2008.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	There is no special rules for the export of blood and blood components for transfusion to EU Member States or third countries. Blood establishments must have standard operating procedures for the act of delivery (distribution) of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products, and for the issuing of blood or blood components for transfusion. The requirements are set by the Blood Service Act (197/2005) and Fimea's regulations 1/2008 and 2/2008.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	There were no blood or blood components exported for fractionation to third countries in 2012.
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	Only two units (Red Cells, Leucocyte Depleted in Additive Solution) were exported for transfusion from Finland to Norway in 2012.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	NAT testing is mandatory; The following nucleic acid amplification tests must be performed for whole blood and apheresis donations, including autologous predeposit donations: Hepatitis B (HBV NAT), Hepatitis C (HCV NAT), and HIV 1/2 (HIV 1 NAT).
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	The blood Directives should be revised regarding autologous plasma and serum derived products. The Directives (2002/98/EC, 2004/33/EC, 2005/61/EC, 2005/62/EC) are directed for the transfusion purposes of blood and blood components. There are currently an emerging number of blood derived products which can be classified as blood products but which are not used for the transfusion purposes. When applying the Directives for these products in which the Directives have obviously not been meant for, different interpretations can be made and cause confusion and uncertainty. It has been discussed in the previous meetings of the national competent authorities for blood and blood components that if such plasma/serum-derived products are used immediately after centrifuging and separating the blood components, they can be considered as part of a clinical act, and, thus, there is no need for a BE license. However, there are i.e. plasma/serum-derived products

	that are stored in hospital laboratories for a few weeks before the autologous use. Such products currently used in the Finnish practices are e.g. Orthokine® and eye drops made of autologous serum.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	28 day deferral after visiting risk areas (according to the ECDC WNV-map for the previous years and observing the current year situation).
8.5. Which other communicable diseases are of relevance to you?	Q fever, Dengue, and Malaria.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Like explained before (answer to question 8.3), if such products are used immediately after centrifuging and separating the blood components (bed-side techniques), they can be considered as part of a clinical act, and, thus, these products do not fall under the EU blood legislation. The National Supervisory Authority for Welfare and Health (Valvira) and the six Regional State Administrative Agencies are competent authorities for healthcare service providers (i.e. hospitals and private clinics). Their relevant primary legislation includes the Health Protection Act, the Act of Specialised Medical Care, the Act on the Status and Rights of Patients, and the Act on Healthcare Professionals.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No other than PRP products, Orthokine, and serum eye drops derived from whole blood.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	It is difficult to define.

A.1.10. Survey response France

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Agence nationale de sécurité du médicament et des produits de santé (ANSM) : French National Agency for Medicines and Health Products Safety
1.1.2. Address of NCA 1:	143-147 boulevard Anatole France - 93285 SAINT DENIS CEDEX
1.1.3. Telephone (central access point):	+ 33 1 55 87 30 00
1.1.5. Website:	www.ansm.sante.fr
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices Other
1.1.6.1. If other, please specify.	The other health products: contraceptive products, advanced therapy medicinal products, non-routine advanced therapy medicinal products, medical devices for in vitro diagnosis, biomaterials, products intended for the maintenance or application of contact lenses, non-corrective eye lenses, cosmetic products, micro-organisms and toxins, tattooing products, biocide products (insecticides, miticides and pesticides), breastmilk.
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	The ANSM is also in charge of the evaluation, the control (external quality control), the vigilance of all health products intended for human application (e.g. medicines, medical devices and medical devices for in vitro diagnosis, blood and blood components, tissues and cells, cosmetic products, tattooing products, biocide products, etc.) and the authorization and inspection of the establishments in charge of the processing, producing or manufacturing and marketing authorization of medicines. ANSM is the French OMCL for medicines, in charge of the official batch release for vaccines and blood derived-medicinal products.
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Direction Générale de la Santé (DGS), Ministère de la santé: Directorate General of Health, French Ministry of Health
1.2.2. Address of NCA 2:	14 avenue Duquesne, 75007 PARIS
1.2.3. Telephone (central access point):	+ 33 1 40 56 60 00
1.2.4. E-mail (central access point):	Raphael.capian@sante.gouv.fr
1.2.5. Website:	www.sante.gouv.fr
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Other
1.2.6.1. If other, please specify.	The DGS is responsible for all health products (Blood and blood components, Pharmaceuticals, including blood derivatives, Tissues and cells, Human organs, Medical devices, etc.) and quality of practices and ethics. The DGS is in charge of the definition of health policy. It is responsible for elaboration of legislation proposals, and supervises health agencies, ANSM in particular.
1.3. National Competent Authority 3?	No
1.4. 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/ The ANSM was created by the Act of 29 December 2011 relating to the increased safety of medicines and health care products. It was implemented on the 1st of May 2012 following the publication of Decree n° 2012-597 on 27 April 2012. As a public body under the supervision of the Ministry of Health, the ANSM has taken over the tasks of the Afssaps and has been entrusted with new responsibilities. It is funded by a State subsidy (around 140 ME for 2012). The ANSM conducts expert assessment of healthcare products and acts as a decision-making body in the field of sanitary regulation. Every year, its General Director takes tens of thousands

	of decisions on behalf of the State. Their aim is to reconcile patient safety with access to therapeutic developments. The staff of ANSM consists of around 1,000 people, who are allocated mainly in 13 divisions in ANSM (8 Products divisions and 5 Operating divisions). The total number of the agents assigned for blood components intended for transfusion is 20. This number is divided, by Division of the ANSM, as follows: 9 people for assessment and haemovigilance, 8 people for BEs inspection and authorization and 3 people for laboratory control of blood components. 2/The Minister of Social Affairs and Health prepares and implements government policy in the fields of social affairs, solidarity and social cohesion, public health and the organization of the health care system.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not applicable.
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	17
2.1.2. How many of the BEs are satellite sites?	153
2.1.3. How many of the BEs are mobile sites?	17
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	1,725,931
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	1,369,527
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	356,404
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Experience for the civil national blood service: From/to surrounding countries. Detailed information is Not available (N/A) (N/A). No experience for the military blood center
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	2,641,930
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	400-500
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	487,804
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	200-750
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	131,875
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	200-650
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	32,643
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	14
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	14
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	Pre-donation information document given to prospective donors. Medical questionnaire filled by the prospective donors.

2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Unfortunately, the French donor selection questionnaire does not currently exist in English. Please find here the French version of this questionnaire : http://www.dondusang.net/rewrite/article/4276/ou-donner-son-sang/conseils-pratiques/infos-pre-don/infos-pre-don.htm?idRubrique=1402
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	The blood donor evaluation, the testing procedures and the blood components details are defined in the procedures of the blood establishment. There are, especially, procedures for donor information. All these details and measures taken are recorded and traced in the blood establishment secure IT system. In addition, for the CTSA, the results of blood testing are transmitted to the donor by a physician.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	For the EFS, there is no system for the self-exclusion. However, the French donor selection questionnaire is often used as a self-deferral tool. For the CTSA, the donor is informed in pre-donation, systematically for blood collection, using a standardised information format and, in Military School, using a standardised blood conference. In post-donation, the donor is informed, using a standardised information format, on the reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	All of them
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Those related to cancer, MSM, malaria, anaphylaxis/hypersensitivity reactions occurred in blood donors, exposure to risk of acquiring a transfusion-transmissible infection “transfusion of blood components”.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	- Adapt the drafting of deferral criteria related risk behaviour (e.g sexual risk, MSM etc.) - Adapt the deferral measures relating to the history of cancer This is to take into account the evolution of medical knowledge. Thus, the draft of the 17th edition of the Guide of the Council of Europe takes into account this fact, now offering a temporary deferral to 5 years for most solid tumors. - Specify the minimum level of donor haemoglobin: “Member States may however adopt requirements for minimum haemoglobin levels down to 120 g/l for females and 130 g/l for males on the basis of the results of studies carried out on their specific populations. Where a Member State adopts these lower requirements, the possibility for individual derogations provided for in the first alinea of point 1 shall not be applicable as regards haemoglobin levels in donor's blood.” Member States shall inform the Commission on the justifications and conditions of application of these lower requirements at the time of their adoption.” - Identify the clinical selection to the risk of West Nile Virus and arboviruses a) Introduce into the Directive a deferral period based on the duration of viraemia in infected donors (more than a few days). It is proposed that the deferral period should not be taken as an example of the Guide of the Council of Europe which mentions a current deadline of 120 days may be excessive. The question of the beginning of the foreclosure action must be resolved. The concept of the duration of complete cure is difficult to define but essential especially in the software to set the duration of medical and technical deferral period. The applying would be a deferral measure based on the date of implementation of a screening test for positive viral genome for a period including a duration of complete

	cure (to be defined) and a duration of deferral (to be defined). The principle is in epidemic situation as in Greece transfusion system that achieves the NAT can rely then on the date of the NAT positive in order to reaccept the donor without entering into considerations the cessation of treatment and absence of symptoms or complete cure, which can be unreliable in the donor personal interview. (b) In annex 1 Add the definition of the West Nile Virus "affected area" The drafting proposed is one that has been developed by the Commission in the preparedness plan: "WNV affected area: an area with 1 or more autochthonous (locally acquired) human WNV confirmed cases (neuro-invasive and non-neuro-invasive) meeting laboratory criteria as per EU case definition (Directive 2008/426/EC). This definition equals the definition of area with ongoing transmission of WNV to humans used by Directive 2004/33/EC,and at least the 1st case in an area should be confirmed according to laboratory tests for case confirmation (Directive 2008/426/EC) and not only tests for probable case." (c) Adapt the temporary deferral criteria for West Nile Virus prospective donors of blood or blood components for allogeneic donations, according to the model malaria (d) Complete the temporary deferral measure 28-day traveler risk area by the possibility of a screening test for viral RNA (NAT). (e) Referral to ECDC by the European Commission on the following topics: - For the West Nile virus: analysis of the appropriateness of a deferral period of 120 days - For Chikungunya and dengue: 1. Analysis of the opportunity to introduce clinical criteria for donors at risk of exposure to the dengue and Chikungunya; 2. Analysis of risk and the measures to be taken against traveler donors because the problem of endemic areas is very different.
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	There is in France a Ministerial order for the selection of donors (Arrêté du 12 janvier 2009 fixant les critères de sélection des donneurs de sang) in particular for risky sexual behaviours and vCJD etc. For risky sexual behaviours: - Unprotected sex with a casual partner - Multiple sex partners: more than one partner in the last 4 months - Unprotected sex with a new partner in the last 2 months - For men: sex with another man - The donor partner has had more than one sex partner in the last 4 months - The donor partner who have any history of non-prescribed IV or IM drug use, including bodybuilding steroids or hormones and his/her HIV or HBV serology status is unknown - The donor partner has a positive serology for HIV, HTLV, HCV, HBV (AgHBs+) For HCV positive donor partner: no deferral of donor when NAT of partner is negative for more than a year. For HBV positive donor partner (AgHBs+): no deferral when donor is vaccinated and immunized (sufficient level of anti-HBs antibodies). The donor partner has had a recent STD (sexually transmitted disease) or is currently under treatment
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Most leading to deferrals: criteria related to infectious diseases Least leading to deferrals: criteria related to CJD risk, vaccines Detailed data are Not available (N/A) (N/A). Overall, 15% of prospective donors. 8,5% of prospective donors are deferred. For the CTSA: visitors to malaria endemic areas, vaccines
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	There is no system of centralized collection of data on deferrals in the EFS. However, there is an only one database in the CTSA.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	For the CTSA, 2212 deferrals (9% of the total number of prospective donors) were recorded in 2012 For the EFS: Overall, 281 646 prospective donors (15% of the total number of blood donation

	candidates) were deferred in 2012, representing 8,5% of the candidacies.
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Authorization, inspection of qualified laboratories of BEs by ANSM
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	All donations are tested NAT HIV, HBV and HCV. However, NAT testing for HBV is not mandatory. For the EFS, ID-NAT in 9 regional BEs and minipools (of 8 samples) in 5 regional BEs in 2012. For the CTSA, ID-NAT Ultrio.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Screening tests for all donations: Anti-HIV 1+2, HIV NAT, Anti-HCV, HCV NAT, HBsAg, Anti-HBc, HBV NAT, Anti-HTLV I/II, Syphilis, ABO/RH grouping. However, NAT testing for HBV is not mandatory. Screening test for Malaria disease: If necessary (individuals who have lived in a Malaria disease area or with history of Malaria disease, visitors to endemic area …). Screening test for Chagas disease: If necessary (individuals who have lived in a Chagas disease area or with history of Chagas disease, visitors to endemic area …). The tests listed above are the minimum laboratory tests required by the French regulation for the blood and blood components donations. Screening tests HEV (hepatitis E virus) NAT was implemented: - by the EFS in December 2012 for FFP-SD NAT (pool of 96 samples), - by the CTSA in the earlier of 2013 for plasma lyophilized pools. Other tests can be added according to the: specific therapeutic indications, particular epidemiologic situations.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	In the French legislation, there are no differences for the mandatory list of screening tests between whole blood and plasma donations
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	Not available
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	Not available
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	Not available
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Not available
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No additional comments
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	- Amotosalen with UVA light exposure is a technique used in France for the Platelets (platelets apheresis leucocyte-depleted and platelets

	recovered pooled leucocyte-depleted) pathogen reduction/inactivation in 3 regional BE in French overseas Departments and 1 regional metropolitan BE. - Several techniques are used in France for the plasma (plasma fresh-frozen leucocyte-depleted) pathogen reduction/inactivation: Solvent-detergent, Amotosalen with light exposure - The other blood and blood components (whole blood, red blood cells, granulocytes etc.) are not pathogen reduced/inactivated.
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	The Director of the CTSA is also its Responsible person. She complied with the requirements of the article 9 of the directive 2002/98/EC. She delegates permanently to other persons, qualified by training and experience, such tasks as the Quality Management System (ISO 9001 since 2002), the definition and monitoring of the quality indicators, the internal and external audits, the vigilance. EFS Deputy Director - Medicine, Safety, Quality Management and Research is the Responsible person for the safety and quality insurance of blood and blood components throughout the blood transfusion chain. His tasks are delegated to 2 other Medical Doctors, qualified by training and experience.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	The inspection of the ANSM verifies regularly the written policies and procedures to describe the approach to training, including a record of training that has taken place, including its contents, and its effectiveness. The inspection of the Regional Health Agency verifies the existence and applying in hospital blood banks of the equivalent procedures
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	There is in France national principles of good practices in BE and HBB since 1993. These principles are in compliance with the requirements and the rules of the blood directives. The EFS is certified ISO 9001.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	The inspection of the ANSM verifies regularly that BEs maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms. The inspection of the Regional Health Agency verifies the existence and applying in hospital blood banks of the equivalent procedures
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	BEs maintain records of the traceability information, and these records are kept for a minimum of 15 years, by using of both paper and electronic (secure IT) archiving systems
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	There is in France national principles of good practices in BE and HBB since 1993. These principles are in compliance with the requirements and the rules of the blood directives on storage, transport, distribution. In addition, the quality system of the EFS is certified ISO 9001. The inspectors of the ANSM verify in regular intervals that these requirements/rules are applied by the BEs. The inspectors of the Regional Health Agency verify in regular intervals that these requirements/rules are also applied by the HBBs.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and	There is in France national mandatory requirements for coding (alpha numeric bar code based system) for the identification of

hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	donors, the blood and blood components donations, the blood and blood components units, the ABO groups and the other biological tests used in BEs and HBBs, the patients. There is also, in the French law, legislative requirement prohibiting any link between the medical files of the donor and the recipient. The inspectors of the ANSM verify in regular intervals that these requirements/rules are applied by the BEs. The inspectors of the Regional Health Agency verify in regular intervals that these requirements/rules are also applied by the HBBs.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	There is in France national mandatory requirements for coding (alpha numeric bar code based system) for the identification of donors, the blood and blood components donations, the blood and blood components units, the ABO groups and the other biological tests used in BEs and HBB. Management and updating of the system is ensured at national level by the ANSM.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	For the EFS, the guide is a very useful tool. Beyond the Council of Europe guide, the CTSA uses the European Agreement on the exchange of therapeutic substances of human origin in Paris December 15, 1958, for the preparation of lyophilized plasma.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	222 (12/2007) Process in progress in 2013
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	ANSM
4.6. How many laboratories performing donor testing are active within your country?	14
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	There is no national authority who is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks. However, there are 26 Regional Health Agencies (22 Metropolitan and 4 overseas Regional Health agencies) responsible for authorization and oversight of hospital blood banks.
4.8. How many hospital blood banks are active within your country?	650
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	Specify the following definitions to ensure consistency between them. Ensure consistency the definition of f) “hospital blood bank” and the definition of k) “distribution” in the article 3 of Directive 2002/98/EC. The definition of “hospital blood bank” doesn’t include “issuing”. To ensure a better understanding, it is also suggested to introduce the definition of “issuing” in the article 3 of the directive 2002/98/CE. The definition of « hospital blood bank " must be revised in the light of the evolution of the definitions of "Distribution" and "Issuing". - « Hospital blood bank » shall mean a hospital unit which stores and delivers blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities, and may perform compatibility tests on

	blood and blood components. It may deliver blood and blood components, within the framework of the vital urgency, some blood and blood components to patients of the other hospitals- "Issuing" (definition in d) Art. 1 of the directive 2005/61/CE): "issue" means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient. Introduce the definition of "issuing in the article 3 of the directive 2002/98/CE.
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	- LFB Biomédicaments – 2 premises (Les Ulis and Lille)- public- manufacturing- albumin, coagulation factors, immunoglobulins - Octapharma – (Lingolsheim) – private- manufacturing and import albumin, coagulation factors, immunoglobulins
4.10.2. If yes, please state the responsible authority within your country.	ANSM
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Biological Products Inspection Department and Control Department - The inspections system was implemented since 1993. An inspections program is defined annually. - The external quality control for blood and blood components was implemented since 1996. An external quality control program is defined annually.
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	3
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Pharmaceuticals (including plasma derivatives) Others
5.2.1.1. If others, please specify.	No overlap since teams are dedicated, but interaction if necessary (e.g. tissues and cells or blood and pharmaceuticals or tissues and cells and GCP in the frame of clinical trials), since the same Division is in charge of the inspection for the whole range of health products and activities during the life-cycle of the products.
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	39
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	5
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	33
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	1
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	- Enhancement of the processing of the amotosalen plasma (plasma pathogen reduced/pathogen inactivated): 7 - Haemovigilance organization: 4 - Mobile collect sessions: 3
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	Inspections based on SARE and following major shortcoming notification
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	17
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	No frequency due to the great number of mobile collect sessions. Satellite collection sites are inspected each 6 years at least. Less than 10 mobile collection sessions are inspected every year.

5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	0
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	3
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	Not applicable
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	20
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	The organising inspections system for Hospital blood banks was updated by the decree published in French Official Journal on 9 September 2007. The inspections were performed, on a regional level, by health inspectors.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	There is no national authority who is responsible for inspection of hospital blood banks. However, there are 26 Regional Health Agencies (22 Metropolitan and 4 overseas Regional Health agencies).
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	No
5.10.2. If no, which guidelines/regulations are used for inspections at national level?	National guidelines and regulations
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	No
5.11.2. If no, why not?	ANSM reorganization (1 in 2013)
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	There is in France national mandatory requirements for coding (alpha numeric bar code based system) for the identification number of blood donors, blood and blood components donations, blood and blood components units, ABO groups and other biological tests used in BEs and HBB. Management and updating of the system is ensured at national level by the ANSM.
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	There is, in France, a national mandatory requirement for coding (alpha numeric bar code based system) for the identification number of all blood and blood components units (about 1400 different codes). Management and updating of the system is ensured at national level by the ANSM.

6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	There is, in France, a national mandatory requirement for data storage. These requirements are in compliance with those of the blood directives. The inspectors of the ANSM verify in regular intervals that these requirements/rules are applied by the BEs.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Key elements on the French haemovigilance system: The French system of haemovigilance was set up since: - January 24, 1994 to collect, supervise and evaluate all the adverse reactions (AR) occurring in patients/recipients - November 2, 2002 to collect, supervise and evaluate Serious adverse events (SAE) related to the incorrect blood transfusion (without adverse reactions) - May 7, 2007 to collect, supervise and evaluate all Serious adverse events (SAE) related to the blood collection, testing, processing, storage, distribution/issuing and transfusion of blood and blood components - May 7, 2007 to collect, supervise and evaluate Serious adverse reactions occurring in donors of blood and blood components (dSAR) - October, 2002 to collect, supervise and evaluate post donation information (PDI) who have a potential impact in blood recipients The reporting establishments are 1508 hospitals/clinics and 17 blood establishments (151 satellite sites who have blood collection and distribution/issuing activities). - Each reporting establishment (hospital and/or blood establishment) notifies the ANSM its adverse reactions, occurring in patients, and its SAE, directly on a secure online reporting system (e-FIT) and directly integrated into a database. - For the events occurring at the blood donors, each blood establishment notifies the ANSM its dSAR and its PDI, directly on a secure online reporting system (e-FIT) and directly integrated into a database. Currently, French haemovigilance system employs: - at the national level in the ANSM: 8 people (3 doctors, 2 pharmacist, 1 epidemiologist, 1 secretary and 1 IT engineer), - at the national level in the EFS (French national blood service): 4 people (2 doctors, 1 pharmacist and 1 secretary), - at the regional level coordination : 30 regional coordinators (doctors), - at the local level in the different geographical locations in blood establishments and regional level in blood establishments: 151 + 17 doctors, - at the local level in hospitals and clinics: 1508 local haemovigilance correspondents (doctors). All haemovigilance adverse events (recipient AR, donor SAR, SAE, PDI) are reported online in on a secure electronic reporting system, e-FIT, and are available in real time. A reform of all vigilances is currently ongoing in France
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	No
6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	We use the EC template only for the annual reporting to the EC. At the national level, there are more details in the French template comparing to the EC template. However, the French template includes the minimum required in the EC template
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	No
6.2.3.1. If no, please specify what guidelines you use? If possible, please upload the template.	We use the Common Approach Document developed for the Annual reporting only for the annual reporting to the EC. At the national level, there are more details in the French template comparing to this

	document. However, the national Common Approach Document includes the minimum required in the EC template
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Same procedure (see above 6.2.1.1)
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	SAE occurred in blood donors Incorrect blood components transfusion (wrong blood component to wrong patient) associated or not to adverse reaction. Transfusion delayed in particular in emergency situations Near misses: patients identification Blood components storage failed Etc.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	The feedback to BEs and is mandatory in France. This is one of missions of the haemovigilance of the ANSM.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	For the NCA, 4 recalls of blood derived medical products were performed as a precautionary measure following the onset of a CJD (sporadic form) in a donor. None for the EFS and CTSA.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	- Rapid alert system of the European commission (CIRCA) for communication with the Commission and between Member States. - National emailing system, together with fax and phone calls - If necessary, a national crisis management team (CMT) is activated
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	We have a mailing list of all the Contact Persons (CP). We must verify they received the alert message. The CP must acknowledge the message.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health Other
6.2.13.1.1. If other, please specify.	Medical devices for in vitro diagnosis, identification of patients vigilance, hospital management reports of nosocomial infections, software vigilance, quality systems in BEs and Hospitals/clinics etc.
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Rapid alert system for tissues and cells (RATC) for the European commission
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No at this point as a reform of all vigilances is currently ongoing in France.
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	There are mandatory rule and conditions for import of blood and blood components authorization in France (decree n° 2006-215 of 22 February 2006). The form for import authorization include: a) The name and address of the importer; b) The nature and quantity of the imported blood component; c) If applicable, the name and address of

	the supplier if it is not the BE responsible of the blood collection and its authorization issued by the local health authorities as appropriate; d) The name and address of the BE responsible of the blood collection; e) The name and address of the receiving institution if it is not the importer of the blood components; f) The intended use of the blood components and the justification of the need to import the blood components, especially when it intended for transfusion for an identified patient or a blood component rare group; g) The nature and results of tests that meet the French requirements. The nature and results of tests are attested by the legal person authorized to perform these operations in the country of origin; h) The identification number of the blood component to ensure traceability; i)) The requirements for the suitability of donors of blood and plasma and the screening of donated blood, including permanent deferral and possible exemptions criteria and the criteria for suspension.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Same decree (see above 7.1) An authorisation is given to the civil and military national blood services (EFS, CTSA) or to a manufacturing authorised site for each import operation or for a succession of import operations.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	There are mandatory rule and conditions for import of blood and blood components authorization in France (decree n° 2006-215 of 22 February 2006). To date, the importations, of blood and blood components intended for transfusion, were realised from certain European countries. Mainly autologous blood components were imported. The convention, signed by the blood establishments (exporter and importer), specifies the French provisions related to the quality and safety, necessary for the import of blood and blood components. An operation of import of blood of rare phenotype was authorized in 2012 by the ANSM.
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	The form for import authorization include: The nature and results of tests that meet the French requirements. The nature and results of tests are attested by the legal person authorized to perform these operations in the country of origin. Screening tests for all donations: Anti-HIV 1+2, HIV NAT, Anti-HCV, HCV NAT, HBsAg, Anti-HBc, HBV NAT, Anti-HTLV I/II, Syphilis, ABO/RH grouping. Screening tests for Malaria and Chagas diseases: If necessary (individuals who have lived a Chagas disease area or with history of Chagas disease, visitors to endemic area …) The tests listed above are the minimum laboratory tests required by the French regulation for the blood and blood components donations. Other tests can be added according to the: specific therapeutic indications, particular epidemiologic situations
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	None.France has never imported blood components for transfusion from third countries
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	- Import authorisations were delivered by the ANSM in 2012 for : * 287 800 litres of plasma for fractionation, * 524 000 litres, to the fractionator “Octapharma”, of blood of the Octapharma suppliers located in Stockholm and Vienna. Blood units have transited through these two suppliers but were collected in collection centres registered in the PMF certified by the EMA on 15 March 2012.

	These centres registered in the PMF collection include collection centres in third countries, * 72 000 litres, from Florida's Blood Centre and New York Blood Centre, of human plasma for fractionation intended to clinical trials in France, USA and EU, * 157 800 litres, from Brazil, of human plasma for fractionation intended to the export to Brazil of medicinal products derived from human plasma, * 18 000 litres, from Morocco, of human plasma for fractionation intended to the export to Morocco of medicinal products derived from human plasma, * 40 000 litres, from Octapharma Mexico, of human plasma for fractionation intended to the export to Mexico of medicinal products derived from human plasma, - Other authorisations were also delivered for human plasma intended for the manufacturing of medical devices and medical devices for in vitro diagnosis (data Not available (N/A) (N/A)).
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	There are mandatory rule and conditions for export of blood and blood components authorization in France (Art. L1222-3 of French public health legislation). There is currently no export of blood collected in France.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	There is a mandatory legislative rule for export of blood components. There is no mandatory authorization procedure. However, the export of blood and blood components, intended for transfusion, to EU Member States and to third countries, is carried out by the EFS, the civil National blood service which into formless the ANSM in the form of notification. There is no specific rules for the export of plasma for fractionation and of the plasma therapeutic lyophilized prepared by the army blood centre.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	There is currently no blood component exported for fractionation.
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	200 units of therapeutic lyophilized plasma were exported in 2012 to the USA. N/A for the EFS.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	Not applicable
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	Not applicable
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	Not applicable
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	- In the organization of the French competent authority, inspection and control are clearly separated and are taken in charge in two different departments. Does an external quality control of blood and blood components (or an equivalent system) exist in other Member States? A feedback from the EC concerning this point seems to us necessary - The implementation of the strict values of the minimum level of donor haemoglobin - The absence of Common approach to

	apply several deferral measures concerning epidemiological situations
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	See above 2.2.3.1, 4.9.1, 6.2.15 Inspection of blood establishments: clarify the frequency, control measures and the definition of mobile collection Adapt the provision of the frequency of inspections of the blood establishment sites (fixed and mobiles sites) and specify what we do understanding of the wording “control measures". The implementation of the article 8 point 2 of the directive 2002/98/EC concerning the interval between two inspections causes difficulties because of the numbers of blood establishments and activities to be inspected. A feedback from the EC concerning this point seems to us necessary as well as the synthesis of these questionnaires filled the competent authorities of the Members States. Many Member States have raised with the European Commission the difficulties of implementation of provisions relating to the periodicity of the Blood establishments inspection (inspection every 2 years) and inspection of mobile sites (EMA issue with response interpretation of the European Commission on 2006). The implementation of the article 8 point 2 of the directive 2002/98/EC concerning the interval between two inspections causes difficulties because of the numbers of blood establishments and activities to be inspected. A feedback from the EC concerning this point seems to us necessary as well as the synthesis of these questionnaires filled the competent authorities of the Members States. Thus, it is proposed to adapt the frequency of BE sites inspection by using "an appropriate frequency based on risk analysis." The French authorities suggest the drafting proposal for article 8.2 (mirrored the wording of article 1111.b of the directive 2001/83/EC on medicinal products for human use): « Inspection and controls measures shall be organized by the competent authority at an appropriate frequency based on risk”. In addition, it would be necessary to introduce in article 3 the definition of the “mobile site”. Moreover, the French authorities believe that "control measures" mentioned in article 8 of directive 2002/98/EC should be specified. Clarify the definition of mobile sites and inspection measures for this type of collection The French authorities are currently working to develop a more precise definition of the mobile collection, which will soon be submitted to the Commission. Provisions relating to mobile collection should be included in this Article 8: “Full information regarding mobile collection teams' operation and management, as well as their equipments, are reviewed during the inspection of the blood establishment. The inspections of mobile collection sites' premises are done as necessary". Proposals related to the blood collection activity Introduce some precautions related to the collection In the Directives, it would be necessary to specify the minimal precautions as for example, measures of safety of the aphaeresis procedures (maximum extracorporeal volume of 20%.for example). Proposals to clarify the legal rules Status of the blood components: A necessary clarification Define their status only according to their destination (intended transfusion purpose or whatever their intended purpose) Difficulties of interpretation appeared on the status of the plasma intended for transfusion (FFP-SD, FFP quarantine, FFP-Intercept, etc.) according to their preparation method (industrial or not industrial method). This difficulty will also arise for the other blood components, considered in France as Labile blood products (LBP) intended for transfusion, as also the dried plasma, or still the platelets concentrates pathogen inactivated (Intercept). Other situations had been raised by the other MS with the European Commission for the status of products such as the PRP (Platelet rich plasma) autologous (see minutes of the meeting of April 19-20th, 2012) and which is classified in the EDQM " as Blood component for topical uses ", Extracorporeal photopheresis. So by suggesting defining the status of the blood components only according to their intended purpose, this adaptation proposed by the French authorities can clarify and secure the status of LBP of certain blood products. The autologous PRP and the

	autologous serum used in ophthalmology are concerned (see discussion proposed in the agenda of the meeting of the blood European competent authorities). Quality of the blood components: Clarify the expression of the standard in factor VIII in the FFP intended for transfusion and introduce a monograph for the FFP pathogen inactivated Fix a minimum value of factor VIII in the FFP intended for transfusion, as a replacement of the current formulation The French authorities consider that the provision drafted in the Annex V of the directive 2004/33/CE is not applicable « Factor VIIIc: Average (after freezing and thawing): 70% or more of the value of the freshly collected plasma unit ». The proposed writing is for quarantine FFP: Factor VIII content: " Not less than (after freezing and thawing), 0.7 UI / mL of factor VIII in individual plasma (non-pooled)" Introduce a monograph for the individual FFP (non-pooled) pathogen inactivated The proposed writing is: Factor VIII content: "Not less than (after freezing and thawing), 0.5 UI / mL of factor VIII in individual plasma (non-pooled) pathogen inactivated" AND Fibrinogen content: "Not less than (after freezing and thawing), 2 g/ of fibrinogen content in individual plasma (non-pooled) pathogen inactivated " Voluntary and unpaid blood donation: Clarify the definition of the non-remuneration Clarify the definition of the "Voluntary and unpaid donation" with regard to the notion of compensation for the donors. It would be necessary to clear up the consensus applied with regard to the compensation of certain donations intended for fractionation (manufacturing of medicines products derived from plasma) with regard to the recital 23 of the directive 2002/98/CE. For medicines products derived from plasma, the Manufacturers have to supply information on the compensations possibly proposed to the donor (Chapter 2.1 (Plasma origin) of Guideline on the scientific data requirements for a plasma master file (EMEA/CHMP/BWP/3794/03), published by the EMA within the framework of the directive 2003/63/ CE which defines the documentation to supply in the file of authorization request of launch on the market of medicines products derived from plasma or in the plasma master file subject with the aim of certification to the EMA The difficulties result from the heterogeneity of the terms used by the different Manufacturers on their files subjected to the EMA (expense allowance, remuneration, small re-imbursement, compensation). However, Most of the Manufacturers consider that the allocation of a sum of money constitutes a remuneration, whatever is its amount. Within the framework of the certification of the PMF, the allocation of a lump sum is recognized as a remuneration, acceptable in certain limits (rising of the order of 25-30 euro by donation) and certain conditions (regular donors). In case of blood donation during the working time, the question of the loss of remuneration for the donor could give rise to debate. In this case, the French authorities underline that it is important that the employers can continue to be authorized to maintain the remuneration in conformance with the exercise of the professional activity of the employees during the necessary duration of the donation without it constitutes a payment in the sense of the French regulations (article L1211-4 of the French public health code). Definitions: Ensure consistency between definitions and specify six definitions Specify the following definitions - “Mobile site” (definition in i) Art. 1 of the directive 2005/62/CE): introduce the definition of “mobile site” in the article 3 of the directive 2002/98/CE. As evoked in 1.1.2, the French are currently working to develop a more precise definition of the mobile collection, which will soon be submitted to the Commission. - Blood establishment (BE) The French authorities suggest thinking about the adaptation of this definition within the framework of the evolution of the organization of the transfusion chain, in particular the development of the cooperation between BE and the pooling of means between establishments, within the framework of an unique national blood service. - Collection It is suggested replacing in the directives the

	term "collection" by that more precise of "donation" - Haemovigilance It is suggested adapting the definition of haemovigilance Translation: verify the translations to avoid the difficulties of interpretation of MS and Manufacturers Revise the translation of the version in English of every language version of directives of the European Union and correct in particular: a) In the directive 2004/33/CE, the mistranslation in French of an item of the questionnaire donor: « il a reçu des réponses satisfaisantes aux questions qu'il a posées ». b) In the directive 2004/33/CE, the mistranslation in French of permanent and temporary deferral criteria for risky sexual behaviour. In the French version, there are the same wording for both temporary and permanent deferral c) In the Directive 2005/62/CE: correct the recurring problem of translation on the term "processing". It was translated into French language sometimes by the word "transformation" wrong translation), and sometimes by the word "préparation" (correct translation). It is suggested to use in the French version the word "préparation".
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	In 2012, temporary deferral measures of prospective donors, returning from countries where WNV cases were reported in 2011, were implemented for the seasonal period of the 1st of June to the end of November. The deferral period for prospective donors is 28 days after return of the affected area Therefore, the systematic deferral measures (i.e. without waiting for any report of epidemiological ECDC) was implemented for travellers returning from the following countries: Albania, Canada, Greece, Hungary, Israel, Italy (Venetia, Friuli Julian Venetia and Sardinia regions) Macedonia, Romania, Russia, Tunisia, Turkey, Ukraine, USA. Later, additional countries have been added to the list: Algeria, Bosnia, Croatia, Italy (Basilicate region), Kosovo, Montenegro, Palestinian territories and Serbia.
8.5. Which other communicable diseases are of relevance to you?	The surveillance and detection plans against chikungunya, dengue and west Nile virus dissemination in metropolitan France include a specific structure recommending measures to be taken in order to reduce risk of transmission from human blood, organs/tissues and cells. This structure is called « crisis management team » (CMT), cellule d'aide à la décision éléments et produits du corps humain". This structure is held under the aegis of the French National Agency for Medicines and Health Products Safety (ANSM) when cases are reported by the French Institute for Public Health Surveillance (Institut de veille sanitaire) in metropolitan France, in overseas departments and in foreign countries. It comprises virologists (reference centre) and experts from various institutions (French Agency for the safety of health products, French civil and Army blood establishments, French Institute for Public Health Surveillance, French biomedecine agency, Ministry oh health, Haemovigilance actors). The objectives are to discuss the relevance of measures regarding blood, tissues, and cells collected in the concerned geographical areas, taking into account the specific alert and also, when available, technologies already in place (e.g. Pathogen reduction, blood screening, existing exclusion criteria). This structure can also be used for other emerging situations (coronavirus, Q fever, malaria in Greece…). In this case, it involves others reference centres. In addition, we take into account of the vigilance notifications including haemovigilance reports. The recent increase of reports on transfusion-transmitted hepatitis E infection has been identified as a new concern.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No

8.6.1. If no, which is the applicable legal framework and the competent national authority?	PRP intended for an autologous use: collection, processing and hospital therapeutic use. The process is performed in is the autologous PRP is not stored. It is administered during the same medical procedure. The French regulation considers that it is an hospital activity of care which is outside of the blood directive and outside of the other directives like tissue-cells directives.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	None
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	None

A.1.11. Survey response Germany

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Paul-Ehrlich-Institut
1.1.2. Address of NCA 1:	Paul-Ehrlich-Straße 51-59 D-63225 Langen
1.1.3. Telephone (central access point):	06103 77-0
1.1.4. E-mail (central access point):	leitung@pei.de
1.1.5. Website:	www.pei.de
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Medical devices Other
1.1.6.1. If other, please specify.	" vaccines " allergens " sera " antibodies " recombinant analogues of blood derivatives " ATMP " Medicinal products for veterinary use: sera, vaccines, distinct immunological veterinary medicinal products, e.g. immune modulators " high risk IVD for human use see also answer to question 1.4
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	" Providing national marketing authorization (licensing) and assessment of marketing authorization applications to the EMA" batch release (if legally required) " authorization of clinical studies " GCP inspections, pharmaco-/haemo-/tissue vigilance inspections and dossier-related inspections prior to licensing, expert participation in inspections of regional authorities " inspections related to the Plasma Master File procedure " batch release of high risk IVD for notified body " vigilance of high risk IVD
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	list will be uploaded
1.2.2. Address of NCA 2:	list will be uploaded
1.2.3. Telephone (central access point):	list will be uploaded
1.2.4. E-mail (central access point):	list will be uploaded
1.2.5. Website:	list will be uploaded
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.3. National Competent Authority 3?	No
1.4. 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 Paul-Ehrlich-Institut is the “Federal Institute for Vaccines and Biomedicines”, thus a higher competent authority of the Federal Republic of Germany. It reports to the “Bundesministerium für Gesundheit” (Federal Ministry of Health). The Paul-Ehrlich-Institut is the National Competent Authority for Blood and Blood Components. 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 Products and Medical Devices” performs tasks related to pharmacovigilance, 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 details 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).
1.5. 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)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance Other
1.5.1. If other, please specify.	The Regional Competent Authorities in the German Laender are basically entrusted with the task of supervising and continuously monitoring the compliance with legal provisions. For this purpose, they grant authorisations of blood establishments and laboratories and organise inspections.
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	There is a splitted competence between the National Competent Authority (PEI) and the Regional Competent Authorities of the Laender. Generally spoken, the Regional Competent Authorities are responsbible for activities in matters of Article 5 and 8 of the Directive 2002/98/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 blood products as well as for the fulfillment 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 directed to the Laender. For further information abregarding the Regional Competent Authorities of the Laender see answer 1.7 of the questionnaire concerning tissues and cells.
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	280
2.1.2. How many of the BEs are satellite sites?	142
2.1.3. How many of the BEs are mobile sites?	184
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	2,867,230
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	2,458,347
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	408,883
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	From Poland to Brandenburg for plasma donation Brandenburg is by extension the 5th largest of the German Laender and has ca. 2.5 million inhabitants (80.5 million inhabitants in Germany), 12 blood establishments acc. to RL 2002/98/EG Article 3 e) and 6 mobile sites acc. to RL 2005/62/EG Article 1 i). No further information available to the competent authorities
2.1.8. For whole blood donations, could you please provide the	4,785,048

number of whole blood donations in 2012 (01/01-31/12/2012).	
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450-500 ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	2,445,918
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	Donation volumes (incl. anticoagulans) allowed as listed below depend on the donors body weight: d60kg - maximal 650 ml d80kg - maximal 750 ml >80kg - maximal 850 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	196,106
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	Maximal donation volume (incl. anticoagulans) allowed is 750 ml per donation which yields an average of 2 platelet concentrates obtained from one apheresis procedure.
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	35,245 (Erythrocytes: 14,699 Granulocytes: 629 Multicomponents: 19,917)
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	141 laboratories perform donation testing
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	92 laboratories perform donation testing
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level Information is collected through a donor evaluation/selection form that is not standardised at national/regional level Other
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	http://www.pei.de/DE/infos/pu/zulassung-humanarzneimittel/verfahren/blut-blutkomponenten/spenderfragebogen/spenderfragebogen-blutspende-inhalt.html
2.1.18.2. Please provide a copy of the donor evaluation/selection form standardised at regional level (in English if possible).	not available
2.1.18.3. If other, please specify.	sec. 31 para 4 sentence 1 number 1 nd number 3 of the Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV) define the eligibility criteria according to the relevant EU-Directives. Furthermore, according to sec. 5 para 1 of the German Transfusion Act and chapter 2.1.3 of the national Hemotherapy Guidelines the information required by Art. 3 and Annex II, Part B of Directive 2004/33 has to be collected through a personal interview with a medical doctor or a health care professional and through a donor evaluation/selection form. The donor eligibility criteria as required according to Annex III 2004/33/EC for the donor history questionnaire are additionally layed down in the national Hemotherapy guidelines. There exists a standardised questionnaire (see 2.1.18.1) which is not implemented to be used mandatory. Both, German Transfusion Act and national Hemotherapy Guidelines require the donor release performed by the responsible medical doctor.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Information of the donor and documentation requirments pursuant sec. 6 and 11 of the German Transfusion Act (Transfusionsgesetz / TFG) and sec. 31 para. 4 number 1 and 3 Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV) Information of the donor: sec. 19 para. 1 sentence 4 and 5 TFG; information and education of patients pursuant sec. 630c, sec. and 630e, documentation pursuant sec. 630f BGB Patientenrechtegesetz
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes

2.1.20.1. If yes, please describe (bar code, etc.).	sec. 6 para 1 of the German Transfusion Act Individual organisation by blood establishment
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Most important deferral criteria are those assuring good health of the donors (limits for Hb, IgG, platelets, deferral of donors with critical diseases which do not allow blood donation like cardiovascular disease) and those protecting recipients from any harm by transfusions (e.g. deferral of donors with severe infectious diseases transmittable by blood or the risk of acquiring such).
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	The eligibility criteria most difficult to implement are deferral criteria which refer to a donor´s behaviour, especially when a yes answer may suggest unwanted social comportment.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	1. Annex III of 2004/33/EC no.2.1 permanent criteria, sexual behaviour, versus 2.2.2 temporary deferral, exposure to risk deferral. because of the following reasons: a) There are no data to distinguish between different risk categories which justify a permanent deferral (sexual behaviour at high risk) on the one hand and a temporary deferral (exposure to risk) on the other hand. b) Behaviour may be changed and hence the persons risk to aquire and bear undetected transfusion transmittable diseases. A permanent deferral based on behaviour at risk therefore lacks any scientific basis. 2. Fixed upper age limits should be deleted and decisions on upper age limits should be made by the physician in charge of donor selection when deciding on deferral or admission for donation. 3. In addition to the total serum protein level also serum IgG levels should be determined in plasmapheresis donors and should not be below 6g/l. (Schulzki T et al. A prospective multicentre study on the safety of long-term intensive plasmapheresis in donors (SIPLA). Vox Sang 2006;91:162-73). 4. Deferral for 4 weeks after flu-like illness to avoid blood component contamination with Yersinia enterocolitica.
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Sex among men, sex workers, risky heterosexual behaviour like sex among heterosexuals with frequently changing partners
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	see number 2 to in the answer to question 2.2.3.1
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	No information available as data on donor deferral reasons are not collected centrally.
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	No
2.2.11.1. If no, what other deferral criteria would you suggest for derogation? Would you have other suggestions on the usefulness and set-up of such temporary derogations?	In case of an influenza pandemic or pandemics with similar characteristics derogation of the deferral criteria Hb levels and deferral window after flu-like symptoms will be useful to sustain blood supply. In Germany, calculation had only been made for influenza pandemic (see presentation at the CA meeting in autumn 2009).The situation may be very different for other types of crises like severe disasters. Therefore, no additional predictions can be

	made for other crisis situations.
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	" authorisation of laboratories pursuant sec. 13 of the German Medicinal Products Act (Arzneimittelgesetz / AMG) " surveillance and regular inspection of laboratories pursuant sec. 64 of the German Medicinal Products Act
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	" Mandatory for routine screening: HIV-1 NAT (10.000mIU/ml) and HCV-NAT (5.000 IU/ml) " Not mandatory, but used for routine screening by many blood establishments, mainly those who also deliver plasma for fractionation: HBV-NAT, HAV-NAT, Parvovirus B19 NAT " Mandatory for confirmatory testing: HIV-1 NAT, HCV-NAT, HBV NAT with highest sensitivity available
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Mandatory for whole blood donations and apheresis donations for transfusion are " Blood grouping: " Rh details (C,c,D,E,e), Kell criterion, serum blood group antibodies on the occasion of first and second whole blood donation. Infectious disease markers: " Anti-HBc antibodies " HCV Genom (NAT) " HIV-1 Genom (NAT) " Anti-Treponema pallidum antibodies
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Mandatory for plasma for transfusion (see 3.1.3.1), not mandatory for plasmapheresis donations intended to be used as plasma for fractionation
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Answer to 3.1.4 is no, but this comment is to be added: No general answer can be given as it depends on national strategies, e.g. use of other tests like highly sensitive combined antigen-antibody tests instead of NAT tests, the specific epidemiology of a given country, the use of pathogen-inactivated blood components etc.
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	114 positive samples, see comment in 3.1.5.4
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	510 positive samples, see comment in 3.1.5.4
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	358 positive samples, see comment in 3.1.5.4
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	for Syphilis: 345 positive samples Note: the numbers in the answers for 3.1.5 and following are NOT the numbers for positive test results, as you have to perform multiple tests including confirmation tests on an initially positive sample. This means: the numbers do NOT include false positive test results and do NOT include confirmationary testing. The numbers are positive samples of people willing to donate blood (as some BEs perform pre-donation tests with first time donors)
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	In case of defined European requirements for testing laboratories and e.g. regular external quality control offered at a European level no further international accreditation systems for testing laboratories seems to be required.
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	a) Therapeutic frozen MB plasma: plasma treated with methylene blue and light followed by absorption of methylene blue and its photo derivatives by blueflex filter. b) Therapeutic frozen SD plasma: plasma pooled and tested according to Ph.Eur. monograph Human Plasma for Fractionation; treatment with solvent and

	detergent and removal of these additives according to Ph.Eur. monograph Human Plasma (pooled and treated for virus inactivation c) Therapeutic frozen Intercept Plasma: plasma obtained from whole blood or apheresis donations treated with amotosalen-HCl and UVA b) Intercept-PC: platelet concentrates from pooled buffy coats or from apheresis donations suspended in plasma and additive solution, treated with amotosalen-HCl and UVA
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	This is part of authorisation and surveillance of blood establishments, see sec. 14 para 1 number 5c and 6a, sec. 64 of the German Medicinal Products Act, see also sec. 4 and sec. 12 AMWHV and sec. 4 sentence 1 number 1 and 2 of the German Transfusion Act
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	Required pursuant sec. 31 para. 1 AMWHV
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	sec. 20 para 2 AMWHV
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Documentation requirements pursuant sec. 10 and 20 para. 2 AMWHV
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Requirements pursuant sec. 31 para. 4 number 7 and sec. 7 AMWHV
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	sec. 11 of the German Transfusion Act
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	no there is no legal basis
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	No
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Other
4.2.1. If other, please specify.	authorisation pursuant sec. 13 of the German Medicinal Products Act
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	233 (December 31st, 2012)

4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	(The answer to question 4.4 covers the year 2012, NOT 2008.) see answer to question 1.2.1
4.6. How many laboratories performing donor testing are active within your country?	141
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	see answer to question 1.2.1
4.8. How many hospital blood banks are active within your country?	reported by Laender Authorities: 144; no complete data available
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	a) Biotest AG, Landsteinerstr. 3-5, 63303 Dreieich, www.biotest.com b) CSL Behring GmbH, Philipp-Reis-Straße 2, 65795 Hattersheim am Main, www.cslbehring.com Comment: all public available information can be obtained from the homepages of the companies. A national CA is not allowed to publish confidential data.
4.10.2. If yes, please state the responsible authority within your country.	Regierungspräsidium Darmstadt Luisenplatz 2 64283 Darmstadt
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	see answers to question 1.2.1 See answers to questions 1.2, 1.5 and 1.6
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	No further data available.
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Pharmaceuticals (including plasma derivatives) Advanced therapies Medical devices Hospitals Others
5.2.1.1. If others, please specify.	Pharmacies, Clinical Trials, (Testing) Laboratories, Active pharmaceutical ingredient (API), SoHO, Comment: Due to the federal organisation of inspections, interaction of inspections differs from inspectorate to inspectorate
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	93 in 2012
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	19 in 2012
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	53
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	1
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	a) Regarding the participation of the agencys assessors in inspections (national and in third countries) of regional authorities as experts, a risk-based approach for inspection planning is applied by

	the regional authorities according to a written procedure. The inspection intervals follow the Compilation of Community Procedures as well as the national legislation. Inspections are conducted at least every two years. Exception: There exist very few establishments in Germany for the preparation of autologous donations where inspections are carried out within an interval of no more than 3 years. b) Concerning inspections in third countries under the centralized procedure (i.e. inspections related to the Plasma Master File) a risk based approach is applied. Inspections are currently conducted every two to three years based on the centres compliance during the previous inspections.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	Correct answer to question 5.5.1 is "YES" Correct question to 5.5.2.1 is: "IF YES, WHY?" This is the answer to "If yes, why?" a) short personal resources b) Current definitions in the EU Blood Directive 2002/98/EC do not provide sufficient detail in the description of site activities (e.g. mobile or satellite sites). This hinders the desired risk-based approach to inspection including those regarding inspections related to the Plasma Master File and control measures.
5.5.3. How many BE have been inspected at least twice in the last 3 years?	84
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Satellite collection sites are inspected on a given cause and on random basis. Satellite sites are inspected from one site in 5 years to 14 sites in one year depending on the resources of the Competent Authority and the causes for inspection. Mobile sites are inspected on a random basis.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Granting of new authorizations Granting of GMP-Certificates all authorisations were automatically renewed
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	Corrective Action Plan: (tracking of shortcomings, determine measures, supervision of actions); granting of GMP-Certificates, authorization for new premises, all authorizations were automatically renewed, expansion of authorizations, granting of new authorizations
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	Corrective Action Plan (tracking of shortcomings, determine measures, putting a deadline for corrective measures, supervision of actions); Granting of a GMP-Certificate (after correction of major shortcomings), Expansion of a license; after correction of major shortcomings all authorizations were finally renewed
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	Not applicable
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	Not applicable
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	Not applicable
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	79
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	No
5.8.1. If no, please explain.	Not all the NCA officials work in the field of inspections, but may perform other taks, e.g. batch release testing for medicinal products, prepare pharmacovigilance reports, or administrative duties of the CA. For the rights of inspectors during an inspection see in particular sec. 64 para. 4 of the German Medicinal Products Act
5.9. Is a system in place for inspecting hospital blood banks?	Yes

5.9.1. If yes, please describe.	See answers to question 5.1 et seqq sec. 64 AMG
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	See answers to question 5.1 et seqq sec. § 64 AMG
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	No
5.10.2. If no, which guidelines/regulations are used for inspections at national level?	National laws (German Medicinal Products Act (Arzneimittelgesetz / AMG), German Transfusion Act (Transfusionsgesetz / TFG), Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV)) National guidelines (Guideline on procurement of blood and blood components and use of blood products- Hemotherapy (Hämotherapierichtlinien)) National aide memoire “Blood” (Inspectors Manuals of Experts of the Laender Authorities)
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	No
5.11.2. If no, why not?	The correct answer to question 5.11 is "yes", to question 5.11.1 is "3". But additionally: Some Laender Authorities nominated inspectors but they were not admitted by EMA. They will consider sending inspectors depending on the content of the future training programs.
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	see answer to question 1.2.1
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT, Eurocode
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Others
6.1.4.2.1. If other, please specify.	Granulocytes
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	the cited Directive 2006/86/EC concerns tissues and cells!! for blood: sec. 20 para. 2 AMWHV
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	According to para 63c and 63i of the German Medicinal Products Act, every marketing authorisation holder for blood preparations is obligated to document and report every suspected serious adverse event and every suspected serious adverse reaction to the Federal Competent Authority immediately, or at the latest within 15 days of acquiring this knowledge. The Paul-Ehrlich-Institut is responsible for the evaluation of any reported event and reaction and the introduction of risk minimization measures.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	No

6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	The blood establishments are requested to use the notification form, which is available on the PEI homepage, or to use the online reporting tool.
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	No
6.2.3.1. If no, please specify what guidelines you use? If possible, please upload the template.	PEI uses the Common Approach Document in combination with specific national requirements (e. g. donor look back procedure).
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	There is cooperation between the federal competent authority and the regional competent authorities of the “Laender”. Each Competent Authority has a responsible person.
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	The appointed transfusion specialist is requested to use the notification form, which is available on the PEI homepage, or to use the online reporting tool.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	Transmission of infections, haemolytic transfusion reactions, TRALI.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	An annual blood vigilance report is published by the PEI.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	33
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	In case of a national rapid alert the PEI informs the responsible regional competent authorities of the “Laender” and the graduated scheme officer/ qualified person by e-mail. Graduated scheme officers are responsible to set up and manage a pharmacovigilance system and to collect and evaluate notifications on medicinal product risks and to co-ordinate the necessary measures.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	See answer to question 6.2.11.1
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Tissues and cells Organs Medical devices
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	no
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion	Import authorisation and certification pursuant sec 72, 72a of the German Medicinal Products Act for import from third countries,

from EU Member States or third countries?	granted by the Regional Competent Authorities, see also sec. 17 AMWHV
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Import authorisation and certification pursuant sec 72, 72a of the German Medicinal Products Act for import from third countries, granted by the Regional Competent Authorities, see also sec. 17 AMWHV
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	According to sec. 72 German Medicinal Products Act, the importing organisation needs a license by regional authorities which implies that the blood component has to fulfil all requirements regarding collection, processing, testing, vigilance, quality assurance etc. as laid down in the German Transfusion Act., i.e. equivalent standards to national standards are required.
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	See answers to questions 7.3.1. and 3.1.3.
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	No imports of blood components from third countries outside the European Economic Area (EU, Norway, Iceland, Liechtenstein) were reported.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	3,952,549 litres from third countries outside the European Economic Area (EU, Norway, Iceland, Liechtenstein). More detailed data are not available. Not all of this is used for fractionation. Overall only 2,158,406 litres were fractionated in Germany.
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	sec. 73 AMG sec. 20 para. 1 AMWHV (Documentation)
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	sec. 73 AMG sec. 20 para. 1 AMWHV (Documentation)
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	3,399,419 litres to third countries outside the European Economic Area (EU, Norway, Iceland, Liechtenstein). More detailed data are not available.
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	No exports of blood components to third countries outside the European Economic Area (EU, Norway, Iceland, Liechtenstein) were reported.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	Yes
7.12.1. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells
7.12.2. If yes to Q. 7.12., what do you do with the surplus of blood or blood components?	The extent of blood component surplus is (a) too low to look for another special destination. (b) The surplus at the end of the shelf life cannot be used for other therapeutic purposes. All non-directed prepared blood components reveal a very low percentage of expired

	products. This is due to the short shelf life of especially cellular blood components and the necessity of compatible transfusion which requires the selection of compatible components from a larger storage pool. Moreover, there is a loss of plasma components which cannot be released after quarantine hold and in many of these cases it is not possible to dedicate it as plasma for fractionation. In contrast, there is nearly no loss of granulocyte concentrates as they are prepared for certain patients.
7.12.3. If yes to Q. 7.12., would you be interested in concluding bilateral agreements with other MS in order to address the surplus?	This is not a national issue as the blood donation system is not a national system. In principle, the BEs can close contracts with other BEs on their own responsibility and risk.
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	The answer to question 8.1.1 cannot be given as "yes" or "no", for the following reason: There are no specific statistical data available relating to infringements against blood regulations.
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	see answer to question 8.1.2
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	see answer to question 8.1.2
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	EU-KOM already started an inquiry among stakeholders on this topic, so these results should be taken into account
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	2003: Visitors returning from USA, Canada, and from 2004 on also from Mexico are deferred for at least 4 weeks from donating blood. 2012: information exchange on impact of deferral of visitors returning from European countries.
8.5. Which other communicable diseases are of relevance to you?	Any kind of severe infectious diseases transmittable by blood.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Two possible cases: 1) Preparation (collection, processing, testing, release) and administration is performed by two different persons under different immediate responsibilities: Blood directives apply. 2) The physician in charge is the person who himself prepares (or preparation is done under his direct responsibility) and administers the blood component: Blood directives do not apply, the activity is regarded as part of patient treatment.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Donor lymphocytes, see our letter from June 3rd, 2013 und last CA-Meeting Tissues and Cells There are more and more medical devices legally on the market which enable the bed-side preparation of autologous blood components like PRP, fibrin glue, so called “growth factor rich plasma”, so called “plasma rich fibrin” etc. To our knowledge there exists no proof of efficacy from clinical studies, however, because of situation No. 2 (see answer to question 8.6.1) blood directives do not apply.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling,	Pooling according to Ph. Eur. like for SD plasma fall under pharmaceutical legislation, i.e. 2001/83/EC. Pooling performed in order to achieve an amount necessary for 1 therapeutic unit (e.g.

inactivation techniques, …)	pool-platelet concentrates made from buffy coats of 4-5 whole blood donations) is not regarded as industrial process and falls under the blood directive regulations (2002/98/EC). Analogous all processing steps, performed on single therapeutic units like pathogen inactivation procedures or lyophilisation of single donor plasma are also regulated under the blood directives and its corresponding national laws.

A.1.12. Survey response Greece

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1.1. Name of National Competent Authority (NCA) 1:	NATIONAL BLOOD CENTRE, MINISTRY OF HEALTH HELLENIC DEMOCRACY
1.1.2. Address of NCA 1:	Olympic Champion Ch. Mantika 7 position Basins 13678 Acharnes - Athens
1.1.3. Telephone (central access point):	00302132146700
1.1.4. E-mail (central access point):	info@ekea.gr
1.1.5. Website:	www.ekea.gr
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Inspection Other
1.1.7.1. If other, please specify.	--Coordinates the blood services for an effective function of all blood transfusion activities --Manages the national blood supply --Recalls blood components if necessary --Implements a quality system --Follows -up maintenance of internal and external quality control --Promotes mechanisms for the protection of personal data --Makes national guidelines for the collection, storage and transportation of plasma as well as for blood testing and processing
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	COORDINATING HAEMOVIGILANCE CENTRE (SKAE) OF THE HELLENIC CENTER FOR DISEASE CONTROL AND PREVENTION
1.2.2. Address of NCA 2:	AVEROF STREET 10 ATHENS 10433 GREECE
1.2.3. Telephone (central access point):	00302108233673
1.2.4. E-mail (central access point):	skae@keelpno.gr
1.2.5. Website:	www.keelpno.gr
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Haemovigilance Other
1.2.6.1. If other, please specify.	EPIDEMIOLOGICAL SURVEILLANCE OF TRANSFUSION TRANSMITTED INFECTIONS
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	SECTION OF BLOOD TRANSFUSION DIRECTORATE OF HOSPITAL UNITS DEVELOPMENT (S BT-DHUD) MINISTRY OF HEALTH
1.3.2. Address of NCA 3:	ARISTOTELOUS STREET 17-19 ATHENS GREECE
1.3.3. Telephone (central access point):	00302132161420
1.3.4. E-mail (central access point):	intrel@yyka.gov.gr
1.3.5. Website:	www.moh.gov.gr/
1.3.6. What are the roles/tasks of the NCA? (more than 1 answer possible)	Other
1.3.6.1. If other, please specify.	--Promotes regulations and examine legal issues in relation to blood donation and transfusion --Collects data on blood logistics --Deals with emergencies --Recommends budgets and funding for the blood services --Manages legal contracts for networking of BEs, HBBs and private clinics -- Manages legal contracts with plasma fractionation Centres abroad and with Swiss Red Cross for importation of RBCs
1.4. 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.).	According to 17 October 2005 Law3402 implementing Directive 2002/98/EC The Ministry of Health has the exclusive competence and responsibility for the organization of blood transfusion and of all blood transfusion activities including the collection testing processing storage distribution and management of blood and blood components. These duties are performed through the National Blood Centre (EKEA) and the blood services (blood centers (BCs), Blood Establishments (BEs) and Hospital Blood Banks (HBBs) as well as the Plasma Fractionation (PFC) EKEA is the national coordinator of all BCs, BEs, HBBs AND PFC and advocates the Minister of Health for the designation, authorization, accreditation and licensing

	of all blood services EKEA performs inspection regularly every two years as well as in emergencies in case of severe adverse event. EKEA is responsible for blood components recall and notification of the PFC in cooperation with the Hellenic CDC. EKEA enacts and follows -up a quality and safety for all donation and transfusion activities.National Guidelines for blood transfusion scientific activities and specifications relating to quality for BEs and HBBs and regulated by EKEA. EKEA's staff (35-40 people) is specialised in transfusion medicine, virology, immunohaematology, biology and administration. The Coordinating Haemovigilance Centre (SKAE) of the Hellenic CDC (Foundation in Nov. 1995, Govermental Journal No 831/29 June 2001 and Govermental Journal -Ministerial Resolution 261/17-02- 2011 is the competent authority for the development and function of haemovigilance system. It collects, records, and analyse information about adverse reactions and adverse events associated with the transfusion and the donation of blood and blood components. Serious adverse reactions and events are notified to SKAE that reports to EKEA and to the Ministry of Health. Traceability of blood components and tracing and recall of potentially infections donations reported to BEs and HBBs are coordinated by SKAE as well as epidemiological surveillance of transfusion transmitted infections (TTIs). SKAE has specialized staff in transfusion medicine, epidemiology, statistics,communication and informatics.SKAE operates through a national network with six bases. The section of Blood Transfusion (SBT-DAMY) Directorate of Hospital Units Development has regulatory responsibilities advocating the Minister of Health on issues related to implementing EU Directives and other relevent regulations of Council of Europe and the WHO Legislative issues concerning blood donation and blood transfusion as well as funding and budgeting of BEs, HBBs and the PFC are within the competence of SBT-DAMY. Other responsibilities are : measures for the increase of Voluntary Blood Donation and the development of a registry for voluntary blood donors, a database for blood logistics (blood collection and blood distribution), regulation of blood sessions in cooperation with the Ministry of Defence , close cooperation with EKEA as well as BEs and HBBs and SKAE
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	9
2.1.2. How many of the BEs are satellite sites?	101
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	333.335 whole blood donors and another 18.123 plateletapheresis donors
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	276.668
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	56.667
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	The majority (4.2%) of your donor travel to EU countries, USA, Canada and to Australia. A small (0.5%) proportion travel to Australia Another 0.3% travel to non EU European Countries as well as in other destinations. People of Albanian origin who live for more than 10 years in Greece (1%) visit their mother country and are accepted for donation in accordance with the suitability criteria
2.1.8. For whole blood donations, could you please provide the	400.002 Comment : These are data from 81% of total blood

number of whole blood donations in 2012 (01/01-31/12/2012).	collection
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	2.146
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	350-470
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	18.123
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	Depending on the equipment usedin aphaeresis and the prescribed quantity of the products the average volume varies from 280 ml (2.8x10") to 400ml (4x10")
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	0
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	92
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	comment: plasma donations are collected only during plateletaphaeresis
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	attached
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	The donor signs the blood donor form (questionnaire on donor medical history) assuring that he/she has not experienced at risk sexoual behaviors and/or in drug abuse. However a multicenter study published in Transfusion Medicine in 2007 on "Factors that motivate and hinder blood donation in Greece" showed that a small percentage of donors confessed to having concealed part of the truth to background information
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	This measure is applied in some blood establishments only
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	--Haemoglobin levels in donor's blood (women) --Medication --Disease outbreakes (seasonally e.g. WNV) --Travel
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	History of HIV-1/2
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	Section 2.3 of 2004/33/EC may be more extended and specific for particular epidemiological situations in affected aress (eg WNV, Malaria, Dengue,HEV)
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	-Persons who have had even one homosexual contact since 1977 -Persons who have injected drugs intravenously -Persons systematically involved in unsafe sexual activity during the last 10 years -Sexual partners of multi-transfused patients -Persons who during the last 12 months had sexoual contact with someone who

	received payment for sex in money or drugs -Generally anyone who thinks that he/she may be exposed to HIV
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	-Hb levels in women and first time donors (3.5% of deferrals) -Medication (3%) -WNV and Malaria outbreaks in Attiki (seasonally 10%) -Travel in various endemic areas for HBV, Malaria , Chagas and because of vCJD 4% AND 2.5% respectively
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	- The total number of deferrals per blood establishment is recorded in the database of the SBT-DAMY/MoH -The Coordinating Haemovigilance Centre collects data on deferrals due to TTIs - Detailed data for each deferral are kept by most BEs
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	4% of total blood collection (about 16,000 units)
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	- By inspections every two years -Through the data on anality issues collected by SKAE -Through ISO Certificates and Proficiency testing from the EDQM and external independed bodies -Use of the Council of Europe "Guide to the Preparation, Use And Quality Assurance of Blood (Greek Edition)
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	In every donation for HIV,HCV,HBV and seasonally in affected areas for WNV
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Donor eligibility criteria testing for TTIs and labelling criteria are mandatory
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Plasma donations by aphaeresis procedures are rare and performed together
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Addition of NAT testing
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	21
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	432
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	86
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	HTLV I/II : 22 SYPHILIS : 73 WNV : 4
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	This is to be considered and planned

3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Photoinactivation of Plasma with Methylen Blue
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	The National Blood Centre is conducting investigation for existing GMPs, promotes processing and packaging instructions and manages various manufacturing operations.SKAE is making enquiries about documentation, pre- established proceduresand other quality parameters.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	Most BEs and many of the HBBs have a system for maintaining quality control, keep records on materials, test results, equipment presentation and maintenance. Self inspections are performed by the responsible persons and in the large blood Centres performing Molecular Biology testing for TTIs anditing is applied.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Through Inspections by the National Blood Centre and by means of an inquiry operated by the Coordinating Haemovigilance Centre. The regional Blood Centres are also entitled to perform visits and to examine documentation of records in the network of HBBs of their region
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	- Through manual as well as computerized systems all procedures are labelled with unique numerical codes - All blood service are following national guidelines for the examination of medical history of donors, store the blood donor forms (signed by the examing physician and the donor) for at least 15 years and store samples of donor blood for at least 1 year. Deferral criteria and blood testing results as well as haemovigilance data are recorded and stored carefully. Documentation and record keeping are favored because of the existing decentralized system
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	The National Blood Centre and the regional as well as the local Health and Hospital Authorities follow national specifications and perform tenders that are under central control from the Goverment
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	The Coordinating Haemovigilance Centre has focused on the issue a data confidentiality of both donors and recipients
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	no
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	It is the golden standard of transfusion internationally . The guide translated in Greek is on the bench of everyone working in the blood services inspiring and guiding all activities, in donations and transfusion Its standards and principles that fully compatible with

	the EU legislation provide the base for every regulatory and scientific act, guaranteeing that consistency with ethics and scientific progress
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Designation Authorisation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	102 (information of records are available by the Directorate of Hospital Units
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	Yes
4.4.1. If yes, what were the reasons for the revocation(s) or suspension(s) (more than 1 answer possible) ?	Others
4.4.1.1. If other, please specify.	Administrative reasons associated with a stepwise centralization system starting with the nationwide implementation of NAT testing for HIV, HCV and HBV in September 2008 followed by the economic crisis and the various structural changes in the national health system (early retirement or suspension of staff, conflation of blood services and in certain situations lack of resources delaying procedures).
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	The Minister of Health after the relative recommendations from the National Blood Centre
4.6. How many laboratories performing donor testing are active within your country?	92
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	AS 4.5
4.8. How many hospital blood banks are active within your country?	83
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	-Blood collection follwing the guidelines of the National Blood Centre - Recruitment of blood donors - Notification and counseling of donors positive for TTIs - Take part in the investigation and management of disturbances of haemostasis and transfusion depended diseases
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	The National Plasma Fractionation Centre "Elias Politis" is located in the area of Thracomacedones in Attiki and is one of the National Blood Centre Units.
4.10.2. If yes, please state the responsible authority within your country.	It collects whole blood derived plasma provided by BEs and HBBs and cooperates with SANQUIN for fractionation and the production of Albumin under mutual contract It is public and its capacity is less than 100,000 liters of plasma per year
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	For regular inspections, the activity is performed by the National Blood Centre in cooperation with the Regional Health Authorities for inspections in specific situations and in case of revocation SEYP (Body of Health Inspectors) is the competent authority
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	Three (1 director of a regional BE, 1 administror ,1 specialized in engineering)
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues	Yes

and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Pharmaceuticals (including plasma derivatives) Advanced therapies Medical devices Hospitals
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	-52 inspections accomplished before 2009 for the purposes of the plasma Master File --41 regular inspections in the blood services of Western Greece, Macedonia and Thrace -- 3 inspections in the Plasma Fractionation Centre performed by SEYP
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	as 5.3.1
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	as 5.3.1
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	as 5.3.1
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	None
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	They have not been inspected
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	No inspections performed in 2012 except for the purpose of centrally planned consolidation of eight blood services
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	as 5.6.1
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	as 5.6.1
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	as 5.6.1
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	as 5.6.1
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	as 5.6.1
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	None
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	No
5.8.1. If no, please explain.	Only qualified NCA officials are entitlited to perform inspections, examine documents and if required to take samples for analysis
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	It is the same system applying for BEs. The inspection Criteria and guidelines have been formulated by the Scientific Committee of the National Blood Centre on the basis of the "Guide" and EU- EUBIS

	and CATIE
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	HBBs are inspected by the National Blood Centre in cooperation with the Regional Health Authorities (abbreviated in greek EPY)
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	Extremely useful for the general functionality of the blood services as well as for inspections, audits, proficiency testing and accreditation
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Coordinating Haemovigilance Centre
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	Whole blood, RBCs, FFP, whole blood derived platelets, apheresis platelets and whole blood derived plasma intended for fractionation
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	For BEs and HBBs without a computerised system, this requirement cannot be fully respected
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	The Coordinating Haemovigilance Centre (Known as SKAE) was founded by the Hellenic Center for Infectious Diseases Control (KEEL, now KEELPNO) in November 1995. It was established for reasons in line with European efforts to promote the strictest possible standards for quality in blood donation and transfusion medicine and particularly to limit the risks that arise in this area of public health, thus to improve the safety of the blood transfusion chain from donor to patient Basic functions of SKAE -Surveillance of transfusion transmitted infections in blood donors and in blood donations - Traceability of blood components -Tracing and retrieval of potentially infectious donations--Look back programme - Surveillance of adverse reactions and adverse events in blood donors during or after donation -Surveillance of adverse reactions and adverse events associated with the transfusion of blood and blood components -Reporting to the competent authorities for blood transfusion (EKEA) and public health (KEELPNO) - Recommending preventine and corrective measures -Informing the medical community about adverse events and reactions associated with blood donation and transfusion - Warning blood services and clinical departments about adverse events and reactions that could involve more than a single recipient -Crisis management -Education-

	Publications
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Ministerial Resolution 261/Febr. 2011 article 2, paragragh 3,4 mandates notification of SAR/SAE of imputability level 2 or 3 attributable to the quality and safety of blood and blood componets to SKAE using a rapid notification format that is followed by a confirmatory procedure. SKAE reports to the National Blood Centre and in some cases to the Ministry of Health. Annual notification data of SARs/SAEs to SKAE are also collected and analysed by SKAE by type, degree of severity, level of imputability, degree of morbitidy and clinical outcome
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	-ABO incompatibility causing immunological haemolysis - TRALI - Transfusion-transmitted infections
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	This information is disseminated in the context of national and regional meetings for haemovigilance as well as in haematology and transfusion medicine congresses
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	Recall of one unit in-date RBCs in the case of transfusion transmitted WNV in a patient who received whole blood platelets and developed severe encephalitis. The FFP that derived from the same blood unit was already transfused in to another patient who remain WNV asymptomatic
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	So far, SKAE is sending classified mails to BEs. A system similar to RAB is now under construction
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	see 6.2.11.1
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	In very rare cases, the National Organization for Drugs (EOF) is communicating a rapid alert for medicine devices defects
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	SKAE is working for tracing of recipients of potentially infections blood donations and for post donation information
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	In the case of importing annualy about 20,000 units of RBCs from the Swiss Red Cross Blood Centre the provisions required from EU legislation are met in the mutual contract with the Ministry of

	Health
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Details of this information can be provided by the Section of Blood Transfusion -Directorate of Hospital Units Development of the Ministry of Health
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	NAT testing for : HIV-RNA, HCV-RNA, HBV-DNA
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	25,200 units of RBCs
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	not applicable
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	not applicable
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	Yes
7.11.1. If yes, how often (per year) is there a shortage of blood or blood components in your MS?	During summer holiday Blood shortage have been intensified because of WNV outbreak
7.11.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Red Blood Cells
7.11.3. If yes, would you be interested in concluding bilateral agreements with other MS in order to address the shortage?	Yes
7.11.4. If yes, would you be interested in establishing short-term/ad-hoc mechanisms for addressing the shortage?	Yes
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	Testing seasonaly for WNV-RNA in the affected areas Testing seasonaly for malaria in the area of Evrotas - Lakonia (affected area in the period 2009-2012) Pathogen inactivation of FFPwith Methylen Blue
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Time - frame of 30 years for data storage Addition of NAT testing for HIV,HCV and HBV

8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	WNV and blood safety measures (in comformity with the final EU preparedness Plan 2012) For affected areas -Deferral of potential donors residing or working in these areas -Quarantine of blood components collected since beginning of July until NAT testing of plasma samples stock has been performed -Retrospective NAT testing and look back procedures of blood collected since 1st July -Donor deferral is withdrawn when NAT testing is implemented For unaffected areas -Deferral of travellers/visitors for a period of 28 days after their return from an affected area General measures -Reinforcement of the donor clinical evaluation, particularly for visitors to the affected areas and continuous information fron the Hellenic CDC web www.keelpno.gr conserning the epidemiological data on the seasonal cycle of the WNV -Deferral of potential donors who reside in USA and Canada Other measures Haemovigilance Persons with diagnosis of WNV may be accepted for blood donation 120 days after diagnosis Post donation information : Request all donors to inform blood collecting services in case of fever, flu-like and other symptoms within 15 days after donation in order to examine for WNV(positive donors reported as a case) Post transfusion information : In case of history of recent blood transfusion in confirmed or suspected WNV cases, apply look back and traceability procedures including call up and testing of implicated blood donors Surveillance of WNV in thalassaemic patients Ensuring blood sufficiency Special attention to the optimal use of blood components and appropriate management of the national blood supply should ensure sufficiency of blood in affected areas Viral inactivation of about 12% of FFP by Methylen Blue
8.5. Which other communicable diseases are of relevance to you?	Malaria
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	Yes
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	We think that pathogen inactivation techniquesapplied in individual blood units or should not fall under the pharmaceutical legislation

A.1.13. Survey response Hungary

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	National Institute for Quality- and Organizational Development in Healthcare and Medicines National Institute of Pharmacy
1.1.2. Address of NCA 1:	H-1051 Budapest, Zrínyi u. 3.
1.1.3. Telephone (central access point):	+36 1 88 69 -300
1.1.5. Website:	http://www.ogyi.hu/
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives)
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection
1.2. National Competent Authority 2?	No
1.4. 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.).	Goverment based, 2 inspectors
1.5. 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)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Centralised system
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1
2.1.2. How many of the BEs are satellite sites?	5
2.1.3. How many of the BEs are mobile sites?	23
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	239133
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	183380
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	55753
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Some people give plasma in private plasma collection centres in Austria. No more information about it.
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	425637
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	-
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	-
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	3573
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	250
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	825
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	2
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	2

2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Véradók nyilvántartása, véradás előtti kivizsgálása és a teljes vér vétele/ Donor selection, register, examination before blood donation and blood collection 2nd Edition, OVSZ, Budapest, 2009.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	eProgesa software is used by the Hungarian National Blood Transfsuion Service, this is covered the whole country, we have only one donor register.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	The donors prepare a declaration about it and sign the document
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	hemoglobin concentration
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	sexual risk
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	MSM, frequent chnage of sexual partners
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	low hemoglobin concentration
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	eProgesa
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	68309
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	The Analysis Certificate are controlled by the CA in the BEs, and to inspect the work of the laboratories. The laboratories are involved in the proficiency tests.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	BE can afford to use this test in the confirmatory process.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are	Yes

additional tests performed on a routine basis?	
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	anti-HBc, anti TP
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	no information
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	4
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	12
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	111
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	68 anti-HBc
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Each of work place have an annual training plan and at the end of the year the QA officer have to close it after controlling of the details of it, and send about a report to the QA director in the Headquaters of HNBTS. During an audit these are controlled by the auditor of the BEs and the inspectors of the CA.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	The Hungarian National Blood Transfusion Service (HNBTS) has a quality system according to the principle of GMP directive and 62/2005/EC directive (it was implemented into the 3/(II.10) 2005. EüM decree). Since 2002 the CA has inspected it in every second year to give the licence.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	During the inspection the documentation is controlled, read the reports, etc.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	On paper form and on the server.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	The refrigerators are validated by the QA department in partly.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	ISBT 128 code identifies each of donation of the donors and only the authorisied staff can see the person in the IT system.

3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	ISBT128
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	QA departmen follows up the modification of the Guide and implements it in the rules.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	1
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	GYEMSZI-OGYI
4.6. How many laboratories performing donor testing are active within your country?	2/1 Blood Service
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	National Public Health and Medical Officer Service
4.8. How many hospital blood banks are active within your country?	23
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	HumanBioplasma Ltd bilongs to Kedrion. This is a private company.
4.10.2. If yes, please state the responsible authority within your country.	GYEMSZI-OGYI
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Inspection department
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	2
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Pharmaceuticals (including plasma derivatives)
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	ni
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	ni
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	5
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012	0

(01/01/2012 to 31/12/2012).	
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	ni
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	1
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	5
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	licence
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	corrective action
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	no
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	licence
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	OK
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	-
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	-
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	BE impelemts the Guide into the regulation.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Yes
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	all of type
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	Barcode

6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Granulocyt
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	To archivate on electronical version
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	No
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Blood Transfusion Regulation 2 edition OVSZ, Budapest, 2010, this rule is mandatory on decree level (3/(II.10) 2005. EüM law, but this data collection have been coordinated since 1976, but the request data was different in the past.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	The Blood Transfusion Service is involved and analyse, and cooperate wit the hospital and the plasma fractionation factory.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	The contact person (who has been delegated by the ministry) works in the Headquaters of the BE service.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	In the last year 11 events were ensured by the responsible persons according to our Hemovigilance rule. The donor made a signal of risk Lyme 4 cases after the blood collection, 1 the donor was infected by tuberculosis (after the donation getting the information), 1 ALL deasis in the donor after the collection, risk the HCV contamination in 2 minipool that was detected PCR technique in the plasma fractionation company, but the infections were not showed in the patients.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	According to the rule the contact person (quality director) will get the information from EU, countryside and it will be analised with the clinical director of the service and coordinate the process.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	look at the 6.2.11.1.
6.2.13. Do you notify alerts communicated via the blood national	Yes

vigilance system also to other national vigilance/alert systems?	
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Collaboration with the national institution
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	no
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	decree
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	decree
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	International standards
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	no
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	no
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	Yes
7.11.1. If yes, how often (per year) is there a shortage of blood or blood components in your MS?	according to the EU directive, Guide and 3/(II.10.) 2005 EüM decree
7.11.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Whole blood Others
7.11.2.1. If others, please specify.	granulocyte concentrate
7.11.3. If yes, would you be interested in concluding bilateral agreements with other MS in order to address the shortage?	Yes
7.11.4. If yes, would you be interested in establishing short-term/ad-hoc mechanisms for addressing the shortage?	Yes
7.12. Is there a regular surplus of blood or blood components in your	No

MS?	
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	No additional problem.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	In 2010 the WN infection was sporadic localization.
8.5. Which other communicable diseases are of relevance to you?	no
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Only the blood establishment responsible to collect blood and prepare blood products.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	no
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	plasma fractionation

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:	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 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices Other
1.1.6.1. If other, please specify.	Cosmetic products, advanced therapy medicinal products, clinical trials, veterinary medicinal products
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	Overseeing recalls, advice to government, international representation, enforcement powers.
1.2. National Competent Authority 2?	No
1.4. 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.).	There are four (4) departments directly involved in carrying out IMB's regulatory functions:1: Compliance (inspections and audits, market compliance and enforcement), 2: Humjan Products Authorisation and REgistration (licensing of medicines for human use, designation and monitoring of notified bodies for medical devices, registration of medical devices), 3: Human Products Monitoring (monitoring of safety of medicines for human use, blood and blodd components, tissues and cells and medical devices, 4: Veterinary Sciences (licensing and safety of medicines for animal use, scientific animal protection). There are three (3) departments which provide cross organisational support: 1: Finance and Corporate Affairs, 2: Human Resources, 3: IT Mangement 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 21 inspectors working accross different specialities including GMP, GDP, GCP, Blood, Tissues Cells and Organs (BTO). There is a dedicated team for Blood inspection comprised of the BTO mangaer, two BTO inspectors and one 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 Blood. The human product monitoring department is made up of pharmacovigilance, medical device vigilance and human products vigilance assessment, comprising of approximately 40 staff, there is 1 dedicated BTO vigilance officer, we also have access to senior management staff as required. The Irish Medicines Board is 85% self funded through licensing, inspection fess, the remainder is funded by the Irish Department of Health.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at	3

31/12/2012.	
2.1.2. How many of the BEs are satellite sites?	1 BE has a satellite site
2.1.3. How many of the BEs are mobile sites?	1 BE has 8 mobile sites
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	117,511
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	102,101
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	15,410
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Minimal due to vCJD restrictions. Generally this would be donors from Ireland who have moved to live in Northern Ireland. No data on actual numbers involved.
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	138,099
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450ml +/- 10%
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	N/A we do not use Irish plasma
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	N/A we do not use Irish plasma
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	12,023
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	Not available - volume collected depends on donation (single/double/treble) - always meets CoE Specification >40ml per 60x10^9 of platelets
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	0
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	3
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	N/A
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	One BE is responsible for obtaining allogeneic donations across the country and the donor/evaluation and selection is standardised by this organisation. The other two BEs are involved in the collection of autologous donations and therefore the donor/evaluation and selection is specific to those organisations and is carried out by appropriately trained staff.
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level Information is collected through a donor evaluation/selection form that is not standardised at national/regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	We have only one BE who obtains allogeneic donations so the evaluation/selction form is standardised across their organisation. Attached are 2 forms, one for repeat donors and the second for new or lapsed donors.
2.1.18.2. Please provide a copy of the donor evaluation/selection form standardised at regional level (in English if possible).	Not applicable
2.1.19. How do you ensure that the donor evaluation and testing	We have only one BE who obtains allogeneic donations, they

procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	manage this through a computerised system called Progesa. These processes can be reviewed on inspection.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	The BE has a website www.IBTS.ie with a section of questions for self exclusion. There is also an FAQ section.
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Specific for BE, unable to provide a response as not appropriate for CA to comment
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Specific for BE, unable to provide a response as not appropriate for CA to comment
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Can be seen on HLQ: If you have ever been given money or drugs for sex; if you are male have you ever had oral or anal sex with another male with or wothout a condom or other form of protection; Do you or your partner have HIV; In the past 12 months have you had: - sex with anyone who has HIV or hepatitis; sex with anyone who has ever been given money or drugs for sex; sex with anyone who may have had sex in parts of the world where HIV is very common? this includes Africa and South East Asia; sex with anyone who may has ever injected or who has been injected with non-prescribed drugs even once a long time ago thisi includes body building drugs; sex with anyone with Haemophilia or other blood clotting disorder who has ever been treated with clotting factor concentrates; if you are female sex with a male who has ever has ever had oral or anal sex with another male with or without a condom or other form of protection
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Low Hb has been the main cause leading to deferral. Total deferral rate is 18.49% of which 8.7% relates to Hb referrals.
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	Progesa, a computer based system
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	18.49%
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	If the testing laboratory is within the BE (as for BE responsible for Allogeneic Donations), the laboratory is assessed during routine inspections of the BE by the CA. If the testing laboratory is outside the BE (as for the two BEs who perform autologous donations) the testing laboratories used are required to have ISO 15189 accreditation, this is a requirement of the BE's authorisation. This can be reviewed on inspection.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is	For all allogenic donations.

used?	
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	NAT PCR performed on all allogeneic donations but not mandatory.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Not applicable
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	1
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	1
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	2
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	3 confirmed positive for syphilis and 9 confirmed positive for bacterial screening, 0 postive for HTLV
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Job description, training records.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	On inspection in the BE the personnel training records are reviewed. The BB's are accredited to ISO 15189 and a part of audit process is to review training records of BB staff.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	BE quality systems incorporate blood legislation, COE guide and PICS inspection guidance for BE. BB quality systems incorporate ISO 15189 requirements and additional IMB/INAB documents on traceability and SAE/R reporting
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	This is ensured through routine inspection for BEs and audits for BBs.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Currently kept forever electronically.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	This is reviewed as part of the inspection process. In 2013 a new BE was authorised specifically for the transport and distribution of blood and blood components in Ireland.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and	A unique identification number is applied at donation and used throughout the process. Any correspondance with third parties uses

hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	the donor identification number, therefore the third party never knows the donor identity.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	All BEs use a codebar system, some use ISBT 128, the rest will eventually use ISBT 128.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	This guide is useful but we would recommend it includes principles of GMP.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	4 (31/07/13)
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	As we mandate that laboratories performing testing are ISO 15189 accredited the national authority responsible is INAB (Irish National Accreditaion Body). However if a BE perfoms testing themselves we authorise it.
4.6. How many laboratories performing donor testing are active within your country?	3
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	INAB is the national authority with IMB supervision. IMB can also perform inspections as required.
4.8. How many hospital blood banks are active within your country?	46
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	As part of ISO 15189 accreditation hospital blood banks are required to meet the requirements of document AML-BB which sets out specific detailed minimum requirements in relation to traceability and SAE/Rs. Hospital blood banks are also required to submit annual reports to the IMB on activities.
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	The Compliance Department of the IMB are in charge of inspections
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	1. Blood, Tissues and Organs Manager, 2. Blood, Tissues and Organs Inspectors, 1. Blood, Tissues and Organs Scientific Officer
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Pharmaceuticals (including plasma derivatives) Advanced therapies Hospitals
5.3.1. Number of inspections by type: Please specify the	In 2012, 6 routine inspections were performed of the main BE in

number of general system-oriented inspections on-site .	Ireland collecting allogeneic donations. (2 in the main processing sites and 4 in donation clinics)
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0 in 2012. However it is possible to perform inspections when we receive an application to vary the BE authorisation, based on the report of a SAE/SAR or serious incident.
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	0
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	We have a small number of authorised BEs and BBs are managed through an accreditation body.
5.5.3. How many BE have been inspected at least twice in the last 3 years?	2
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	They are inspected every 2 years.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	N/A
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	Corrective actions were propsed by the BEs and assessed by the IMB, if acceptable they will be followed up on the next inspection.
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	Corrective actions were propsed by the BEs and assessed by the IMB, if acceptable they will be followed up on the next inspection.
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	none
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	did not occur
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	N/A
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	we have none
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	The CA may perform an inspection on foot of an SAE /R or upon suspension of ISO15189 accreditation. All HBBs routinely inspected for ISO 15189 compliance by the national accrediting body, INAB.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	Only upon suspension of ISO15189 accrediation or upon reporting (or lack thereof) of SAEs/SARs of concern. All BBs also required to submit annual report to CA based on activities and compliance with requirements of legislation.
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	Contains relevant guidance for BEs - However more GMP guidance

	is needed.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	3
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	IMB is the CA that oversees traceability by the BE. Our BE have to demonstrate traceability on inspection.
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	All blood components.
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128 is currently applied to all donations in conjunction with the codabar system. This is to facilitate BBs who have not yet moved to ISBT 128. It is envisaged that all BBs will move to ISBT 128 in due course.
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Neonatal products, granulocytes etc.
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By verification on inspection.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	A National Haemovigilance Office was established prior to implementation of the Directive. Hospitals report SAEs/SARs associated with blood components to this office. The IMB as CA has an agreement in place with this office and quarterly meetings are arranged to review SAEs/ SARs reported in the intervening periods.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	No
6.2.6.2. If no, how do you ensure that SAR/E are reported from Hospital Blood Banks to BEs?	There is no mandatory procedure in place for this. However, the National Haemovigilance Office is based at the main BE in Ireland

	(for allogeneic donation) and thus all BBs report SAEs and SARs to the BE via this office. Concerns regarding quality and safety are communicated to the relevant personnel at the BE and the process is reviewed on inspection.
6.2.7. Do you perform root cause analyses of the SARE?	No
6.2.7.2. If no, why not?	The reporter (BB) performs RCA and the National Haemovigilance Office in association with the CA assess adeqacy.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	When published by the EU, the IMB will circulate the reports to all BEs.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	In 2012, 229 recalls in total: 159 (69.4%) recalls due to post donation information (including abnormal FBC); 29 (13%) recalls due to suspected bacterial contamination; 33 (14.4%) recalls due to suspected adverse reaction to product; 8 (3.5%) repeat reactive virology test; 3 (1.3%) platelet aggregates; 2 (1%) air in line; 6 (2.6%) Others.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Due to small number of BEs and BBs in Ireland, it is possible for the CA to communicate national rapid alerts via email to all relevant personnel and through use of CA website where required.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Due to small number of BEs and BBs in Ireland, it is possible for the CA to communicate rapid alerts received from CIRCA-BC via email to all relevant personnel and through use of CA website where required.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Same team at CA responsible for Tissues & Cells and Organs and so therefore possible to communicate vigilance alerts through these systems if required. There are also close links within the CA to Medical Devices and Pharmacovigilance sections so communication with these sections is also possible if required.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Importers must be authorised BEs.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Not applicable
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	International standards
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	Possiblly NAT Testing and perhaps West Nile Virus Testing.

	However, there is a need to discuss this with the Blood Establishments throughout Europe and the ECDC.
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	2 red cell units both from USA
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Not applicable
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Export is to third countries. It has only occurred once on response to humanitarian disaster in Haiti. All exported products must meet the requirements of the EU Directives.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	not applicable
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	0
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	not applicable
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Regulation of BB, SAE.R definitions, the control of distribution/transport of blood components and the standard to be met for same.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Deferral and more recently the introduction of testing those donors attending clinics who have been to endemic areas in the previous 28 days.
8.5. Which other communicable diseases are of relevance to you?	Hepatitis E prevalence is currently under study at the Irish Blood Transfusion Service. There are concerns regarding the use of Hep E positive donations in neonates and immunosupressed patients.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	These are regulated outside the scope of the Blood Legislation at the moment in Ireland. There is a potential for these techniques to fall within medicines law if there is a medicinal claim associated with

	the product.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Any products collected, processed and applied at the bedside need careful consideration and do not necessarily fit within the requirements of the Blood Legislation.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Where under the control of the BE, these activities should remain under the remit of the Blood Legislation.

A.1.15. Survey response Italy

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health
1.1.2. Address of NCA 1:	Viale Giorgio Ribotta, 5 00144 Rome, Italy
1.1.3. Telephone (central access point):	+39 06 59941
1.1.4. E-mail (central access point):	segr.dgprev@sanita.it
1.1.5. Website:	http://www.salute.gov.it
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Tissues and cells Human organs Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Other
1.1.7.1. If other, please specify.	Blood and blood components legislation, planning of blood activities at national level (upon technical indications from the National Blood Centre), labile blood components import-export authorization, promotion of research in blood activities and transfusion medicine.
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	National Blood Centre (on behalf of the Ministry of Health)
1.2.2. Address of NCA 2:	c/o Istituto Superiore di Sanità Via Giano della Bella, 27 00162 Rome, Italy
1.2.3. Telephone (central access point):	+39 4990 4953
1.2.4. E-mail (central access point):	cns@iss.it
1.2.5. Website:	http://www.centronazionalesangue.it
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Haemovigilance Other
1.2.6.1. If other, please specify.	Coordination and technical-scientific control on all issues concerning blood and blood components as regulated by national and European provisions (including cord blood and peripheral haematopoietic stem cells collection, processing, banking and distribution); definition of plans for B and BC regional and national self-sufficiency and relevant monitoring actions; production of guidelines for B and BC quality and safety; definition and promotion of national plans and guidelines for appropriate use of blood resources; education and qualification of blood inspectors.
1.3. National Competent Authority 3?	No
1.4. 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.).	a) Ministry of Health: the Blood and Transplant Office is a branch of the Directorate General of Prevention; it is managed by an Office Director with longstanding experience in blood, cells, tissues and organ legislation, legal affairs and vigilance. The Office has a dedicated staff composed of 10 persons, both healthcare professionals and administrative. The Ministry of Health is entrusted with the definition of the "national basic healthcare services", including blood and transfusion medicine services, that must be homogenously guaranteed nationwide. b) National Blood Centre (NBC): the NBC is a technical/scientific centre operating at the Istituto Superiore di Sanità (National Health Institute); it acts as blood competent authority on behalf of the Ministry of Health, reporting to the latter on all issues pertaining to its tasks. It coordinates the 21 Regional Blood Centres (which are by law instituted in each Region) as concerns blood and blood product self-sufficiency, quality and safety, haemovigilance, information flows, etc. The NBC provides blood inspectors' education and qualification, as well as the management of a national list of qualified blood inspectors and the periodic assessment of their skills. The NBC also cooperates with the National Medicines Agency (AIFA) as concerns quality and safety of plasma for fractionation produced at national level. It is managed by a Centre Director who must be a physician experienced in blood, blood products, transfusion medicine and healthcare management. It has a staff of 25 operators, including a medical affairs and inspection systems manager, a national haemovigilance officer, a plasma and plasma products manager, a research and education manager, an information system manager, as well as administrative staff.
1.5. 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)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance

1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	The Regional Competent Authorities (RCAs) are by law entrusted with authorisation and accreditation of Blood Establishments (BEs) and Blood Collection Units (BCUs). Authorisation/accreditation of BEs and BCUs is issued by the RCAs based on inspections which must be performed every two years. Inspection programs and teams are managed by the RCAs; the latter must guarantee that in each inspection team at least one nationally qualified blood inspector is included. Authorisation and accreditation requirements are defined by national State-Regions agreements in compliance with EU blood directives and, as applicable, EU GMPs. The Regional Blood Centres are entrusted with regional blood and blood products self-sufficiency, haemovigilance data collection and reporting to the NBC, regional coordination of BEs and BCUs, relations with plasma fractionation industries and other tasks related to the regional blood activities.
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	313
2.1.2. How many of the BEs are satellite sites?	None
2.1.3. How many of the BEs are mobile sites?	None
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	1,739,712
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	1,443,770
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	295,942
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	2,683,127
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	403,554
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	Std < 650 Avg. 560
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	80,051
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	300-400
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	26,417
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	174
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	same as 2.1.15
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Other
2.1.17.1. If other, please specify.	Information to donors will be standardized at national/regional level by the issuing of a new decree of the Minister of Health which is in a final phase of definition and will presumably be issued by the end of 2013 (current form and draft standardized form enclosed at 2.1.18.2).
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is not standardised at national/regional level
2.1.18.2. Please provide a copy of the donor evaluation/selection form standardised at regional level (in English if possible).	The donor/evaluation form will be standardized at national/regional level by the issuing of a new decree of the Minister of Health which is in a final phase of definition and will presumably be issued by the end of 2013 (current form and draft standardized form enclosed - in Italian).
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Donor evaluation and testing procedures must be recorded in the automated BEs' information systems. Reporting of abnormal findings to the donor is envisaged as mandatory by law.

2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	In the pre-donation information material each donor is informed that he/she may exert self-exclusion at any moment of the donation procedure, as well as after donation.
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	a) Haemoglobin levels in donor's blood, especially concerning women in child-bearing age who are most prone to iron depletion following whole blood / red blood cell donation b) Transfusion transmissible infections, especially concerning donors having been in/coming from national areas/countries where: i) prevalence/incidence of transfusion transmissible infections are higher than at national level; ii) emerging pathogens are endemic/epidemic c) At risk/high risk sexual behaviours
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Least reliable to verify: at risk sexual behaviours
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	Concerning 2.1 "Infectious Diseases: Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune", it should be clarified what is to be intended by "demonstrated to be immune", considering that persons testing anti-HBs positive with (or even without) anti-HBc may test HBV DNA positive, thus resulting OBI (Occult HBV Infection) carriers.
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Any risky sexual behaviours are considered for donor deferral with no distinction of gender and sexual orientation; differentiation between risk and high risk behaviours is adopted, applying temporary and permanent deferral respectively. In 2001, the criteria for blood donor eligibility were modified by a ministerial decree from a permanent deferral for "men who have sex with men" to an individual risk assessment of sexual behaviours.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Criteria most leading to donor deferral: a) Exposure/potential exposure to transfusion transmissible pathogens b) Haemoglobin concentration measured at pre-donation screening (supported by mandatory full blood count at each donation and ferritin testing once a year)
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Through the application of national legislation transposing Directives 2002/98/EC, 2005/61/EC and 2005/62/EC and the inspection system established by the transposition of Directive 2002/98/EC.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	NAT testing for HBV, HCV and HIV is performed at each donation by CE marked diagnostic systems, either ID (Novartis diagnostic system) or 6-minipool (Roche diagnostic system). WNV NAT testing is performed at each donation of blood donors living in affected areas, during defined Summer periods.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	NAT testing for HBV, HCV and HIV at each donation. HCV NAT has been mandatory since 2002, HBV and HIV NAT since 2008.
3.1.3.2. If yes, please specify whether these are mandatory under	YES

national legislation for plasma donations.	
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Introduction of HBV, HCV and HIV NAT testing should be evaluated for adoption according to specific epidemiological assessments. WNV NAT testing should be regulated as an option to screen donors living in affected areas and to screen potentially exposed donors.
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	143
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	868
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	351
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Positive WNV NAT tests: 14 (fourteen)
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	European Proficiency Testing Studies, as already performed by EDQM, should be enhanced.
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	BC pathogen reduction/inactivation is not mandatory so far. Pathogen inactivation techniques are applied to a minor percentage of fresh frozen plasma for transfusion (riboflavin/UV, amotosalen/UVA, methylene blue, S/D) and platelets (riboflavin/UV, amotosalen/UVA). Two specific full Health Technology Assessment studies, respectively on FFP and PLT pathogen inactivation, are in progress at the National Blood Centre, in order to make adequate data and information available for eventual national regulatory decision-making.
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	By law, physicians must hold an academic specialty in or equivalent to transfusion medicine. By law, biologists must hold an academic specialty in or equivalent to clinical pathology. Newly employed physicians, biologists, nurses and medical technologists are specifically trained when assigned to a BE/HBB. All staff's skills must be periodically verified and, as necessary, additional training must be provided.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	The BE/HBB quality system is defined by specific national regulation compliant with Directives 2002/98/EC, 2005/62/EC and the applicable EU-GMPs (State-Regions Agreement of 16 December 2010).
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	By the relevant regulation (see 3.2.4.1) and the inspection system.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	By BE information technology systems.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	By the relevant regulation (see 3.2.4.1) and the inspection system.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is	Acces to all data is restricted to authorised operators (e.g. access to IT systems). Labels on blood components are anonymized and any information concerning blood donors is basically encrypted in

rendered anonymous so that the donor cannot be identified (Article 23)?	codes/barcodes.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	YES
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	The Guide is used as a complementary reference. The experience is quite positive.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation Accreditation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	No
4.3.2. If no, how many BEs have not received authorisation by [please provide date of record]?	All BEs are authorised according to preceding regulation. By 30th September 2013, about 6% BEs have been authorised according to the new regulation complying with EU Directives; as to the remaining BEs the new authorisation process is in progress and expected to be completed by 31st Dec 2014.
4.3.3. If no, when will this approval process be completed?	By 31st December 2014 (established by State-Regions Agreement of 16 December 2010 and Law of 26 February 2010, n.10).
4.3.4. If no, what is (are) the difficulties / reason(s) for the delay in the approval process?	a) Lack of homogeneous performance among Regions; b) the fulfilment of some GMP requirements results significantly demanding; c) excessive number of BEs.
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Regional health authorities are responsible for the authorisation and accreditation of laboratories performing donor testing.
4.6. How many laboratories performing donor testing are active within your country?	174 (75 of which perform NAT testing beyond serology testing)
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Regional health authorities.
4.8. How many hospital blood banks are active within your country?	313. NOTE: All BEs function also as hospital blood banks, being BEs hospital-based by law.
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	Extra rules are in place setting requirements concerning the activities of the vein-to-vein process not covered by the provisions indicate at 4.9, including the clinical activities performed by BEs.
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	1) Kedrion Biopharma SpA: - locations: a) Italy, Bolognana (Lucca); b) Italy, Sant'Antimo (Naples) - products: human albumin, IVIg, FVIII, FIX, Prothrombin complex, Antithrombin, Iper-immune Igs (including anti-Rho(D) and anti-HBV), Plasminogen concentrate, S/D plasma, FV forthcoming. - capacity: 1,100,000 Kgs - owners: national company - import/export: a) import plasma and intermediates from US and European countries; b) export plasma-derived medicinal products to 60 countries worldwide. 2) Baxter - locations: a) Italy, Rieti (plant performing only plasma fractionation and production of intermediate fractions); b) Italy, Pisa (plant performing only human albumin filling) - products: in Italy Baxter produces only intermediate fractions which are sent for further manufacturing to plants located in other European countries (e.g. Austria) - capacity: 700,000 Kgs - owners: international company - import/export: a) import plasma and intermediates from US and European countries; b) export only intermediate fractions.
4.10.2. If yes, please state the responsible authority within your country.	National Medicines Agency (Agenzia Italiana del Farmaco - AIFA)
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge	Regional health authorities.

of inspections.	
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	Regional health authorities inspectors: n.a. Nationally qualified inspectors: 113 (part-time); at least one nationally qualified inspector must be included in each regional inspection team.
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Hospitals
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	Inspections performed according to the new authorisation/accreditation system: 18 at BEs, 30 at Collection sites.
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	None.
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	Routine inspections performed according to the new authorisation/accreditation system: none.
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	3
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	None.
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	Not envisaged at the moment but it will be defined within 2014 in order to make the overall inspection system less demanding while ensuring the requested levels of quality and safety.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	None.
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Every two years, but a risk based approach will be introduced (See 5.5.1.1)
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	positive
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	positive
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	positive
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	No BE authorisation was suspended.
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	No BE was closed following inspections.
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	None.
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	No establishments performing only plasma collection exist in Italy.
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	HBBs coincide with BEs (see 4.8)
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	The Guide is used as a complementary reference. Experience is quite positive.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes

5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Ministry of Health and National Blood Centre: setting regulation. Regional health authorities: application of rules.
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	ALL
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	National mandatory requirements, verified during inspections.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	The national HV system is thoroughly web-based and managed by the National Blood Centre. The BEs collect data on SAR/E in hospitals and report to the Regional Blood Centres which, in turn, report to the National Blood Centre. The National Blood Centre elaborates data and publishes results. First national report (2008-2011) just issued.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	BEs and HBBs coincide (see 4.8)
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	Cases with high severity (grade 3-4).
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Diffusion of data.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	Recalls related to safety and quality of blood/blood components are mandatory but reporting to CA is not mandatory.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Rapid alert is part of the web-based HV system, performed by automated launch of emails to involved parties.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	The National Blood Centre notifies the Regional Blood Centres which, in turn, notify the respective BEs.
6.2.13. Do you notify alerts communicated via the blood national	Yes

vigilance system also to other national vigilance/alert systems?	
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Medical devices
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Tissues and cells
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	None
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Import of blood and blood components from other EU MS or third countries is a very rare event (very few cases concerning red blood cells bearing rare phenotypes). Import must be authorised by the Ministry of Health according to a specific procedure defined in the blood legislation. Imported blood and blood components must comply with national quality and safety requirements.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Import of plasma for fractionation is regulated according to EU provisions on medicinal products. The National Medicines Agency (Agenzia Italiana del Farmaco - AIFA) is the CA entrusted with authorisation to import and the relevant control measures.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	Concerning blood components for transfusion their import is a very rare event, basically related to the exceptional need for blood components bearing rare/specific phenotypes; they must be certified as compliant with the Italian quality and safety requirements which are preliminarily notified to the issuing organization(s); derogations are allowed upon specific risk assessment in case of vital need of the involved patient(s). Concerning plasma for fractionation see 7.2.
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	See 7.3.1.
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	ZERO.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Concerning plasma for fractionation, national plasma can be exported only to EU MS and only for contract fractionation purposes (being its commercialisation strictly prohibited). The National Medicines Agency (Agenzia Italiana del Farmaco - AIFA) is the CA entrusted with authorisation to export and the relevant control measures.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Export of blood components for transfusion must be authorised by the Ministry of Health according to a specific procedure defined in the blood legislation. Exported blood components must comply with national quality and safety requirements.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	ZERO, so far.
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	126 red blood cell units exported to Congo, Paediatric Hospital of Kimbondo, for humanitarian aid. 70 red blood cell units exported to the Republic of San Marino according to bilateral agreement.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	Yes
7.12.1. If yes, for which blood components (more than 1 answer possible)?	Red Blood Cells

7.12.2. If yes to Q. 7.12., what do you do with the surplus of blood or blood components?	The surplus is seasonal (mainly April-June / October-December); basically, it causes prolonged RBC turn-over, less frequently higher RBC discard.
7.12.3. If yes to Q. 7.12., would you be interested in concluding bilateral agreements with other MS in order to address the surplus?	Yes. Also planned surplus RBC production could be organized.
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	No penalties imposed so far.
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	No penalties imposed so far.
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	No penalties imposed so far.
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	a) Annex IV. Basic testing requirements for blood and plasma donations: introduction of mandatory HCV NAT testing in 2002 and mandatory HBV and HIV NAT testing in 2008. b) Article 9 (2): Responsible person: must be a licensed physician, specialist in transfusion medicine or equivalent discipline, with at least 5 years of post-graduate full-time service in a BE.
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	The main difficulty was represented by the fact that the organisation of BEs assumed by the Directives is significantly different from the Italian organisation (see 4.8). Issues for a potential revision of Directive 2002/98/EC: a) Article 3(e): BEs' responsibility for processing, storage and distribution of blood and blood components when they are NOT intended for transfusion should be clarified, considering that most BEs produce and release – by the same processing, storage and distribution - plasma which can be intended both for transfusion and for fractionation; b) Articles 5(1) and 9(1): same comment as for article 3(e); in particular: concerning article 9(1), who should be responsible for processing, storage and distribution of blood and blood components when they are NOT intended for transfusion, as in the case of plasma for fractionation? c) Article 8(1): a reflection on the hypothesis/opportunity of defining basic common requirements for blood Competent Authorities' functions should be done, particularly as concerns requirements for inspectors, third-party independence of inspections, common definitions of and common schemes for BEs licensing, authorization, accreditation procedures; d) Whereas (29) and Article 21: given the important scientific and technical advances in blood testing, particularly as concerns HCV, HIV and HBV NAT, and the evidence on window period shortening associated to these tests, a reflection on the introduction of NAT testing for HCV, HIV and HBV (excluding autologous donations) should be done, supported by specific epidemiological assessments.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	As already reported at the Blood CAs meetings, in Italy the following measures for the prevention of WNV transmission by blood mainly consist of: a) introduction of NAT testing for all donors resident in the areas recognised as affected by the national WNV surveillance plan issued by the Ministry of Health, during seasonal periods in which vector mosquitoes are active (July-November); b) 28 day deferral of donors having been for at least one night in the affected areas during the above seasonal periods; alternatively, these donors can be admitted to donate provided their donations are tested by WNV NAT. Inter-institutional and multidisciplinary cooperation as well as adoption of the EC WNV preparedness plan are of paramount importance at national and international level to make preventive plans successful.
8.5. Which other communicable diseases are of relevance to you?	Other vector-borne diseases from Arboviruses transmissible by blood require adequate epidemiological surveillance.
8.6. Do you consider bed-side techniques of collection, processing	Yes

and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	None
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	NA

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):	www.zva.gov.lv
1.1.5. Website:	www.zva.gov.lv
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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.).	State Agency of Medicines is the state institution under supervision of the Ministry of Health of the Republic of Latvia, that carries out evaluation, marketing authorisation, monitoring, control and regulation of distribution of medicines and medical devices in 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.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	No regional authority
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	10
2.1.2. How many of the BEs are satellite sites?	1
2.1.3. How many of the BEs are mobile sites?	3
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	36113
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	24108
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	12005
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	55590
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	During the year 2012 there was no plasma collected by apheresis
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	800 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	3461
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	180 ml

2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	0
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	1
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	During the year 2012 there was no plasma collected by apheresis
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Donor evaluation/selection form accessible in Blood establishments.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Visits at the Blood establishments and Blood center. Analysis of the mandatory documentation
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	We accept all the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC .
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Identification of persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Low Haemoglobin levels in donor's blood
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	It is maintained by the National Blood Servise- PROSANG network.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	Data not available
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	All donor samples are tested in the laboratory of the National Blod Service.
3.1.2. Do you use NAT technology for routine testing blood or blood	Yes

components in your Member State?	
3.1.2.1. If yes, please specify how and how often NAT technology is used?	All donations with the negative screening results are tested by NAT technology.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	No
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	12
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	52
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	205
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	No
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Blood establishments can delegate some of the responsible person's tasks to other persons qualified by training and experience to perform these tasks.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	• Visits of the blood establishments, Blood center and hospital blood banks • Audits of the documentation - diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences and evidence of practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution Regular training of the staff (certificate or other evidence).
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	Each BE and hospital blood bank establishes and maintains a quality system based on the principles of good practice.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	• Visits of the BEs and hospital blood banks. • Audits of documentation on operational procedures, guidelines, training and reference manuals, and reporting forms.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	PROSANG network Records
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	• Visits of Blood establishments and hospital blood banks • Audits of documentation – SOP and records

3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	• Visits of Blood establishments and hospital blood banks • Audits of documentation • Each operator processing personal data must register with the Data State Inspectorate.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	ISBT 128
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	These recommendations provids eksperts with a set of standarts and principles relating to the preparation, use and quality assurance of blood components
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Designation Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	10 www.zva.gov.lv
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Latvian National Accreditation Bureau
4.6. How many laboratories performing donor testing are active within your country?	1
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	State Agency of Medicines of Latvia
4.8. How many hospital blood banks are active within your country?	54
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
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 (full time equivalents) are responsible for inspecting BEs?).	2
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Pharmaceuticals (including plasma derivatives) Advanced therapies
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	4
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to	3

31/12/2012).	
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	Type of Inspections is selected depending on the particular situation and information available to CA. Type of Inspections is selected depending on the particular situation and information available to CA.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	4
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Once in 2 year period
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	4
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	0
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	No any other outcome
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	SOP in place for inspecting hospital blood banks.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	SOP in place for inspecting hospital blood banks. They are inspected once in 2-3 year.
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	These recommendations provids experts with a set of standarts and principles relating to the preparation, use and quality assurance of blood components.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections	Yes

with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Traceability is ensured by the National Blood Service.
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	• Inspections of the blood establishments and center. • Inspection of the documentation and computerized system
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Senior expert of Pharmaceutical Activities Compliance Evaluation Department is responsible of data collection, documentation, analysis, corrective and preventive actions. Also for issue of Rapid Alert System (if necessary) at a national level or communication to EU CIRCA platform.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	All hospital blood banks using application forms have to report any SAR/SAE - relevant information to CA and Blood establishment/ Blood center engaged in the donation, preparing, testing, processing, storage and distribution of blood components in order to facilitate traceability and ensure quality and safety.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	Evaluate suspected serious adverse reactions according to the imputability levels (likely, probable, certain) and specify clinical outcome.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	No
6.2.8.2. If no, why not.	No SAR/SAE was reported
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012?	No cases

Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	All blood establishments using application forms have to report any SAR/SAE cases to CA
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	CA using SOP to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	No
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	CA receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs and medical devices
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	National regulations require that blood components are not imported
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	National regulations require that blood components are not imported
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	National regulations require that blood components are not imported
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Manufacturing license for the manufacture of medicinal products is required. export to another MS for fractionation is regarded as Outsourced activities and are evaluated during GMP inspections.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	We do not export blood and blood components for transfusion to EU Member States or third countries.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No

8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	None
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	No
8.5. Which other communicable diseases are of relevance to you?	None
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	Yes
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	None
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	None

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:	Aeulestrasse 51 9490 Vaduz Liechtenstein
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:	
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices Other
1.1.6.1. If other, please specify.	reimbursement of pharmaceuticals and medical devices, public medical office, health prevention and promotion
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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.).	n/a
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	n/a
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1
2.1.2. How many of the BEs are satellite sites?	0
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	5
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	no
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	no
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	5
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450ml +/- 50ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	na
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	na
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	na
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	na
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	none

2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	1
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	none
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	verification during regular inspections
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	The BE has to have relevant procedures in place, describing the handling of abnormal findings. Procedures and records are verified during the regular inspections.
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Every criterium is an important part of the whole. There is not a criterium more important than another.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Persons whose behaviour /activity places them at risk of acquiring infectious diseases that may be trasnmitted by blood
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	- previous, current sexual partners with HIV - new sexual partners different sexual partners within the last 12 months MSM sex-workers sexual partners who is sex worker or had MSM
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	na, only autologous pre-deposit donations
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	by inspections
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	is not compulsory for autologous donations
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	No
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No

3.1.5. Do you have a system of centralised collection of data with test results?	No
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	persons must be trained and qualified for this support of validated IT systems handling of deviations must clearly be defined
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	training must be recorded training records are subject of regular inspections
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	it is required SMF or Quality Manual written guidelines and SOPs qualification/calibration-ystem for equipment (incl. maintenance) documentation system (procedures and records) training and qualification of personnel system to handle deviations, recalls, changes, look-backs, post-donation information, hemovigilance
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	maintenance, storing and archiving of documents and records must be defined in SOPs verification during inspection
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	paper-based storage
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	temperature monitoring of storage equipment temperature alert system regular checks of temperature sensors qualification of storage equipment transport in insulated boxes (only short time transports within Li)
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	na (autologous pre-deposit donations only)
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	No
3.2.9.2. If no, why not?	na: homologous blood and blood components are imported from Austria which use their own code
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	the separation of principles from standards is confusing and of no value (inspectors' opinion)
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre

4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	1, since 2013 revoked
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Amt für Gesundheit (authorisation for lab) and Swissmedic (donor testing)
4.6. How many laboratories performing donor testing are active within your country?	1
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Amt für Gesundheit
4.8. How many hospital blood banks are active within your country?	1
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Arzneimittelkontrolle des Amtes für Gesundheit in charge of coordination, inspections delegated to Swissmedic by agreement
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	6 Swiss inspectors available
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	2012:0
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	2012:0
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	0
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	We get the inspectors of Swissmedic according to schedule
5.5.3. How many BE have been inspected at least twice in the last 3 years?	2
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	na
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	na (no inspections in 2012)
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	na
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings	na

were noted?	
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	na
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	na
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	na, no blood inspection carried out in 2012
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	No
5.8.1. If no, please explain.	The NCA mandate includes many different activities (p.e. reimbursement, health promotion etc). For the issues of blood etc. only 2 persons are qualified.
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	according to directive 2002/98/EG
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	We coordinate the inspections and perform enforcement measures if necessary. The inspection is carried out by Swissmedic inspectors (agreement)
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	since the structuring between principles and standards it is not so simple anymore; bad experience
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	No
6.1.1.1. If no, why not?	we have only autologous pre-deposit donations in Liechtenstein
6.1.2. Which is the CA for ensuring traceability in your Member State?	na
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Only paper records
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	by inspections
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes

6.2.1.1. If yes, please give a short description of the system.	SARE reported for Austrian blood/components are reported to the Austrian manufacturer ... (and only for information to the AG) SARE of the autologous donations, and SARE at the hospital are to be reported also to the Amt für Gesundheit and Swissmedic
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	The (only 1) Li-hospital gets the blood/components from the Austrian hospital LKH Feldkirch by agreement. This agreement requires the reporting. During inspections reporting is checked.
6.2.7. Do you perform root cause analyses of the SARE?	No
6.2.7.2. If no, why not?	was not necessary till now
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	No
6.2.8.2. If no, why not.	Should we?
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	0
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	by fax and phone
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	only if necessary, by fax and phone
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	No
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	No
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	we have only one national vigilance/alert system contact point located in the Amt für Gesundheit
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	only import form the Austrian hospital LKH Feldkirch, Austria, is accepted, the import has to be authorised
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	na
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	na
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes

7.4.1. If yes, please specify.	if necessary
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	The Austrian Red Cross, section Vorarlberg, is allowed to collect blood in Liechtenstein. An authorisation of Liechtenstein is needed.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	na
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	na
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	na
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	na
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Being in the Customs Union with Switzerland we already had good legal requirements for blood in place. We had to take over the EU regulations which means now that we have to do good explaining (in the inspections...)
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	No
8.5. Which other communicable diseases are of relevance to you?	Dengue Fever, Chagas, Malaria
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	partly in the Li-Ärztegesetz (consent)
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	-
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	we have no experience with industrial processes in Li when applied on blood components

A.1.18. Survey response Lithuania

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health
1.1.2. Address of NCA 1:	Vilniaus str. 33, LT-01506 Vilnius, Lithuania
1.1.3. Telephone (central access point):	(+370) 5 266 1400
1.1.4. E-mail (central access point):	ministerija@sam.lt
1.1.5. Website:	www.sam.lt
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	Coordination of blood donation/transfusion activities
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	State Health Care Accreditation Agency under the Ministry of Health
1.2.2. Address of NCA 2:	Zalgirio str. 92, LT-09303 Vilnius, Lithuania
1.2.3. Telephone (central access point):	(+370) 5 261 51 77
1.2.4. E-mail (central access point):	vaspvt@vaspvt.gov.lt
1.2.5. Website:	www.vaspvt.gov.lt/en
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection
1.3. National Competent Authority 3?	No
1.4. 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.).	Ministry of Health is responsible for coordination and control of blood donation / blood transfusion activities. State Health Care Accreditation Agency under the Ministry of Health is responsible for: Licensing of the health care organizations (blood establishments including) Market surveillance of medical devices Supervision and control of quality of health services (blood establishments' services including) Special department / unit in charge of inspections and control measures of BEs has not been established yet. Staff working on implementation of blood directives, haemovigilance is responsible for other domains as well.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	4
2.1.2. How many of the BEs are satellite sites?	2
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	56332
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	32962
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	22922
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	79367
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml ± 50
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	11

2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	650 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	1049
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	> 40 ml per 60x109 of platelets
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	Multicomponent 2221
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	6
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	1
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Donor questionnaire is approved by the Ministry of Health
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	By organization of BEs inspections, desk-based analysis of the mandatory documents.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	According to the order of the Ministry of Health, self-exclusion by a donor procedures are defined in the documents of the BEs
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Hemoglobin levels in donor's blood Infectious diseases (hepatitis B, hepatitis C, HIV)
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Item 2.2.2 First section - tattoo and acupuncture performance time and sterility Second section
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	In item 2.2.2 behaviour at risk of acquiring infectious diseases that may be transmitted by blood should be listed
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	According to international recommendations (CoE, WHO, etc.)
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	The main causes of temporary deferral: Low haemoglobin or platelets level High blood pressure Tattoo Usage of medications The main causes of permanent deferral: Hepatitis B and C positive test results Syphilis positive test results Serious diseases (cardiovascular, CNS, gastrointestinal, immunological, metabolic)
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	The data on deferrals are collected in the Blood Donors' Registry.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	561 from June 1 to December 31, 2012
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to	No

allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	By organization of BEs inspections, desk-based analysis of the mandatory documents.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	HIV NAT, HBV NAT and HCV NAT are mandatory for every blood and blood components donation
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Yes, HIV NAT, HBV NAT and HCV NAT.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Yes, HIV NAT, HBV NAT and HCV NAT.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Additions to basic testing requirements: HIV NAT, HBV NAT and HCV NAT testing
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	29
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	167
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	482
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	None
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Mirasol technology is used for approx. 3 % of platelets.
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	By organization of BEs inspections, desk-based analysis of the mandatory documents.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	A quality system for BEs based on the principles of good practice is mandatory by law.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and	By organization of BEs inspections, desk-based analysis of the mandatory documents

Article 6)?	
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Mandatory by law.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Storage, transport and distribution requirements of blood and blood components are defined in the order of the MoH.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	By organization of BEs inspections, desk-based analysis of the mandatory documents
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Not mandatory
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	This Guide is partly transposed into the order on requirements to the preparation and quality assurance of blood components.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	4 BEs have been authorized / licensed:
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	State Health Care Accreditation Agency under the Ministry of Health
4.6. How many laboratories performing donor testing are active within your country?	5
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	State Health Care Accreditation Agency under the Ministry of Health is responsible for licensing of hospitals.
4.8. How many hospital blood banks are active within your country?	47
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Ministry of Health is responsible for coordination and control of blood donation / blood transfusion activities. State Health Care Accreditation Agency under the Ministry of Health is responsible for: Licensing of the health care organizations (blood establishments including) Market surveillance of medical devices Supervision and control of quality of health services (blood establishments' services including) Special department / unit in charge of inspections and control measures of BEs has not been

	established.
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	It is difficult to define staffing responsible for inspecting BEs because the same employees are responsible for supervision and control of various health care services (BEs services including).
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Medical devices Hospitals
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	12
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	16
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	0
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	5
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	3 inspections due to a whistle-blower
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	The planning of inspections is based on following: Number and severity of non-compliances observed during the previous inspections; SARs and SAEs notified since the previous inspection Recalls of blood components notified since the previous inspection Complaints of consumers of blood components received by CA since the previous inspection
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	4
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	BE's affiliates are inspected at least every two years
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Licenses issued
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	-
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	-
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	-
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	-
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	-
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes

5.9. Is a system in place for inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	This Guide is partly transposed into the order of the MoH on requirements to the preparation and quality assurance of blood components.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Ministry of Health
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By organization of BEs inspections, desk-based analysis of the mandatory documents.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	According to the order of the Ministry of Health, blood establishments, hospital blood banks or hospitals where transfusion takes place shall notify to the Ministry of Health all relevant information about serious adverse reactions and/or serious adverse events. Reporting establishments evaluate SAR/SAEs to identify preventable causes within the process. Blood establishments have in place a procedure to withdraw from distribution blood or blood components associated with notification mentioned above.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood	Yes

and blood components (Art 5.1)?	
6.2.6.1. If yes, please provide a brief description.	According to the order of the Ministry of Health, hospital blood banks shall report about SAR/SAEs to the blood establishments which distributed the blood and blood components as well as to the MoH.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	Root cause analysis is performed for SARE imputability level 2 or 3.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Written information about SAR/SAEs recorded at EU level is forwarded to the BEs
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	0
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	In case of a national rapid alert BEs are notified via emails and phone calls
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	In case of rapid alert at European level BEs are notified via emails
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Medical devices
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	no
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	According to the order of the Ministry of Health, imported blood components intended for transfusion shall meet equivalent standards of quality and safety as laid down in the blood directives transposed into Lithuanian law
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Blood components for fractionation have never been imported to Lithuania
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	International standards
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	Blood components for transfusion have not been imported to Lithuania from third countries in 2012.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	Blood components for fractionation have not been imported to Lithuania from third countries in 2012
7.7. Which rules exist for the authorisation and control of the export	According to the order of the Ministry of Health, blood components

of blood and blood components for fractionation to EU Member States or third countries?	for fractionation intended for export to the European Economic Area member states shall meet equivalent standards of quality and safety as laid down in the blood directives transposed into Lithuanian law and requirements which are given in the general monograph Human plasma for fractionation (0853) of the European Pharmacopoeia (Ph. Eur.).
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	According to the order of the Ministry of Health, blood components for transfusion intended for export to EU Member States or third countries shall meet equivalent standards of quality and safety as laid down in the blood directives transposed into Lithuanian law.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	Blood components have not been exported for fractionation from Lithuania to third countries in 2012
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	Blood components have not been exported for transfusion from Lithuania to third countries in 2012.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	Yes
7.12.1. If yes, for which blood components (more than 1 answer possible)?	Plasma
7.12.2. If yes to Q. 7.12., what do you do with the surplus of blood or blood components?	Search for realization of surplus plasma
7.12.3. If yes to Q. 7.12., would you be interested in concluding bilateral agreements with other MS in order to address the surplus?	Yes
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	Yes
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	Due to non - compliance with testing documentation requirements
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	None
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	Revoke of licence
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Issues to be addressed: deletion in Annex III Labeling requirements „composition of anticoagulant and/or additive solution“
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Temporary deferral 28 days after leaving an area with ongoing transmission of WNW to humans
8.5. Which other communicable diseases are of relevance to you?	HBV, HCV, HIV, tuberculosis
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the	Bed-side techniques of collection and processing of blood and blood

competent national authority?	components are not applicable in Lithuania
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	No

A.1.19. Survey response Luxembourg

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Health Directorate - Inspection Sanitaire
1.1.2. Address of NCA 1:	5a, rue de Prague L-2348 Luxembourg
1.1.3. Telephone (central access point):	+352 247-85650
1.1.5. Website:	http://www.ms.etat.lu
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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 Inspection Sanitaire is a department of the Health Directorate of the Ministry of Health. 1 senior inspector and 1 trainee inspector are part of the NCA. The Inspection Sanitaire is depending of the Government. The budget is undefined and is depending on the incoming costs.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	n/a
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1
2.1.2. How many of the BEs are satellite sites?	0
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	13704
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	9364
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	1106
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Ca.20-30% of the donors are coming from other countries. Most of them from France, some others from Belgium and Germany. Unfortunately numbers are unavailable. Donors from Luxembourg who are donating in other countries is quite rare.
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	20631
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	500
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	3132
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	200
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	679
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	254-380
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	0
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	1
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	1

2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	5 documents upoloaded, all exists in german, french and english language
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	With a personal interview for the medical problems and with letters for all biological problems
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	infectious diseases including temporary exclusion for any infection
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	sexual behaviour of the donors as they provide the information which can not be verified.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Sex with an HIV positive person. Sex with a person who injects or has injected drugs People are asked if they practise prostitution. Sex with a person who practise prostitution Sex with a person who regularly receives blood transfusion Sex with a person who originates from Africa For men: Sex with another man before 1977 Fro women: Sex with a man who had sex with another man before 1977
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	Raising the maximum age up to 70 years (in Luxembourg since August 2012)
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	No response after convocation (581 persons in 2012) personnel reason (295 persons in 2012) age criteria (64 persons in 2012) medical criteria: neoplasia (33 persons in 2012) heart problems (13 persons in 2012) bad veins (10 persons in 2012)
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	IT data: MAGIC (system of the BE of Luxembourg)
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	1219 persons (567 men, 652 women)
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Control of the SOP's during the inspection

3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	for all donations: PCR HIV, HVA, HVB, HVC and Parvovirus B19
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	not mandatory under national legislation for whole blood donations, law only sais that additional tests can be required
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	not mandatory under national legislation for whole blood donations, law only sais that additional tests can be requires
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	0
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	3
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	0
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis: 1
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	only for FFP, plasma SD is used
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Dr.Paul Courrier Médecin biologiste détenteur du DUTS 3 years of exercise EFS
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	internal and external training practical training in each department supervised by quality managment
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	internal managment supervised by a quality committee
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	accessible on Intranet QUALIOS (R) and a copy is ranged in a secured manner by the documentalist of the BE
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	- electronical form - paper form - on CD, in MAGIC (system of BE of Luxembourg), on optical disc UDO
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	quality managment ensured by SOP's
3.2.8. How do you ensure that all data, including genetic	personnel logins and passwords for informatical access where all

information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	information is available anonymisation with barcodes from the beginning of the donation All people working in BE have a professional secret The data collection has been authorised by the national comittee of data protection (ref. T007125)
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Yes
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	very good, it is used as a GMP
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Designation Authorisation Accreditation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	1
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Health Directorate - Inspection Sanitaire
4.6. How many laboratories performing donor testing are active within your country?	1
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	legal agreement by minister of health
4.8. How many hospital blood banks are active within your country?	9
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Health Directorate - Inspection Sanitaire
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	2
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	0
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	0
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of	0

inspections that were conducted and how many (e.g. due to a whistle-blower).	
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	For any problem, The NCA is informed and will plan, if necessary an onsite inspection
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	Not concerned on inspections of BE's working with medicaments on humans
5.5.3. How many BE have been inspected at least twice in the last 3 years?	0
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	No mobile and satellite collection site in Luxembourg
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	No inspections in 2012
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	No inspections in 2012
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	No inspections in 2012
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	No inspections in 2012
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	No inspections in 2012
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	No inspections in 2012
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	HBB will be inspected starting end of 2013 in the same way than the BE
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	As NCA we have to inspect either BE and HBB
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	inspections will only start end of 2013, but the Guide will be used
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member	Directorate of Health - Inspection Sanitaire

State?	
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	for homologous, autologous and paediatric RBC concentrate, plasma apherisis concentrate, mix of platelets concentrate, homologous and autologous fresh frozen plasma
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	IT data
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Notification is given by the hospital to the BE and/or NCA, further investigation will be done by BE or/and NCA
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	notification form is part of the legislation
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	infectious diseases death
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	transmission of all information
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	0
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	direct information from NCA to BE
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	direct information from NCA to BE
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Other
6.2.13.1.1. If other, please specify.	All departments are part of the Health Directorate, so everybody who needs the information will get it.
6.2.14. Do you also receive alerts via other national vigilance/alert	Yes

systems, such as for tissues and cells, organs, or medical devices?	
6.2.14.1. If yes, please specify.	See 6.2.13.1.1 = idem
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Convention of approvisioning is done between the BE of Luxembourg and the EFS Lorraine/Champagne in France
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Importation only done from EFS Lorraine/Champagne in France (less than 10 units per year), only from voluntary donors
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	None
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Plasma Masterfile Octopharma on the way of realisation: Plasma Masterfile CAF-DCF Belgium
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	None
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	None
8.4. During the last years there have been outbreaks of West Nile	Yes

Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	
8.4.1. If yes, please provide us with detailed information.	Temporary deferral for people who have been travelling to countries, where outbreaks have been. Control of vectors of West-Nile-Virus in Luxembourg (mosquitoes)
8.5. Which other communicable diseases are of relevance to you?	None
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	Yes
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	None

A.1.20. Survey response Malta

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Superintendence of Public Health
1.1.2. Address of NCA 1:	Superintendence of Public Health SLH - OPD - Level 1 St. Lukes Road G' Mangia
1.1.3. Telephone (central access point):	+00356 25953302/25953328
1.1.4. E-mail (central access point):	healthstandards.sph@gov.mt
1.1.5. Website:	https://ehealth.gov.mt/HealthPortal/public_health/publichealthregulation/introduction.aspx; https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/blood_bloodcomponents.aspx
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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.The Health Care Standards Directorate which is accountable to the Superintendent of Public Health in managing issues related to the regulation of subtances of Human Origin. There is 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. Inspections of the blood establishment in Malta have till now been carried out by a foreign inspector as a lead inspector assisted by two GMP inspectors from the Malta Medicines Authority.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1 (One)
2.1.2. How many of the BEs are satellite sites?	2 (Two)
2.1.3. How many of the BEs are mobile sites?	One
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	11394
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	2905
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	771
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	16995
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	475mls
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	Nil
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	Not applicable

2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	469
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	300mls
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	nil
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	One
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	One
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Copy is found in the uploaded document below.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	The mandatory testing is done. Any positive results are traced so that the donor can be contacted and the results explained by a medical doctor and any necessary relevant referrals made and actions taken.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	If the person self excludes himself, he is not registered into the system
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	It is not possible to answer this question since in specific circumstances all factors are important.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	The assessment of risky sexual behaviour.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	Changing the haemoglobin levels
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	High risk sexual behavior including MSM, multiple sexual partners, new sexual contact within the last 6 monthss.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Low Hb, Weight < 50kg, Medical Reasons (History, Blood Pressure).
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	Since in Malta there is only one blood establishment, this establishment would have all the national data.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	The deferral rate is that of 25.5%.
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No

2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	The laboratories and tests are also assessed during the inspection of the blood establishment.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	NAT testing is expensive and the benefit to cost ratio is minimal.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Anti HBc testing is performed.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Not applicable as there is no plasmapheresis in Malta.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	0
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	0
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	Two (2)
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Two (2) positive tests for syphilis
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	Nil
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	The Licensing Authority checks the availability of formal qualifications and requests documentation of regular training and proficiency testing of the personnel. Qualification and training of the personnel is part of the quality system and it is inspected during the inspections.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	The qulaity system is based on GMP and GLP
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	These are inspected at the inspection by asking for the documentation and for written SOPs
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	The information is kept for 15 years both in the form of paper

	records and of electronic records. Blood establishments have to have a documentation retention policy in place.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Yes this system is inspected during the inspection for the purpose of licensing. There has to be a fully validated and auditable sytem of storage, transport and distribution in place.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	The donor is given a unique identifier number. All donations are anonymised.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	No
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	The guide gives a lot of valuable information based on best practices and is continously updated.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	One licenced establishment
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	The same Licensing Authority that licences blood establishments (Superintendence of Public Health)
4.6. How many laboratories performing donor testing are active within your country?	One
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	The same Licensing Authority that licences blood establishments (Superintendence of Public Health)
4.8. How many hospital blood banks are active within your country?	Two public hospital blood banks
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	The Superintendent of Public Health
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	Three
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Pharmaceuticals (including plasma derivatives)

5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	One
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	One
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	Nil
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	0
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	The aim is to have a general inspection every two years and follow-up themed inspections in between to ensure that corrective and preventive actions were taken on any identified deficiencies.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	0
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	0
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	0
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	Nil
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	It gives valuable information on good practice and provides a basis for inspection against these best practice guides.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	

6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	The Superintendent of Public Health
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	For all blood components
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By randomly asking for tracebility records of a randomly selected donor
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Serious adverse events and reactions collected by wards and hospitals are first reported to the hospital blood bank which investigates and decide whether the reactions/events are reportable to the blood establishment that distributed the blood and to the Competent Authority. The blood establishments too report any reportable events and reactions to the Competent Auithority.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	End users (transfusion nurses, etc) report any SAE's and SAR's to the blood bank that issued the blood which in turn investigates the cause and reports to the blood establishment that distributed the blood and to the Competent Authority.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	Root cause analysis is carried out even in the case of near misses.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Annual National Haemovigilance reports for Malta are published online . Such reports contain a section about the Maltese reports on SARs and SAEs that are reportable at EU level according to the Directives and the Common Approach Document
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	There were no recalls.

6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	The Competent Authority has a Haemovigilance Unit that is also responsible for forwarding both National alerts to the Blood Establishment and other stakeholders and is also responsible for alerting such establishments on relevant alerts at an EU level received through the CIRCABC system.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	The rapid alert received through the CIRCABC is forwarded through the National Rapid Alert system to all stakeholders for which it is relevant including blood establishments, blood banks, clinical end users, epidemiologists, microbiologists, infectious disease control unit, Medicines Authority, Tissue and Cell establishments and organ transplant centres (if relevant) and to the Comptent Authority responsible for medical devices (MCCAA) (if relevant)
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health Other
6.2.13.1.1. If other, please specify.	End users (hospitals/wards, etc).
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	The Competent Authority responsible for haemovigilance systems is also responsible for national vigilance/alert systems for Tissues and Cells and Organs.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	Nil
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	No person shall import into Malta any blood or blood components, including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products, from a country or territory outside the European Community which does not meet standards of quality and safety equivalent to those laid down in Annex V of Directive 2004/33/EC and any amendments thereto.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Not applicable- there is no blood fractionation in Malta.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Not applicable. Blood is not exported for fractionation.
7.8. Which rules exist for the authorisation and control of the export	Export can only occur through a blood establishment authorised to

of blood and blood components for transfusion to EU Member States or third countries?	do so after ensuring equivalence of standards.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	Not applicable
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	Nil
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	Not applicable
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	Nil
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	No
8.5. Which other communicable diseases are of relevance to you?	Any communicable disease that can potentially be contracted by potential donors while travelling and subsequently inroducing any such diseases in Malta.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	The National Competent Authority has to be informed about this procedure and it in turn will check that adequate safeguards are in place.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Nil
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Nil

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 van 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)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Health Care Inspectorate (Inspectie voor 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. What are the role/tasks of the NCA? (more than 1 answer possible)	Inspection Haemovigilance
1.3. National Competent Authority 3?	No
1.4. 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.).	NCA1 Ministerie van Volksgezondheid, Welzijn en Sport (VWS, Ministry of Health, Welfare and Sport); responsible for policy making; divisions Public Health, Curative Care, Long-term Care; staffing: total 4200 fte's, 8 dedicated to EU (legal) affairs; budget ca € 18 billion; 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 blood; staff for international/European inspection and vigilance: 2 senior, 1 junior, 1 support, 1 legal.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	N/a
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	1
2.1.2. How many of the BEs are satellite sites?	-
2.1.3. How many of the BEs are mobile sites?	-
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	379.846
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	295.891
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	37.468
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Only very small numbers from and to neighbouring countries.
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	498.117

2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	500 ml.
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	321.184
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	650 ml.
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	4723
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	Depending on trombocytes-count.
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	Not under Blood Directive.
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	1
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	1
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Files too large.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Data is recorded in digital database. Reporting of abnormal findings to the donor is regulated in BE's standard operating procedures and documented in the donors' dossier.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	Donor can inform BE after donation by telephone about circumstances that might disqualify him/her as donor.
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	all
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Criteria concerning behaviour.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	delete: in case HBV-NAT screening is performed, HBsAG screening can be cancelled; delete: WNV-NAT in stead of temporary deferral after vist to affected area; replacement: update criteria for Malaria, Q-fever;
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	-having sex for which donor received drugs or money; -during last 12 month having sex for which donor paid with drugs or money; -during last 12 month having sex with IV-druguser; -during last 12 month having sex with person originating from region with high AIDS prevalence; -during last 12 month having sex with HIV or HTLV I/II infected person; -during last 12 month having sex with person with venereal disease or hepatitis; -during last 12 month having sex with person suffering from haemophilia -MSM: Man

	who has had sex with other men -Female having had sex during last 12 month with man who has had sex with other men.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	With more people ageing healthy, donor population could be increased when we replace age criteria with medical condition criteria.
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Donor deferral in 2012: Cardio Vascular Diseases 2158, malignity 1467, blood transfused in the past 1634, difficulties during venapunction 877, Hb value 736, Anti-HBc/Anto-HBs 707.
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	One BE, so one database
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	12.160
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Tests are performed by BE's laboratories, wich are accredited and inspected regularly
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	Highly automated NAT testing of all donations on HIV, HBC, HCV. Testing on pools of donations, in case of positive results the pool will be further tested untill the individual positive donation is found.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Not mandatory.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Not mandatory.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	Addition to last sentence: "Additional tests OR ALTERNATIVE COMBINATIONS OF TESTS may be required for ..." ; This will allow the listed tests to be omitted if another test or combination of tests makes the listed test redundant.
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	2
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	19
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	4
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Lues: 15 HTLV I/II: 2
3.1.6. Do you have any additional comments on testing (e.g.	No addition to remarks above.

international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Irradiation: plasma Washing: all products Solvent Detergent: plasma
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Supervision of the processing of blood and blood products is delegated to other qualified persons.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Checked during on-site inspections.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	Quality system in place.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Checked during on-site inspections.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Records are kept in hard copy and in digital database, and process is regulated in BE's Standard Operating Procedures.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Process is regulated in BE's and hospitals' Standard Operating Procedures.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Coding system.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	No, but system is broadly implemented.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	The BE in the Netherlands consider the Guide of the Council of Europe as a field guide. National guidance documents regarding quality and safety of blood and blood products are based on the CoE-Guide.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Designation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	1, by 31/12/1997
4.4. Have authorisations been revoked or suspended by the	No

competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	NCA1: Ministry of Health, Welfare and Sport
4.6. How many laboratories performing donor testing are active within your country?	1
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Hospital blood banks are NOT authorised. Hospital bloodbanks in The Netherlands are regulated by a general Law on Quality of Health Care Institution.
4.8. How many hospital blood banks are active within your country?	circa 100
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	Hospital bloodbanks in The Netherlands are regulated by a general Law on Quality of Health Care Institution.
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	Sanquin;
4.10.2. If yes, please state the responsible authority within your country.	NCA1: Ministry of Health, Welfare and Sport
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	NCA2: Health Care Inspectorate
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	3
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Pharmaceuticals (including plasma derivatives) Advanced therapies Medical devices Hospitals
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	27 collection sites as part of BE and 2 BC in 2012
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0 in 2012
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	27 collection sites as part of BE and 2 BC in 2012
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	At the moment we manage the 2-year frequency, but we experience little result compared to the time and effort.The frequency could be extended to 3 or 4 years combined with a risk-based approach.
5.5.3. How many BE have been inspected at least twice in the last 3 years?	all (=1)

5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	mobile randomly, fixed collection sites every 2-year.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Outcome of inspections in 2012: 29 authorisations renewed
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	See 5.6.1
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	See 5.6.1
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	N/a
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	25
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	We use it as useful background information
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	NCA2: Health Care Inspectorate
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	All components.
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	This is regulated in BE's standard operating procedures and quality system.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply	Yes

to hospital blood banks?	
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	A delegated institute (TRIP) collects and analyses all SAR/E.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	No
6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	http://www.tripnet.nl/pages/nl/documents/MELDINGVANEENBLOEDTRANSFUSIEREACTIE.pdf
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	Delegated to institution (TRIP).
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Implemented in national regulation
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	In all SAR/E root cause analysis is performed.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Feedback to the BE is regulated in written standard operating procedures of NCA2 (IGZ).
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	In the Netherlands 394 recalls were issued in 2012, mostly because of withdrawn donations and positive BactAlerts.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Only one BE in the Netherlands, we contact them regularly.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	We contact the BE by email and telephone.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	see 6.2.13.1.
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	no
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	No import in the Netherlands for transfusion, we are self-sufficient. Import is restricted to Dutch BE (Sanquin).
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for	No import for fractionation.

fractionation from EU Member States or third countries?	
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	No import.
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	No import. But any imported product has to comply to national standards.
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	No plasma imported in The Nertherlands for fractionation from third countries. Plasma from Viropharma/US is processed in NL, but the whole batch is exported back to US.
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	No specific rules; plasma is only collected for fractionation in The Netherlands.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Only authorised Blood Establishment is allowed to export for transfusion. Exception for export is made for Military Blood Bank that supplies the Dutch troops in third countries.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	This regards export for UN-missions; no data available.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	-
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	-
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	-
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	To be discussed
8.4. During the last years there have been outbreaks of West Nile	Yes

Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	
8.4.1. If yes, please provide us with detailed information.	Exclusion criteria for donors who have visited WNV affected areas
8.5. Which other communicable diseases are of relevance to you?	Q-fever; Hep E;
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	National Law on quality of health care institutions NCA2: Health Care Inspectorate
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	- blood samples used for educational purposes/research - "blood" tears - therapeutic blood cells
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	inactivation steps, pooling for further processing.

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:	PO Box 7000 St Olavs plass, N-0130 Oslo, Norway
1.1.3. Telephone (central access point):	+47 24 16 3000
1.1.5. Website:	www.helsedir.no
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Tissues and cells Human organs Medical devices Other
1.1.6.1. If other, please specify.	The Norwegian Directorate of Health is an executive agency and competent authority subordinate to the Norwegian Ministry of Health and Care Services.The Directorate of Health shall improve the health of the entire nation through integrated and targeted activities across services, sectors and administrative levels. The Directorate shall do so by virtue of its role as a sub-ministerial agency, as a regulatory authority and as an implementing authority in areas of health policy.
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Haemovigilance Other
1.1.7.1. If other, please specify.	EU affairs and legal matters. Issuing national Guidelines to Blood Establishments.
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:	PO Box 8128 Dep. NO-0032 Oslo Norway
1.2.3. Telephone (central access point):	(+47) 21 52 99 00
1.2.4. E-mail (central access point):	postmottak@helsetilsynet.no
1.2.5. Website:	www.helsetilsynet.no
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Inspection
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:	Postboks 63 Kalbakken NO-0901 Oslo Norway
1.3.3. Telephone (central access point):	+47 2289 7700
1.3.4. E-mail (central access point):	post@noma.no
1.3.5. Website:	http://www.legemiddelverket.no/
1.3.6. What are the roles/tasks of the NCA? (more than 1 answer possible)	Inspection
1.4. 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.).	NCA 1: The Norwegian Directorate of Health is an executive agency and competent authority subordinate to the Norwegian Ministry of Health and Care Services. Responsible for the implementation of the provisions of the Blood Directives on delegation from the Ministry of Health and Care services: 1,25 senior offiicers. Vigilance: 3 officers, each 20% position. NCA 2: Norwegian Board of Health Supervision performs inspections according to the Blood Directives and national guidelines. Senior inspectors;1,5. NCA 3: Norwegian Medicines Agency performs inspections according to the Blood Directives with special focus on blood components intended for medicinal products. Senior inspectors: 1,25
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at	74

31/12/2012.	
2.1.2. How many of the BEs are satellite sites?	31
2.1.3. How many of the BEs are mobile sites?	3
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	100052
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	83463
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	16589
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	198584
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	4693
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	600 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	5100
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	600 ml
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	4654
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	19
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	19
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Not avaliable in English
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Electronic donor and transfusion management systems
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	All are relevant
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	None
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes

2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	New partner in the last 6 months, MSM, prostitutes, sex with prostitutes.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Travel activities. Donors' health; use of medicinal products.
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Testing laboratories are included in the routine inspections performed by the NCA 2 and NCA 3
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	Cost/benefit analysis
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Ant- HBc when > 6 months since last donation
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Ant- HBc when > 6 months since last donation
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	0
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	4
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	2
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	0
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Solvent Detergent for all plasma units. Patogen Reduction of 11 % of platelet concentrates (Intercept and Mirasol)
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes

3.2.2.1. If yes, please specify.	Delegation is documented
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Covered by inspections performed by NCA 2 and NCA 3
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	Principles of good practise is implemented i SOPs
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Covered by inspections performed by NCA 2 and NCA 3
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	All data stored in the Blood Donor registers
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Covered by inspections performed by NCA 2 and NCA 3
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	All data collected are linked to a unique donation number which can not identify the donor by third parties
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	ISBT 128 mandatory
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	Very useful
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	74
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	NCA 1
4.6. How many laboratories performing donor testing are active within your country?	19
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	NCA 1
4.8. How many hospital blood banks are active within your country?	3
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control	Yes

measures of BEs?	
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	NCA 2, Dept of planned inspections NCA 3, Dept for inspections and narcotic drugs control
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	2,5
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Pharmaceuticals (including plasma derivatives)
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	36
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	36
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	The usual frequency is every second year, but if the risk factors identified are larger than expected, the sites frequency may be increased
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	BEs are inspected by two NCAs,
5.5.3. How many BE have been inspected at least twice in the last 3 years?	74
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Every second year
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	No cases
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	Corrective actions carried out
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	Corrective actions carried out
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	No cases
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	No cases
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	N/A
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	All plasma establishments are blood esablishments. All blood establishments produce plasma, so the same number of inspections, i.e. 36
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes

5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	The Hospital Blood Banks are implemented in the inspection plan for BEs conducted by NCA 2
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	ref 5.9.1
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	very useful
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	3
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	NCA 1, The Norwegian Directorate of Health
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	All components
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Buffy Coat
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Only electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Implemented in the inspection program for NCA 1 and NCA 2
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	No
6.1.7.1. Please explain why not.	30 years data storage is OK as long as the time-frame is a minimum. National law in Norway requires that for some data there is no upper limit for data storage, meaning endless storage.
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	The system is established under the responsibilityof NCA 1, run by the Norwegian Knowledge Centre for the Health Services. It is a national system to which it is manadtory for all BEs to notify electronically all SAR/E. The system is based on previous voluntary Haemovigilance system in place from 2004.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	No
6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	The forms used are based om the previous voluntary system, amended according to the provisions of the Blood Directives. There are sevearl forms, one example attached

6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	No
6.2.3.1. If no, please specify what guidelines you use? If possible, please upload the template.	National guidelines. File with guideline is too large
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Is included in the The national "Blood Regulation"
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	In complicated cases
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Annual report Annual seminar
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	507 recalls, 1139 components. No list avaliable
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	We have a standard operating procedure for notifying rapid alerts, and an updated mailing list of contact persons in all BEs
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Same as 6.2.11.1.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	For all systems mentioned above the Competent Authorirty is the same as NCA 1 for blood. We have internal procedures for alerting the other systems
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Requirements to traceability, notification of SAR/E, and requirements to standards and spesifications relating to quality systems are the same for blood/blood components from EU Member States and third countries
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	N/A.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No

7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Same requirements as for blood / blood components used for transfusion in Norway
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Same requirements as for blood / blood components used for transfusion in Norway
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	none in particular
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	28 days deferral for donors who have spent at least 24 hours in affected areas
8.5. Which other communicable diseases are of relevance to you?	All communicable diseases with outbreaks in southern Europe where many Norwegians go on summer holidays
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	Yes
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	has not been considered

A.1.23. Survey response Poland

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health (MH)
1.1.2. Address of NCA 1:	00-952 Warsaw, Miodowa Street 15
1.1.3. Telephone (central access point):	48 (22) 634-96-00
1.1.4. E-mail (central access point):	kancelaria-mz@mz.gov.pl
1.1.5. Website:	www. mz.gov.pl
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices Other
1.1.6.1. If other, please specify.	• organization of public health in Poland • treatment procedures
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Institute of Hematology and Transfusion Medicine (IHTM)
1.2.2. Address of NCA 2:	02-776 Warsaw, Indiry Gandhi Street 14
1.2.3. Telephone (central access point):	48 (22) 3496 100
1.2.4. E-mail (central access point):	sekihit@ihit.waw.pl
1.2.5. Website:	www.ihit.waw.pl
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Inspection Haemovigilance Other
1.2.6.1. If other, please specify.	.regular training for : physicians, diagnosticians, nurses from blood establishments (BE) and hospitals
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	National Blood Center (NBC)
1.3.2. Address of NCA 3:	00-080 Warsaw, Miodowa Street 1
1.3.3. Telephone (central access point):	48 (22) 55 64 900
1.3.4. E-mail (central access point):	nck@nck.gov.pl
1.3.5. Website:	www.nck.gov.pl
1.3.6. What are the roles/tasks of the NCA? (more than 1 answer possible)	Other
1.3.6.1. If other, please specify.	• organization • finacing
1.4. 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.).	• IHTM was delegated as CA by the Polish Blood Transfusion Act of 22nd August 1997. • NBC was designated by Ordination of the Minister of Health of 12 October 2006. Within the scope related to blood collection, the IHTM and the NBC are financed from the central budget.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	167 BEs; 21 regional blood transfusion Centers (subordinate to MH) , one (1) Military Blood Transfusion Center (subordinate to the Ministry of Defence) and one (1) Blood Transfusion Center of the Ministry of Internal Affairs (subordinate to the Ministry of Internal Affairs).
2.1.2. How many of the BEs are satellite sites?	144
2.1.3. How many of the BEs are mobile sites?	11 103 mobile collections organized in 2012 by 21 BEs
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	627 847
2.1.5. Could you please provide the number of repeat donors active	456 526

in 2012 (01/01-31/12/2012).	
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	171 321
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Data unavailable
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	1 173 050
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml +/- 10%
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	21 042
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	600 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	34 133
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	200-300 ml
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	• Red Blood Concentrate – 488 • Granulocyte Concentrate – 102
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	donor testing in BE (23); reference laboratory in IHTM; syphilis confirmation tests in designated diagnostic laboratories.
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	donor testing in BE (23); reference laboratory in IHTM and syphilis confirmation test in designated diagnostic laboratories.
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level Other
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Blood Donor Questionnaire & Information on infectious diseases for Blood Donors
2.1.18.3. If other, please specify.	One exemplary donor questionnaire has been prepared by IHTM according to Medical standards for collection, preparation and distribution of blood and blood components. BEs can adapt this document to address their specific regional and local needs.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Double documentation system in place (paper form, IT system) Donor notification procedure in place – prior to donation the donor signs the following statement: Upon receipt of the notification to collect my test results I pledge to report in the BE in due time. I fully acknowledge If - despite triple notification - I do not report to collect my test results, the BE is released from responsibility for the consequences that may ensue.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	Special „boxes" for self-exclusion are provided at the BE site and local procedures implemented to inform donors of the possibility of self exclusion at any stage of blood donation. Additional information provided at the bottom of the Blood Donor Questionnaire.
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	All criteria are relevant to safety of blood

2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	No problems are encountered
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	Suggestions of our CAs regarding changes in Directives (related among others to Annex III of the 2004/33/EC) was sent to the European Commission at the beginning of September 2012. Nevertheless, please find below: 1. The Directive should state that donor under 17 years of age may donate blood in exceptional circumstances (for instance: donation of HLA – compatible blood components for family members). 2. The Directive should state the donor weight in case of 2 unit red cell apheresis. 3. The Directive should state the value of donor hemoglobin concentration in case of 2 unit red cell apheresis. 4. There should be no inconsistency between coagulopathy and bleeding tendency (the term coagulopathy includes also thrombotic events) 5. "metabolic disease" and endocrine disorders (eg. hypothyroidism) should be mentioned separately. 6. In case of diabetes only disease when treated with insulin is mentioned. It should also include donors on oral medication. 7. The Directive raises doubts as to the category of donors to be deferred;donors with hepatitis or donors with present HBV or HCV markers. In case of HIV and HTLV the detection of disease markers is sufficient for donor deferral. 8. Borreliosis (Lyme disease) should be included as cause of deferral. In terms of epidemiology the Lyme disease is an important entity because the number of cases is steadily growing. Although there is no direct evidence of Borrelia transmission with blood in humans (the available studies on borreliosis transmission are however old and date back to the 1990 ies) transmission with blood was proved on animal models and Borrelia survives in the temperature of blood storage. 9. The Directive should be more precise in case of deferral for chronic Q disease. 10. The Directive should state the value of body temperature in case of deferral due to fever. 11. We suggest to actualize the Directive referring to malaria in accordance with current medical knowledge as there is some discrepancies between the Directive and the last EDQM edition of Guide to the Preparation, Use and Quality Assurance of Blood Components. 12. For West Nile Virus we suggest to make precise the length of stay in an affected area as ground for donor deferral as well as to introduce guidelines for donors who recovered from West Nile Fever. 13. There should be reference to Hepatitis B and HIV in the right column of point 2.2.2. 14. We suggest one common deferral period (e.g. 6 months) for persons with exposure to risk of acquiring a transfusion-transmissible infection : hepatitis B, C and HIV" (in a sentence of Directive " close household contact" there is reference only to hepatitis B (but not to hepatitis C and HIV). In this point there are mentioned persons with hepatitis B (eg. diseased people), but there is lack of category: "disease carriers". A "carrier " is not the same category as person with hepatitis (sick person). 15. It would seem reasonable to extend the deferral period Hepatitis B (possibility of false positive results of HBV test after vaccination). 16. We suggest precise donor deferral following "exposure" to tick born encephalitis and after recovery from tick born encephalitis. 17. There should be guidelines for deferral during breast feeding period. 18. "Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood " in one case refers to permanent deferral, while -in the other one "Persons whose behavior or activity places them at risk of acquiring infectious diseases that may be transmitted by blood →defer after cessation of risk behavior for a period determined by the disease in question, and by the availability of appropriate tests " –refers to of temporary deferral. The difference between those two donor categories and reason for discerning between permanent and temporary deferral should be made precise. 19. We suggest precise

	recommendations for handling persons detained in the juvenile correctional institutions (homes). These are persons aged 18-21 years who are not in the strict sense and under legal regulations the prisoners. Can they give blood or should be deferred as regular prisoners?
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Medical standards for collection, preparation and distribution of blood and blood components. Quote from the Blood Donor Questionnaire: Do not donate blood if you have had any of the following hazardous contacts that have put your blood at risk: - present or past intravenous drug abuse - sexual contacts with partners who use intravenous drugs - sexual contacts with many - sexual contacts with partners (men or women) whom you know for a short time - sexual contacts for money, - sexual contacts with partners with positive test results for syphilis, AIDS (HIV), HCV and HBV, We are fully aware that by referring to these issues we intrude on very private spheres of life. However, the already small risk of transmitting infectious diseases by blood transfusion can be reduced even further only if you carefully analize the above situations before donating blood and provide acurate information. The answers remain confidential. If test results are positive (infection) you will be informed by the doctor.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	Yes
2.2.7.1. If yes, please explain and suggest your alternative.	Lower age limit for young blood donors is being considered providing there is no conflict with other Polish regulations. Persons over 65 can donate blood if there are no contraindications.
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Permanent deferrals : Internal disorders including metabolic disorders, diseases of the endocrine system, respiratory and circulatory disorders Temporary deferrals : low hemoglobin and other abnormal test results
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	• The National Registry of Blood Donors (NRBD) is a uniform IT system set up in 2011. The system is regularly updated. • annual reports from BEs
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	number of permanent deferrals - 10 582; number of temporary deferrals – 222 121
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	BE laboratories are subject to Quality Control internal audits and external inspections according to: • Polish Blood Transfusion Act of 22nd August 1997 • Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy (updated)
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	All donations are tested for HBV DNA, RNA HCV and RNA HIV.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes

3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	All donations are tested for HBV DNA, RNA HCV and RNA HIV (mandatory).
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	All donations are mandatory tested for HBV DNA, RNA HCV and RNA HIV.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	52 in 1 272 572 donations tested
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	731 in 1 272 572 donations tested
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	557 in 1 272 572 donations tested
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis: 149 in 1 272 572 donations tested; Parvovirus B19: 4 in 63 819 donations tested.
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	The following pathogen inactivation systems are used in Poland: Mirasol PRT for platelets and plasma for clinical use and Macopharma Macotronic system for plasma for clinical use.
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	The tasks specified under Article 9 (1) can be delegated to other qualified persons
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	• Verification through exams and tests performed at regular intervals • Regular updated training provided • Specialization encouraged
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	• Polish Blood Transfusion Act of 22nd August 1997. • Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy • Medical standards for collection, preparation and distribution of blood and blood components prepared, published and regularily updated by IHTM based the regulations of the Polish Blood Transfusion Act
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	BE and hospital blood bank documentation on operational procedures is subject to internal audits and external inspections according to: • Polish Blood Transfusion Act of 22nd August 1997 • Decree of the Minister of Health of 16 April 2004 regarding procedures for inspections of blood establishments of the public blood transfusion service • Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy • Act on Medical Activity of 15 April 2011
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Archivizations of records • on paper • IT system
3.2.7. Is there a system in place to ensure that storage, transport and	Yes

distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	
3.2.7.1. If yes, please specify.	Specific recommendations referring to the conditions for storage, transport and distribution of blood and blood components are set down in : • Polish Blood Transfusion Act of 22nd August 1997. IHTM organizes regular inspections to ensure that these recommendations are met. • Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy Medical standards for collection, preparation and distribution of blood and blood components prepared, published and regularily updated by IHTM based the regulations of the Polish Blood Transfusion Act decree of the Ministry of Health of 2 February 2011 regarding facility requirements
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	system ISBT 128
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Mandatory
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	Recommendations of the Guide to Preparation, Use, and Quality Assurance of Blood Components were gradually implemented in BE activity since 1995.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Accreditation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation Other
4.2.1. If other, please specify.	training
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	By 2012 all blood transfusion centers were authorized: 21 regional BEs + 1 Blood Transfusion Center of the Ministry of Internal Affairs (subordinate to the Ministry of Internal Affairs + 1 Military Blood Transfusion Center (subordinate to the Ministry of Defence)
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	MH based on IHTM recommendations
4.6. How many laboratories performing donor testing are active within your country?	23 in BEs + reference laboratory in IHTM and designated diagnostic laboratories.
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	23 blood transfusion centers
4.8. How many hospital blood banks are active within your country?	546
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conduct medical activities with readings to blood and blood components therapy

4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	BIOMED Lublin SA - Lublin Factory of Sera and Vaccines. Production of anti D immunoglobulin and anti HBs only. (private)
4.10.2. If yes, please state the responsible authority within your country.	Main Pharmaceutical Inspector
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	IHTM – Department of Transfusion Medicine • Polish Blood Transfusion Act of 22nd August 1997; • Decree of the Minister of Health of 16 April 2004 regarding procedures for inspections of blood establishments of the public blood transfusion service
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	17 inspectors: each inspection team includes: Inspector of Quality Assurance (1 person), Immunology for Transfusion Medicine (1 person), Virology (1 person), registration, collection, donor examination, preparation and issue (1 person). Inspections are conducted within working hours.
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	24 inspections: 10 inspections in blood transfusion centers + 14 in satellite sites
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	24 inspections
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	2 inspections
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	According to Medical Standards for collection, preparation and distribution of blood and blood components each SAR is reported to one of the 23 blood transfusion centers within 24 hours of transfusion (on a standard form). Immediate Inspections follow. Post-control recommendations are sent back to the hospital and the whole documentation to IHTM. The SAR is analized by a special team appointed by the IHTM Director. Recommendations, if any, are sent to the blood transfusion centers. In 2012 the IHTM team analized 22 SAR cases.
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	additional inspections are called in case of organization changes in BEs
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	It is routine procedure according to our national guidelines
5.5.3. How many BE have been inspected at least twice in the last 3 years?	16 BEs
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	IHTM Inspections in blood transfusion centers are performed every 2 years. An inspection of a blood center also includes 1 satellite site or 1 mobile site.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Following 24 BE inspections/2012 there were no BE with no shortcomings
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	Following 24 BE inspections in 2012 minor shortcomings were found in 23 BEs.
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings	Following 24 BE inspections in 2012 major shortcomings were found in 24 BEs

were noted?	
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	no BE inspection of 2012 was followed by suspension of authorization.
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	There was no BE closure
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	2012 inspections resulted in dismissal of one BE director in 2013.
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	IHTM inspects blood transfusion centers and their respective hospital blood banks – every 2 years (rotation) according to: Polish Blood Transfusion Act of 22nd August 1997. BEs inspect hospital blood banks regularly.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	IHTM inspections in blood transfusion centers and their respective hospital blood banks – every 2 years (rotation) According to Polish Blood Transfusion Act of 22nd August 1997 BE inspections - regularily performed in hospital blood banks.
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	Medical standards for collection, preparation and distribution of blood and blood components prepared, published and regularily updated by IHTM according to the Polish Blood Transfusion Act of 22nd August 1997 and Decree of 16 April 2004 are based on the recommendations of the Guide and the EU Directives
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	The Ministry of Health / the Institute of Hematology and Transfusion Medicine
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	Concerns all blood components (ISBT 128)
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Granulocyte Concentrates/ Cryoprecipitate/cellular blood components – irradiated, inactivated, leukodepleted, pediatric, for

	neonatal use
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Audits and inspections of documentation
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Hospitals are under obligation to report SARE to respective BE ; BEs report SARE from their own territory/region to the CA
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	According to Medical Standards for collection, preparation and distribution of blood and blood components each SAR is reported to one of the 23 blood transfusion centers within 24 hours of transfusion (on a standard form). Immediate Inspections follow. Post-control recommendations are sent back to the hospital and the whole documentation to IHTM. The SAR is analized by a special team appointed by the IHTM Director. Recommendations, if any, are sent to the blood transfusion centers.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	All "severe" cases reported to CAs by BEs
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Outcome of CA analysis and appropriate recommendations are referred back to the BEs
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	Storage – 66 Distribution – 13 Transport – 3 Other (no specify) – 52
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Information on any new focus of infection are reported by National IHR Focal Point or Main Sanitary Inspectorate to CA. CA inform BEs.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Information from CIRCA-BC are immediately sent to CA. CA inform BEs
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Pharmacovilance Medical devices Communicable diseases and other threats to health

6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Main Pharmaceutical Inspector; The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, National Center for Cell and Tissue Banking; Poltransplant
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	Additional comments of our CA on traceability and SAR/E reporting were sent to the European Commission at the beginning of September 2012. Nevertheless, please find below. 1.We suggest that the legally binding SAE definition is more precise. In particular it should distinguish between: • SAE –as only an event which is a real threat as result of improper component being issued for transfusion • SAE –as any event that might have endangered the recipient's health, even though identified and eliminated according to internal control procedures. It is unclear whether the definition of "serious adverse events" also includes events that had taken place in a hospital laboratory, on a hospital ward or during the transfusion procedure. 2. We suggest to simplify the table related to Serious adverse events – imputibility level to run as follows: Transfusion-related imputibility level: 0 - not assessable 1 - no relation – there is evidence for attributing the adverse reaction to alternative causes 2 - relation assessed – evidence includes results of diagnostics tests
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	According to article 16.2.1 Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy [Dz. U. 2013 poz. 5], one of the main duties of the blood banks is placing orders for blood and blood components in the appropriate blood establishment, according to the orders of the hospital departments. So the only source of blood and blood components for therapy in health care entities, that is for transfusion, are blood establishments, which implemented the quality system and all quality requirements (parameters, the minimal scope of laboratory tests, the manner of storage, including system of identifying blood and blood components), in accordance with appointed directives. These requirements were also determined in "Medical Standards for collection, preparation and distribution of blood and blood components", and were implemented for applying in all blood establishment.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	According to article 16.2.1 Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy [Dz. U. 2013 poz. 5], one of the main duties of the blood banks is placing orders for blood and blood components in the appropriate blood establishment, according to the orders of the hospital departments. So the only source of blood and blood components for therapy in health care entities, that is for transfusion, are blood establishments, which implemented the quality system and all quality requirements (parameters, the minimal scope of laboratory tests, the manner of storage, including system of identifying blood and blood components), in accordance with appointed directives. These requirements were also determined in "Medical Standards for collection, preparation and distribution of blood and blood components", and were implemented for applying in all blood establishment.
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	According to article 16.2.1 Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy [Dz. U. 2013 poz. 5], one of the main duties of the blood banks is placing orders for blood and

	blood components in the appropriate blood establishment, according to the orders of the hospital departments. So the only source of blood and blood components for therapy in health care entities, that is for transfusion, are blood establishments, which implemented the quality system and all quality requirements (parameters, the minimal scope of laboratory tests, the manner of storage, including system of identifying blood and blood components), in accordance with appointed directives. These requirements were also determined in "Medical Standards for collection, preparation and distribution of blood and blood components", and were implemented for applying in all blood establishment.
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	In emergency: requirements provided in Annex IV + NAT testing
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	According to article 16.2.1 Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy [Dz. U. 2013 poz. 5], one of the main duties of the blood banks is placing orders for blood and blood components in the appropriate blood establishment, according to the orders of the hospital departments. So the only source of blood and blood components for therapy in health care entities, that is for transfusion, are blood establishments, which implemented the quality system and all quality requirements (parameters, the minimal scope of laboratory tests, the manner of storage, including system of identifying blood and blood components), in accordance with appointed directives. These requirements were also determined in "Medical Standards for collection, preparation and distribution of blood and blood components", and were implemented for applying in all blood establishment
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	According to article 16.2.1 Decree of the Minister of Health of 11 December 2012 regarding blood and blood components therapy in health care entities which conducts medical activities with readings to blood and blood components therapy [Dz. U. 2013 poz. 5], one of the main duties of the blood banks is placing orders for blood and blood components in the appropriate blood establishment, according to the orders of the hospital departments. So the only source of blood and blood components for therapy in health care entities, that is for transfusion, are blood establishments, which implemented the quality system and all quality requirements (parameters, the minimal scope of laboratory tests, the manner of storage, including system of identifying blood and blood components), in accordance with appointed directives. These requirements were also determined in "Medical Standards for collection, preparation and distribution of blood and blood components", and were implemented for applying in all blood establishment
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your	No

MS?	
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	no penalties imposed
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	no penalties imposed
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	no penalties imposed
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	No
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	The National Consultant for Transfusion Medicine is responsible for the monitoring the spread of West Nile Virus on the territory of Poland and informing BEs for appropriate measurest to be immediately implemented.
8.5. Which other communicable diseases are of relevance to you?	Other communicable diseases relevant for Poland: malaria, Dengua fever, Chikungunya.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	National guidelines: • Act on Medical Activity of 5 April 2011; • Decree of the Ministry of Health of 11 December 2012 regarding blood transfusion
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	None. Blood and blood components should not fall under the pharmaceutical legislation.

A.1.24. Survey response Portugal

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Direção-Geral da Saúde (DGS)
1.1.2. Address of NCA 1:	Alameda D. Afonso Henriques, 45 - 1049-005 Lisboa
1.1.3. Telephone (central access point):	+351 21 843 05 00
1.1.4. E-mail (central access point):	sanguetransplantacao@dgs.pt
1.1.5. Website:	www.dgs.pt
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Tissues and cells Human organs
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Instituto Português do Sangue e da Transplantação (IPST)
1.2.2. Address of NCA 2:	Avenida Miguel Bombarda n. 6, 1000-208 Lisboa
1.2.3. Telephone (central access point):	+351 210 063 063
1.2.4. E-mail (central access point):	dirips@ipst.min-saude.pt
1.2.5. Website:	ipsangue.org
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Haemovigilance
1.3. National Competent Authority 3?	No
1.4. 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.).	DGS: This new CA is only responsible for this área since the end of 2012. It is an área included in the DGS Quality Departement, which is depending of the Ministry of Health; the staff is composed by a medical doctor, an hospital manager, a pharmacist (also veterinary doctor) and an architect; we may consider that 2 of them are seniors and 2 juniors, but none is a formal inspector. 1 members (the MD) participates in EU affairs. IPST: Haemovigilance Group - responsible for collecting information from blood establishments, hospital blood bank and facilities where the transfusion takes place (activity monitoring and notification of serious adverse reactions and events) Composed by five medical professionals.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Not Applicable
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	(IPST: 34)
2.1.2. How many of the BEs are satellite sites?	(IPST: 10)
2.1.3. How many of the BEs are mobile sites?	(IPST: 0)
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	(IPST: 249168)
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	(IPST: 204291)
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	(IPST: 44877)
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	(IPST: 387222)
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	(IPST: 450 (+/- 10%))
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	(IPST: 0)
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your	(IPST: 0)

country (in ml per donor).	
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	(IPST: 4568)
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	NA
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	(IPST: 346)
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	(IPST: 22)
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	0
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Donor questionnaire (Portuguese version only)
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	DGS performs regular inspections, accordingly with the law. (IPST: performs internal audits)
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	DGS: All of them are relevant, but those related with blood levels in donors (1.2 - 1.4), donors diseases and exposure to transmissible diseases are considered the most relevant ones.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	DGS: Asymptomatic diseases that are dificult to identify and that the donor is not aware of and sexual behaviors (IPST: Risk Sexual behaviors)
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	More than one sexual partner in the previous 6 months; new/different sexual partner in the previous 6 months; sex for drugs or money; MSM: men who have sex with men
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	(IPST: Low Hemoglobin levels - 22408; Flu or flu like symptoms: 4714; Travel: 2475; Risk behavior: 2078)
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	(IPST: Annual report of blood establishments)
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	(IPST: 97915)
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the	Yes

deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Inspections and documental analysis
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	In all blood donations (NAT for HIV, HCV and HBV)
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	NAT for HIV, HCV and HBV; EiA IgM and IgG testing for Syphilis - All blood donations EiA HTLV 1 e HTLV 2 - First Time donations Malaria Testing according the Directive 2002/98/EC
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Not Applicable
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	(IPST: 33)
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	(IPST: 55)
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	(IPST: 32)
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	(IPST: Syphilis: IgM positive IgG negative - 13; IgM positive IgG positive - 23; IgM negative IgG positive - 599; IgM/IgG positive (not discriminated) - 695)
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	(IPST: inactivation of pathogens by Amotosalen UVA (Intercept) in 1 BE)
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	No
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Inspections and documental analysis
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	Confirmed by inspections and documental analysis Mandatory by law
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Confirmed by inspections and documental analysis Mandatory by law
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Data bases and sometimes also in paper; confirmed by inspections

	and documental analysis (IPST: Annual Survey/report)
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Confirmed by inspections and documental analysis Mandatory by law
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Validated in inspections.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	No
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	DGS: Not much yet, as this new CA is only in charge of this field since the end of 2012. (IPST: the Co-E Guide is used by IPST BE as a reference tool/guidelines)
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	This information is not yet available as some BE are still being evaluated by this new CA
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	Yes
4.4.1. If yes, what were the reasons for the revocation(s) or suspension(s) (more than 1 answer possible) ?	Problems with donor testing Poor compliance with the good practices and quality system issues in the establishment
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	NCA1 - DGS
4.6. How many laboratories performing donor testing are active within your country?	(IPST: 22)
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	NCA1 - DGS
4.8. How many hospital blood banks are active within your country?	(IPST: 107)
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	NC1 - DGS (Department of Quality in Health)
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	There is no full time inspectors. The 4 members of the staff are responsibles for inspections, but none is formal inspector. 2 of thme as just done the CATIES's course.
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common	Yes

documentation, etc.)?	
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	15 (11-T&C and 4 BE)
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	15 (11-T&C and 4 BE) since the end of 2012
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	0 (By the new CA)
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	0 (By the new CA)
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	The planning of the inspections is based on the potencail risk for the Public Health.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	0 (By the new CA)
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Not yet defined by the new CA.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0 (By the new CA)
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	0 (By the new CA)
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	0 (By the new CA)
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0 (By the new CA)
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0 (By the new CA)
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	0 (By the new CA)
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0 (By the new CA)
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	Accordingly with national law (coming out of the Directives)
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	Accordingly with national law and together with the General Inspectorate of Health Activities
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	For the time being it is yet limited for the new CA
5.11. Did you (do you intend to) send your inspectors to the trainings	Yes

organised by EU-funded projects (e.g. EUBIS, CATIE)?	
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Direção-Geral da Saúde (NCA) and Instituto Português do Sangue e da Transplantação
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	All other blood components
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Inspections and documental analysis
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	(IPST: A web based system for notification of all adverse reactions and eventes (SAR and SAE) in all transfusion chain)
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Mandatory by the National Law (Decreto-Lei n.º 267/2007; Article 15º): all blood establishments, hospital banks and transfusion points, are obliged to report to the NCA all SARE
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	(IPST: In all cases of imputability levels 1, 2 and 3)
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	(IPST: Annual Haemovigilance System meeting (for all notifiers)
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012?	(IPST: 122 Total (positive bacterial - 91 blood components; pos donation information - 21 blood components; TRALI - 5 blood

Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	components; HIV positive - 1 blood component; other - 4 blood component))
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	(IPST: email communication send to the responsible persons of blood establishment)
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	(IPST: email communication send to the responsible persons of blood establishment)
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	(IPST: Tissues and Cells; Organs; communicable diseases and other threats to health)
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	(IPST: Portugal doesn't send blood components to other Member States, as well as doesn't import/export blood components from third countries)
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	(IPST: Portugal doesn't send blood components to other Member States, as well as doesn't import/export blood components from third countries)
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	(IPST: NA (Portugal doesn't send blood components to other Member States, as well as doesn't import/export blood components from third countries))
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	(IPST: Portugal doesn't send blood components to other Member States, as well as doesn't import/export blood components from third countries; Please, see answer 3.1.3.1)
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	NA
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	NA
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	(IPST: Portugal doesn't fractionates plasma)
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	(IPST: Portugal doesn't send blood components to other Member States, as well as doesn't import/export blood components from third countries)
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside	Yes

EU) in 2012 (01/01/2012 to 31/12/2012)?	
7.9.1. If yes, please provide this data by country of destination.	NA 0
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0
7.11. Is there a regular shortage of blood or blood components in your MS?	Yes
7.11.1. If yes, how often (per year) is there a shortage of blood or blood components in your MS?	(IPST: There was a blood shortage in the 1st semester 2012; does not occur frequently)
7.11.2. If yes, for which blood components (more than 1 answer possible)?	Red Blood Cells
7.11.3. If yes, would you be interested in concluding bilateral agreements with other MS in order to address the shortage?	No
7.11.4. If yes, would you be interested in establishing short-term/ad-hoc mechanisms for addressing the shortage?	Yes
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	No penalties
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	No penalties
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	No penalties
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	(IPST: NAT screening test for HIV, HBV, HCV; EiA screening test for syphilis; EiA screening test for HTLV (first time donors); RT-PCR Dengue screening test at epidemiological context (Dengue outbreak in Madeira Island))
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	The new CA is still in process of internal organization, so it is to soon to identify issues of this kind. For the time being the main difficulty to implement BD is lack of resources.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	(IPST: Donor deferral criteria)
8.5. Which other communicable diseases are of relevance to you?	(IPST: Dengue outbreak in Madeira Island (October 2012 - March 2013); Malaria)
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	(IPST: we don't have yet a position in this matter)
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	(IPST: Data not known)
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	(IPST: level of pooling)

A.1.25. Survey response Romania

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Ministry of Health
1.1.2. Address of NCA 1:	no. 1-3, Cristian Popișteanu alley , district 1, 010024, Bucharest
1.1.3. Telephone (central access point):	+4 021 3072 500 +4 021 3072 600
1.1.4. E-mail (central access point):	dcspms@ms.ro
1.1.5. Website:	www.ms.ro
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Other
1.1.6.1. If other, please specify.	Food, cosmetic products, biocides, water, health care, etc.
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance Other
1.1.7.1. If other, please specify.	- elaboration of national policy and strategy for sustained development of the national blood transfusion system - organization of national transfusion system and elaboration of annual national program -ensure human, financial and technical resources to the national transfusion system -take necessary measures, through its specific structures, to ensure self-sufficiency on blood and blood components - monitoring of optimal and rational use of blood and blood components - setting up the responsibilities for all categories of institutions involved in any stage of the transfusion activity - elaboration of primary and secondary legislation to regulate the transfusion field - take all the necessary measures to ensure implementation of a quality management system based on good practice principles by any institution involved in the transfusion activity - coordinates the collaboration of all institutions involved in the promotion and support of blood donation - elaborates and implements a unique national system for the identification of each blood donation, each unit of blood and blood component collected and processed - ensure elaboration and implementation of a unique codification system for the donors' identification data , to be used in case of reporting to third parties, in charge with collection and monitoring of epidemiologic data
1.2. National Competent Authority 2?	No
1.4. 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 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 is one directorate with responsibilities in the field of blood and blood components: the Public Health and Control in Public Health Directorate (PHCPHD). The main responsibilities in the field of blood and blood components are: - developing of legal acts (PHCPHD); - carrying out inspections and control measures in BE and HBB regarding the quality and sanitary safety of blood and blood components - organizing and coordinating the vigilance system and taking the necessary measures in the field 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 Order no 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection. We have inspectors (86 inspectors) who are dedicated to inspect establishments with transfusion activities – BEs and HBBs- 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 and blood 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 State Sanitary Inspectorate.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	RO does not have a federal or decentralized system
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	50 (42 BE legal entities + 5 buses + 3 satellites sites)
2.1.2. How many of the BEs are satellite sites?	3
2.1.3. How many of the BEs are mobile sites?	5 buses
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	521132
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	245568
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	91902
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	399848
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450ml/donation
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	1
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	Maximum 750 ml/procedure
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	6830
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	Maximum 650ml/procedure
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	1037 (128 eritrocytapheresis+ 909 combined apheresis procedures
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	42
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	42
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	Requirements regarding the scope of information to be provided to the prospective donors have been set up through a specific regulation (Order no. 1193/2007)
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Romanian version has been uploaded
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are	These requirements are regulated by: - Order no. 1193/2007 updated by 293/2010, - 1226/2007 updated by 650/2012, - 1132/

reported to the donor (Art. 18(2) of Directive 2002/98)?	2007. - Additionally, SOPs are in place in each BE . - Additionally, SOPs are in place in each BE .
2.1.20. Do you have a system for the self-exclusion by a donor?	No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	- eligibility criteria: age, body weight (minimal limit to estimate the volume allowed for collection), haemoglobin, protein, platelets (for apheresis), blood pressure, puls. - deferral criteria: cardiovascular diseases, abnormal bleeding tendency, history of syncope, convulsions, infectious diseases, malignant diseases, drug use, sexual behaviour, psychiatric diseases , gastrointestinal diseases, etc. They allow basic objective selection and protection of both donor and recipient.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	vCJD, malaria, drug use, history of different infectious diseases
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	* addition as eligibility criteria: -Complete cell blood count- for leucocytes, platelets, indirect signs of iron deficiency- at least for apheresis, first time donors, repeat/regular donors with borderline Hb value - evaluation of iron status at least in particular situation, based on physician decision * addition as temporary deferral criteria : leucoytosis (leucocytes over 11000/mmc- 12000) * replacement: - point 2.2.2, 1st raw: introduce "…provided a NAT test for HCV, HBV, HIV is negative' to replace "NAT test for hepatitis C is negative" - point 2.2.2, 1st raw, last line: introduce "….close household contact with persons with hepatitis B, C, HIV, tuberculosis" to replace "close household contact with hepatitis B"
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	-According to Annex III, POINT 2.1(table-last row) transposed in Order 1193/2007, permanent deferral for "persons whose sexual behavior puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood " . -Temporary deferral according to Annex III, point 2.2.2 , 2nd row : "persons whose behaviour…place them at risk of acquiring infectious diseases that may be transmitted by blood". -The national standardized questionnaire contains questions focused on identifying these risks: - sexual contact with partners infected with HBV/HCV/HIV/TP - sexual partner using i.v. drugs - paid sexual partner - has he/she ever been paid for sex - multiple partners - recent change of sexual partner (last 6 months) - number of sexual partners during the last 6 months
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	most frequent: - anemia and Hb lower than minimal standard - higher blood pressure - cardiovascular diseases - sexual risky behaviour - history of or acute infectious diseases - high ALT values (mandatoty testing) • least frequent: - psychiatric diseases - neurologic diseases - malignant diseases - vaccination - malaria - vCJD
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	No

2.2.11.1. If no, what other deferral criteria would you suggest for derogation? Would you have other suggestions on the usefulness and set-up of such temporary derogations?	Derogation of Hgb level only for first time donors
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Regulation on authorization of BEs- Order 1225/2006; verification during inspections; national protocol for testing, endorsed by National Institute of Transfusion Hematology
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	- limited financial resources - reorganization of BEs is under discussion, concentration of testing in several laboratories is foreseen; after the accomplishment of this objective, progressive implementation of NAT in routine, based on the results of a pilot study, will be introduced, if financial resources available
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Yes, MoH Order no. 1226/2007 updated by Order 650/2012.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Yes, MoH Order no. 1226/2007 updated by Order 650/2012
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	Yes
3.1.4.1. If yes, please specify (additions/deletions/replacements, …).	- addition: testing for syphilis
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	66
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	2612
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	422
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	-Ab anti HTLV: 28; -Ab anti TP (EIA): 1237
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Tasks are delegated to one or more persons in most of the BEs, if the responsible person is absent and the delegated person replace her. Still, because of shortage of specialized personnel, in some BEs only one person with universitary degree is hired, the director (physician or scientist). Given this situation, no other person is qualified to be delegated as replacement for the responsible person in those BEs.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Mandatory requirements set up in Order 1214/2007 on qualification and training requirements; verification during inspections, self-inspections and accreditation process (the last one for HBBs only)
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes

3.2.4.1. If yes, please specify.	Mandatory requirements set up in Law no. 282/2005 and Order no. 1132/2007
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	By organizing: - a self-inspection program by BEs and hospitals - regular inspection in BEs and hospitals; - data on documentation, training, testing and other aspects of mandatory activities are collected at county level on annual basis from hospitals/HBBs, transmitted and collated at MoH level - BEs report on regular basis on the status of internal management control system, that includes the documentation on quality.(Government Decision 946/2005 for public institution)
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	- mandatory provisions covered by the existing regulations - organization of archive is under responsibility of each institution
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Mandatory requirements covered by regulations. SOPs in place, Documentation of temperature monitoring; verification during inspection Self-inspection program
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Mandatory requirements regarding confidentiality responsibilities and measures foreseen in Law 506/2004
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	No
3.2.9.2. If no, why not?	Only few BEs have introduced lately an internal IT system, no extension so far to the related HBBs. Even though these BEs use barcodes, they must use numeric codes in parallel, to ensure traceability. Each donation has a nationally unique numeric code.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	We consider it very useful. It is used as a guidance for technical issues. 16th edition was translated by MoH. It is foreseen to translate the 17th edition , too. Having a representative in the GTS group, ensures direct contact, information exchange for the technical aspects.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Designation Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	No
4.3.2. If no, how many BEs have not received authorisation by [please provide date of record]?	BEs have been designated by Law 282/2005 and by County Public Health Authority,(authorization to function, yearly renewed), NITH to perform activities in the field, according to the scope of the BE definition.The authorization process hasn't yet started. So, none of the BEs has been authorized yet.
4.3.3. If no, when will this approval process be completed?	2014
4.3.4. If no, what is (are) the difficulties / reason(s) for the delay in the approval process?	Delay in setting up the Government Decision on organization and functionality of BEs, as set-up in the Law 282/2005. Need to revise the Order on authorization of BEs and revise and complete the national standards to ensure the legal basis for verification during inspection. For 2013, the Government has launched a project for the administrative reorganization of the country, to create regions. In the

	frame of this project, reorganization of the transfusion system is foreseen.
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	MoH through the DPHCPH. During the authorization procedure, each activity is authorized, including testing.
4.6. How many laboratories performing donor testing are active within your country?	42
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	MoH through the County Public Health Authority
4.8. How many hospital blood banks are active within your country?	340
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	Requirements related to art. 8 - inspection, 12(2) are mandatory for HBBs also. A national guide on rational clinical use of blood and blood components has been adopted through Order 1343/2007.
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	PHCPHD in the MoH coordinates inspection activities performed by inspectors working at county level (Public Health County Authority-department of inspection) HG 524/ 2013 foresees a Sanitary State inspection department in the MoH
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	86 : 2 in MoH + 84 at county level
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Organs Hospitals Others
5.2.1.1. If others, please specify.	Clinical laboratories, health care cabinets, dental cabinets
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	BEs: 41 /year, organized each 2 years (2011 and 2013)
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	0
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	BE: 0; HBB: 220 in 2012
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	4
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	None
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	We decide the type of inspection to be conducted 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 conducted, • volume of activity including significant changes
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No

5.5.2.1. If no, why not?	They have been planned so as to comply with Directive requirement
5.5.3. How many BE have been inspected at least twice in the last 3 years?	41
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Each 2 years
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	-
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	-
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	-
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	-
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	-
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	For the 4 inspections organised for SARE or suspicion of: - 3 of them: procedures compliant with the regulations applied - 1: administrative measures (clerical errors)
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0. This type of establishment does not exist in Romania.
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	According with Law no. 282/2005; same requirements as for BEs: at least 1 inspection each 2 years
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	- Coordination of county inspection units, - collection of data on inspection outcome, - organization of training for inspectors, - elaboration of inspection guidelines and procedures
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	It is used as a guidance for technical issues.16th edition was translated by MoH. It is foreseen to translate the 17th edition , too. Having a representative in the GTS group, ensure direct contact, information exchange for the technical aspects. The EuBis Guide is very useful. It was translated into Romanian by MoH and provided to all CPHCPHA, inspectors and BEs. It is used for training, elaboration of technical documents/SOPs, inspection and self-inspection plans and activities.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	MoH

6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	Platelets, Plasma, Red Blood Cells, Whole blood
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Mandatory requirements by regulation SOP Verification during inspection
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	No
6.1.7.1. Please explain why not.	Too long. Difficulties are foreseen to ensure archiving space and document management.
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Order 1228/2006 Some changes have been discussed and revision is foreseen for 2014. The general scheme includes: - National haemovigilance coordinator is the MoH, through Sanitary State Inspection department. - county coordinator: county public health authority- inspection service - local coordinator of BE - local coordinator of hospital If SAR/E, the local coordinator of hospital reports to the county public health authority and to the BE providing the blood components. From county level, information is sent to MoH. If SAR/E in BE, information is sent to the county public health authority and to the National Institute of Transfusion Hematology. From here, to the MoH. Other adverse reactions and events are centralized locally and regularly reported: BE to the national institute and HBBs to the county inspectors. Both the national instituite and the county inspection services send the data to the MoH on annual basis.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	The sanitary inspectors who are responsible for the formal control in the transfusion field are in charge of collecting SAR/E at county level.
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Order 1228/2006
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	SAR/E
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Information provided during meetings of CAs representatives are disseminated to BEs representatives during half-yearly meetings with directors or other occasions. There is no standard formal procedure or mandatory requirement for that
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of	Data not available

blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Informative message is send by MoH or Center for transmissible Diseases (depending on the case) to the NITH and from there to the BEs. If it is the case, BEs inform hospitals in their territory.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Informative message is send by the CA contact person to the NITH and from there to the BEs. If it is the case, BEs inform hospitals in their territory
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	X Tissues and cells X Organs X Communicable diseases and other threats to health
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Order 608/2013
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Order 608/2013
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	Same mandatory testing as at national level (RO)
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	No imports done in 2012
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	No imports done
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Order 608/2013
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Order 608/2013
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes

7.9.1. If yes, please provide this data by country of destination.	No exports done
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	No exports done
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	Yes
7.12.1. If yes, for which blood components (more than 1 answer possible)?	Plasma
7.12.2. If yes to Q. 7.12., what do you do with the surplus of blood or blood components?	Discarded
7.12.3. If yes to Q. 7.12., would you be interested in concluding bilateral agreements with other MS in order to address the surplus?	Yes
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	- Additional eligibility/deferral criteria - mandatory requirement for authorization of HBBs - mandatory inspection for HBBs - mandatory registration and reporting of all incidents and adverse reactions, including the activity performed at clinical service level
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	- during implementation: progressive shortage of medical staff in BEs, leading to overlapping of functions, non-compliant facilities, lack of national IT system
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Romania was member of the working group that drafted the EU preparedness plan for WNV outbreaks adopted by MS. Based on this one, a national plan was enacted by MoH Order in 2011: Order no. 1483/2011.Since 2011, this plan has been activated by the task force each season. Measures are implemented according to the evolution of outbreaks, in direct collaboration with RO Centre for disease control, information provided by ECDC site and other MS.
8.5. Which other communicable diseases are of relevance to you?	HBV, HCV, HIV, sifilis, TBC, new emerging agents
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	-
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Ozonetherapy Local application of autologous blood components in dermatology/ cosmetics
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Any intervention on the blood unit for further processing, treatments, pooling, etc

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:	Limbová 2 P.O. BOX 52 837 52 Bratislava 37
1.1.3. Telephone (central access point):	++421 2 593 73 111
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)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Human organs Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	State Institute for Drug Control
1.2.2. Address of NCA 2:	Kvetná 11 825 08 Bratislava
1.2.3. Telephone (central access point):	+421-2-50701 111
1.2.4. E-mail (central access point):	sukl@sukl.sk
1.2.5. Website:	www.sukl.sk
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Inspection Haemovigilance
1.3. National Competent Authority 3?	No
1.4. 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 state institute that is a state administration body for the field of human pharmacy and drug precursors. The State Institute is a budget organization. It is headed by a director that is appointed and withdrawn by the Minister of Health. The State Institute for Drug Control is the institution of the Ministry of Health of the Slovak Republic responsible for ensuring surveillance of the quality, efficacy and safety of medicinal products for human use and medicinal products used in health care. Three inspectors of Inspection Section are responsible for conducting of inspections of blood establishments. Section of drug safety and clinical trials of The State Institute for Drug Control is responsible for haemovigilance.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	N/A
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	47
2.1.2. How many of the BEs are satellite sites?	0
2.1.3. How many of the BEs are mobile sites?	0
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	121 542
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	91 557
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	29 985
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Slovak donors traveling to Austria to donate plasma by apheresis (in private plasmapheretic establishment close to the Slovak-Austrian border - Hainburg an der Donau).
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	203 825

2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 ml +/- 45 ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	152
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	600 ml
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	6 257
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	200 - 400 ml
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	108
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	47
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	14
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	These data are part of the selection form (questionnaire).
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	N/A
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	It is mandatory based on Decree of the Ministry of Health of the Slovak Republic No. 333/2005 Coll.
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	box for questionnaires from self-excluded donors in every blood establishment
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	All eligibility/deferral criteria are equally relevant.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Defferal criteria concerning malaria - we do not perform malaria testing in our labs. Donors, who have suffered from malaria or have spent first five years of life in malaria endemic region, are definitively excluded from blood donation.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood. Persons whose sexual partners have tested positive for HIV.
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	There were no data available.
2.2.9. Do you have a system of centralised collection of data on	Yes

deferrals?	
2.2.9.1. If yes, please specify.	Datas on the total number of the defferals, total number of the defferals in first time donors and total number of the defferals in repeat/regular donors are collected on central bases.
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	27 874
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Labs are audited on regular basis. These controls are part of inspections of blood establishments. Labs must participate in external quality control.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	economical; acceptable epidemiological situation / data
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	anti- HBcore (total) and ALT are mandatory under national legislation
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	yes, anti- HBcore (total) and ALT are mandatory under national legislation
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	2
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	24
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	25
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	31 - syphilis
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	No
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	in the absence of responsible persons, their responsibilities are delegated to other persons qualified by training and experience to perform such tasks
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	All personnel in blood establishments shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice. The contents of training

	programmes shall be periodically assessed and the competence of personnel evaluated regularly.This requirements are mandatory based on Decree of the Ministry of Health of the Slovak Republic No. 487/2006 Coll. Criteria and responsibilities of The Quality Assurance Manager and Processing or Operations Manager are defined in Act No. 362/2011 Coll. on Drugs and Medical Devices and on Amendment and Supplementing of Certain Acts as amended later. Quality Assurance Managers participate in regular courses at Slovak Medical University.
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	The principles of good practice are mentioned in Decree of the Ministry of Health of the Slovak Republic No. 333/2005 Coll. on Requirements for the Good Preparation Practices for Blood Products.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	It is mandatory to maintain documents setting out specifications, procedures and records covering each activity performed by the blood establishment based on Decree of the Ministry of Health of the Slovak Republic No. 487/2006 Coll. This documentation is controlled during regular inspections.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	It is mandatory based on Decree of the Ministry of Health of the Slovak Republic No. 487/2006 Coll. and controlled during inspections.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	The specifications of storage, transport and distribution conditions are implemented in Decree of the Ministry of Health of the Slovak Republic No. 333/2005 Coll.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Privacy is mandatory based on Decree of the Ministry of Health of the Slovak Republic No. 333/2005 Coll. and Act no. 122/2013 Coll. on Protection of Personal Data and about amendment of other acts.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	This system is mandatory.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	This guide is helpfull for all processes conducted in BE.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	47
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Ministry of Health of the Slovak Republic

4.6. How many laboratories performing donor testing are active within your country?	47
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Ministry of Health of the Slovak Republic
4.8. How many hospital blood banks are active within your country?	46 blood banks not depended on blood establishments and 34 as a part of blood establishment
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Inspection Section of The State Institute for Drug Control.
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	3 inspectors
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Pharmaceuticals (including plasma derivatives)
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	Every BE is inspected in 2-years intervals.
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	When it is necessary.
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	15
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	1
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	1 follow-up inspection
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	we have sufficient number of inspectors
5.5.3. How many BE have been inspected at least twice in the last 3 years?	23
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Blood establishments are inspected every two years. Mobile site can be included in this inspection.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	State Institute for Drug Control issued Certificate of good preparation practice for blood products. This certificate is valid for 2 years.
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	After eliminated minor shortcomings was issued Certificate of good preparation practice for blood products. This certificate is valid for 2 years.
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	After eliminated major shortcomings was issued issued Certificate of good preparation practice for blood products. This certificate is valid for 2 years.
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	No suspension of authorisation
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by	No closure of blood establishment

closure of the blood establishment?	
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	State Institut for Drug Control - proposal for sanction. Ministry of Health is responsible for sanctioning.
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	1
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	Decree 333/2005 Coll. on good practice of the blood preparation, Annex VI.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	Act 362/2011 Coll. on Medicinal Products and Medical Devices § 129(2)o). Decree 333/2005 Coll. on good practice of the blood preparation, § 14
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	It is helpfull.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Ministry of Health in collaboration with State institute for Drug Control
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	for all
6.1.4. Do you apply an international coding system for blood components?	No
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	It is mandatory based on Decree of the Ministry of Health of the Slovak Republic No. 333/2005 Coll.
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Vigilance system is ensured by State Institute for Drug Control (Inspection section, Section of drug safety and clinical trials), Head expert for Transfusion and Regional experts for Transfusion. Haemovigilance system is described in Decree of the Ministry of Health of the Slovak Republic No. 487/2006 Coll.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes

6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	70-99%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Hospital blood banks have to notify blood establishments which distributed the blood and blood components. Investigation of serious adverse reactions are usualy performed by regional BE in its specialized lab.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	We perform root cause analyses of serious adverse reactions (Immunological Haemolysis, Transfusion-transmitted bacterial infection, Transfusion-transmitted viral Infection...) for all patients except some patients (depend on the adverse reaction) with known multiple anti- HLA antibodies or repeat allergies already investigated.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Serious adverse reactions (which are reported on EU level by State Institute for Drug Control) are investigated by regional BEs under the supervision of Regional experts for Transfusion and final repport is sent to blood establishments. Very serious adverse events are immediately repported to Head Expert of MofH in Transfusion and to Ministery of Health if investigations on place are needed. Investigations are conducted by State Institute for Drug Control and (depend on type of SAR or SAE) with collaboration of Ministry of Health.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	No recalls.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	In case of national rapid alert, this serious information is reported to State Institute for Drug Control and Ministry of Health. Inspectors of State Institute for Drug Control condact non- routine inspection and warn Head expert for Transfusion.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	In this case Ministry of Health and Head expert for Transfusion notify Regional experts for Transfusion. Regional experts warn single blood establishments in their regions.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Pharmacovilance Communicable diseases and other threats to health Other
6.2.13.1.1. If other, please specify.	in case of endemia, we report endemic areas and warn Public Health Authority of the Slovak Republic.
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	No
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion	They have to meet equivalent standards for quality assurance. Blood and blood components imported from third countries, including

from EU Member States or third countries?	those used as starting material/raw material for the manufacture of medicinal products derived from human blood and human plasma, should meet the quality and safety requirements set out in this Decree of the Ministry of Health of the Slovak Republic No. 333/2005 Coll.
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	There are not any plasma fractionation facilities in our country
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements)
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	Certificate of CA. No import.
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0 (No import of blood components from third countries)
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0 (No import of plasma from third countries)
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	The rules are designated in national legislation: Act No. 362/2011 Coll. on Drugs and Medical Devices and on Amendment and Supplementing of Certain Acts as amended later, § 70. Ministry of Health of the Slovak Rebublic issues authorisations for export of human plasma.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Ministry of Health of the Slovak Rebublic issues authorisations for export of human plasma. Act 362/2011 Z.Coll. § 70.
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	3063 L of plasma - country of destination Ukraine
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	0 (No export of blood components to to third countries)
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	Yes
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	One of imposed major shortcomings was not eliminated after inspection.
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	1
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	1 - suspension of authorisation, 1 - fine
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No

8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	No difficulties.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Donors, who visited endemic areas can not donate blood and blood components during 1 month after return. Donor with the symptomes of WNV desease cannot donate the blood during 3 month after his recovery.
8.5. Which other communicable diseases are of relevance to you?	Dengue, Chicungunya, Malaria
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Pharmaceutical legislation, but separated from blood and blood component legislation - Act No. 362/2011 Coll. on Drugs and Medical Devices Competent authority is Ministry of Health
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	no
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	In our country, legal framework for blood and blood components, which implement EU blood legislation, is a part of pharmaceutical legislation, Act No. 362/2011 Coll. on Drugs and Medical Devices and on Amendment and Supplementing of Certain Acts as amended later in our country.

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, 1000 Ljubljana
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)	Blood and blood components Pharmaceuticals (including blood derivatives) Tissues and cells Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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.).	JAZMP is an Independent agency founded 1.1.2007. The Agency was established and operates according to the legislation which explicitly states its competences and tasks (“Medicinal Products Act” (2006, 2008), “Medical Devices Act” (2009), “Blood Supply Act” (2000, 2004, 2006), “Act on Quality, Safety of Human Tissues and Cells” (2007), “Public Agencies Act” (2002, 2004, 2011) and “Decision on the establishment of the Public Agency for Medical Products and Medical Devices of the Republic of Slovenia” (2006). JAZMP is organised in 12 sectors. EU issues are as a rule treated with very high priority by JAZMP.
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	NA
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	3 BE (with dislocated blood departments, total number of sites: 15)
2.1.2. How many of the BEs are satellite sites?	9
2.1.3. How many of the BEs are mobile sites?	3, Each BE is authorised to perform blood collection with mobile site.
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	59.634
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	NA
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	10.706
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	Some sporadic blood donors (less then 0,5 %) do come for whole blood collection, mostly because of longer staying in Slovenia due to work, imigration, study..). They came from EU countries, Bosnia, Croatia...
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	93.099
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 mL
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	623
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your	500 mL

country (in ml per donor).	
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	2.343
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	single dose unit with additive solution = 300 mL, double dose unit with additive solution = 600 mL
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	granulocytes, apheresis: 125
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	3
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	2
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	- Other paper material - web sides of Red Crossand Transfusion Service - educational program for prospective young donors (Club 25)
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Please see uploaded document.
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	Legal requirement (Rules on mandatory testing of blood and blood components, Official Gazzette 9/2007, Art.6)
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	Pre-donation exclusion is based on questionnaire and interview with medical doctor, post-donation self exclusion is possible by telephone call
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	Medical condition of donor (which are relevant to not harm donor).
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Deferral for particular epidemiological situation, sexual behaviour.
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	Specialy for the first time donors (whole blood and apheresis blood components) the criteria not just body weight, but it would be appropriate to calculate extracorporal volume (on the basis of body weight and body high).
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	During the last 12 months have you had sexual contact with: - a partner who is HIV positive or has viral jaundice (hepatitis)? - a partner who has injected drugs? - a partner who receives payment for sex, in money or drugs? - a man who had sex with another man? Have you ever - injected drugs? - accepted payment for sex, in money or drugs? - had sex with another man (male donors)?
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor	Low level of Hb = 28,5% High/low blood pressure = 8,2% Deferral for particular epidemiological reasons = 4,9% Not feel well = 5,3%

deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Flu-like illness and fever > °C = 5% Medication = 3.8% Too short time between two donation = 2,1% (Data from BTCS)
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	Annual report to Competent Authority
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	12.979
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	Checking during Authorisation procedure and during Inspection
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	According to Slovene legislation NAT testing for viruses (HIV, HBV, HCV) is mandatory for all allogenic donations.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Additional test for syphillis is required: anti-Treponema pallidum, not required for autologous donations.
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Additional test for syphillis is required: anti-Treponema pallidum, not required for autologous donations.
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	2
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	8 HbsAg pos and 4 HBV DNA -only pos
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	4
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Anti-TP(syphillis): 10
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Amotopsoralen + UV radiation (Intracept) for Plateles
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Tasks are delegated Only In cases of absence of QP, however the QP or Deputy should be available 24/7.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	The requirements are certified during authorisation procedure and during inspections.

3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	ISO 9001:2008
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Legal requirement, verified during authorisation procedure and during inspections.
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Documentation should be maintained for 30 years, in paper records.
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Provision in legislation.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Provision in legislation, Genetic data are not specified in our legislation.
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Yes.
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	Very useful. There are some differences in eligibility criteria for donors.
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	1.7.2013: 3 (WITH ALL SITES)
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	Ministry of Health
4.6. How many laboratories performing donor testing are active within your country?	3
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	Ministry of Health
4.8. How many hospital blood banks are active within your country?	3
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	No
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Inspection

5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	4
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	1.1.2008-31.12.2012: 28
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	1.1.2008-31.12.2012: 15
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	7
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	1
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	1
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	Based on findings in previous inspections, legal requirements (at least 2-years inteval) and after authorisations of new activity (ctitical steps could be assesed/ inspected earlier than legal requirement) annual plan of inspections for current year is prepared.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	Small country, we do not have a lot of BE.
5.5.3. How many BE have been inspected at least twice in the last 3 years?	3
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	The 2-years inspection intervals are equal for all sites.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Complient, 2-years inspection period is forseen.
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	CAPA, CAPA assess, 2-year period
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	CAPA, CAPA assess, after 1 year follow-up or routine inspection in 2-year period
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	NA
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	NA
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	NA
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	We do not have plasma establishments (sites just for plasma collections)
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	No
5.8.1. If no, please explain.	Only inspectors can inspect blood establisments and any third parties.
5.9. Is a system in place for inspecting hospital blood banks?	Yes

5.9.1. If yes, please describe.	Quality manegement service on the BTCS is involved in inspecting hospital blood banks by contract.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	Very good tool
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	JAZMP
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	For all blood components (Ertc, Pt, Plasma, Lkc, Whole blood)
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	CODABAR
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	granulocyte apheresis
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Provision in legislation
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Any serious adverse event related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority. All SAR/E reports are reported on prescribed forms-templates. These templates have two parts, in the first part there are basic informations about SAR/E and in the second part there is a conformation question regarding the SAR/E. As basic information there is a needs to indicate the institution that reports, identification of report, day of report and day of the SAR/E. For SAR they need to then specify the blood component/s, type od the reaction and rate of connection between transfusion and reaction. At the second part they confirm SAR, rate of connection between transfusion and reaction and clinical outcome. For SAE they need to specify irregularity and type of specification. At the second part they confirm the event, root

	cause analysis and corrective action taken. We keep records of all the received reports and, if necessary, inform inspectors. Reports that we receive through CIRCABC, Rapid Alert System for Human Blood and Blood Components we sent to the appropriate recipients for further consideration. Then they take all the necessary measures and inform us about them.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	All SAR/E reports are reported on prescribed forms-templates. These templates have two parts, in the first part there are basic informations about SAR/E and in the second part there is a conformation question regarding the SAR/E. As basic information they need to indicate the institution that reports, identification of report, day of report and day of the SAR/E. For SAR they need to then specify the blood component/s, type od the reaction and rate of connection between transfusion and reaction. At the second part they confirm SAR, rate of connection between transfusion and reaction and clinical outcome. For SAE they need to specify irregularity and type of specification. At the second part they confirm the event, root cause analysis and corrective action taken.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	In cases when SARE may be connected with quality and safety.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	No
6.2.8.2. If no, why not.	No legal requirement
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	23 units of blood components
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	Ad hoc meeting on BTCS, the short describtion of alert and actions send to BE. In cases of SARE CA is informed.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	CA informs Hemovigilance service at BTCS. Ad hoc meeting on BTCS, the short describtion of alert and actions send to BE.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Via Rapid alert system for human tissues and cells, Medical Devices Vigilance System, Pharmacovigilance system, National system for communicable diseases

6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	No
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	The imported blood must fulfill the national requirements. (Blood Supply Act, Official Gazette No.104/2006, Art. 26)
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	NA (Slovenia does not import blood and blood components for fractionation; Slovenia does not have fractionation facilities)
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	International standards
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	Yes
7.4.1. If yes, please specify.	Our demand goes more beyond the minimum requirements, as NAT testing f.exp. in Slovenia is done on single donations, as in others countries is done on pooled donations.
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	0 blood component was imported in 2012.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	0 units of plasma was imported in 2012, we do not have plasma fractination facilities in Slovenia.
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Contract and quality assurance agreement.
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Only in emergency cases as humanitarian help, with special authorisation of Minister of Health. (Blood Supply Act, Official Gazette No.104/2006, Art. 28)
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.9.1. If yes, please provide this data by country of destination.	No units of blood components were exported for fractination to third countries in 2012.
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	No units of blood components were exported for transfusion to third countries in 2012.
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	NA
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	0

8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	NA
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	In our legislations the formal uniform transfusion service as one organisation is not supported enough, so we are experiencing different organisation and approaches
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	28-days deferral for donors coming from impacted aereas.
8.5. Which other communicable diseases are of relevance to you?	Flue, Tick borne disease
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	We regulate PRP under Tissue and Cells legislation. The National Competent Authority is JAZMP. The decision for regulating other »borderline« products and techniques under Tissue and Cells, Blood or Medicinal Product legislation, should be taken case-by-case.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	No
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	No

A.1.28. Survey response Spain

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	1. General Directorate for Public Health. Ministry of Health, Social Services and Equality 2. Autonomous Communities: Health Departments (17)
1.1.2. Address of NCA 1:	Paseo Del Prado 18-20. 28014. Madrid.
1.1.3. Telephone (central access point):	34 91 5962062
1.1.4. E-mail (central access point):	dgspci@msssi.es
1.1.5. Website:	http://www.msssi.gob.es/profesionales/saludPublica/medicinaTransfusional/home.htm
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Haemovigilance Other
1.1.7.1. If other, please specify.	1. Basic legislative 2 It dictates guidelines for action in transfusion security national policy 3. Authorization of importation/exportation of blood and blood components
1.2. National Competent Authority 2?	No
1.3. National Competent Authority 3?	No
1.4. 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 Ministry of Health exercises the activities linked to the National System for the Transfusional Security (SNST), and is competition to establish common basic standards that set the conditions and minimum requirements, chasing an equalizing basic conditions in the functioning of public services The Ministry has set as objectives the self-sufficiency of blood and derivatives based on altruistic donations, to guarantee safety for the donor and recipient and an optimal use of blood and blood components in accordance with guidelines from the European Union. For advice on this matter, it has a Scientific Committee (CCST) 1. The Scientific Committee for Transfusion Safety (CCST) is a technical advisory body under the Ministry of Health through the General Directorate of Public Health The technical advisory is responsible for proposing the guidelines on transfusion safety at national level. The committee operates under the principles of objectivity, impartiality and confidentiality in the performance of their duties. 2. The National Commission for Hemotherapy (CNH): coordinating body
1.5. 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)	Designation, authorisation, accreditation, licensing of Bes Inspection Haemovigilance
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	Spain is divided in 17 autonomous communities (also called regions). Each of these regions has a competent organization for implementing health policies and for developing further regulations than national ones.
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	24 (Will be 20 in 2014)
2.1.2. How many of the BEs are satellite sites?	If it refers to establishments-dependent units it is 4
2.1.3. How many of the BEs are mobile sites?	The number of units estimated is 150 (national total)
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	1.214.281 donors (first time + repeat + known donors)
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	828.955
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	233.062
2.1.7. Do you experience cross-border movement of donors	No

into/from your country?	
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	1.702.768
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450 cc
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	22.564
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	550 cc
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	7.880
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	75% Units should be > 3 x 10 (11) of platelets.
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	Multicomponent aphaeresis = 24.235 Erithroaphereis: 493
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	24
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	24
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at regional level
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).*	http://www.msssi.gob.es/profesionales/saludPublica/medicinaTransfusional/publicaciones/docs/criteriosBasicosTomoII_2006_030907.pdf
2.1.18.2. Please provide a copy of the donor evaluation/selection form standardised at regional level (in English if possible).*	See Annex I (see Attached files) (Selection form of two regional)
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	1. Through regular inspections carried out by the regional authorities (regional) 2. Assessments carried out by The Scientific Committee for Transfusion Safety
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	In the information provided to the donor, there is a specific questionnaire opt-out, but it is not usual to have the Blood Establishments unit of opt-out
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	All of them are relevant
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Aspects related to sexual risk behaviours
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	http://www.msssi.gob.es/profesionales/saludPublica/medicinaTransfusional/publicaciones/docs/criteriosBasicosTomoII_2006_030907.pdf (page 39)
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current	No

age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	There is a computerized registry of donors in the 24 BEs. The specific causes and their frequencies are recorded in each BE (24). Is not collected at national level
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	24 Centers of Blood Transfusion (BEs) report to the Ministry annually total number of excluded donors, and of these the number of temporary and permanent exclusions
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	Total number of excluded donors: 194.346 (total registered donors: 1.214.281) Excluded temporarily: 176.013 (90, 7%) Excluded permanently: 18.333 (9, 3%)
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	No
2.2.11.1. If no, what other deferral criteria would you suggest for derogation? Would you have other suggestions on the usefulness and set-up of such temporary derogations?	-
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	The corresponding authorizations are applied to the autonomous communities, as well as proof of registration Annually the 24 BE are asked for the type of tests used, (including the trademark), for each infectious marker
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	HIV: Tested Units: 100% HBV: Tested Units: 100% HCV: Tested Units: 100% Total Tested Units NAT: 1.762.042 (100%)
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	No
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	142
3.1.5.2. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	474
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	252
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Selective test: HTLV-I-II: 35 positives (Tested units: 534.886) Paludismo: 124 positives (Tested units: 17. 6739 Tripanosoma Cruzi: 125 positives (Tested units: 87.609)
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	-
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Methylen-Blue inactivation for plasma (transfusion)
3.2. Processing	

3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	1 Inspections carried out by regional authorities (CCAA) 2 Inspections carried out by the CAT Foundation (Committee on accreditation in Transfusion), this Agency has been recognized in 2010 by the national accreditation entity (ENAC), as certification for BEs and transfusion services (HBB). About the CAT Foundation: It is an organization made up of the Spanish society of Hematology and Hemotherapy (AEHH) and the Spanish society of Blood Transfusion and Cellular therapy (SETS) of December 11, 2008. Its origins lie in 1973, with the creation of the accreditation program of blood banks
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	1. Annually information on quality systems implemented in both BEs and HBB is collected. The 100% of HBB have "standard operating procedures of work".
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	A) Through the implementation of quality systems certification bodies, such as: 1. CAT Foundation inspects and certifies the quality systems of BEs and HBB 2. Organisms dependent on regional authorities such as the accreditation agency of health centers of Andalusia (ACSA) 3. Private independent agencies: Bureau-Veritas, AENOR etc. (B) By the publication and distribution of manuals and guides of quality:
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Specific computer systems
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Specific computer systems
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	1. There is legislation specifies: law on data protection, and bioethics Research Act 2. Specific computer systems
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	It is mandatory to have a code system but is not mandatory to be the same system for all the country. Currently the following systems are used: ISBT- 128: 76% CODABAR: 18% Others (CODE 39):6%
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	The experience has been excellent. Spain since 1988 is part of the Group of experts on the elaboration of the Guide to the preparation, use and quality control of the Council of Europe. It has been translated several times, and is systematically disseminated to alls BEs
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	

4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	The authorization of establishments is granted by the regional authority
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	All BEs (n=24). See table in annex II.
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	The laboratories are approved by the regional authorities (17)
4.6. How many laboratories performing donor testing are active within your country?	24
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	By the regional authorities
4.8. How many hospital blood banks are active within your country?	There is 368 Hospital Transfusion Services (HBB)
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	Yes
4.9.1. If yes, please specify the scope of these extra rules.	The implementation of quality Systems (art. 32 RD 1088/2005) The implementation of Hospital Transfusion Committees (art. 40 RD 1088/2005)
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	Laboratories Grifols (private) were founded in 1940. (Barcelona. Catalonia). In 2006, the company changed its name to Grifols S.A.The plasma sent by the BEs to Grifols is processed into therapeutic plasma products, and returned to them for distribution to the hospitals In Barcelona, Grifols fractionation plant has a fractionation capacity of 2.1 million litres annually In 2012 it fractionated 365.000 litres of Spanish plasma
4.10.2. If yes, please state the responsible authority within your country.	Jurisdiction of the Spanish Agency for Drugs and Medical Devices (Agency)
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	1. The Regional Health Authority Inspection Department 2. Accreditation systems carried out by scientific societies (CAT)
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	1. Inspector of the Regional Health Authority Inspection Department, together with one or two experts in transfusion medicine (2-3) 2. CAT: Experts in transfusion medicine (2)
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	See annex II table inspection
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	See annex II table inspection
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	-
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	-

5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	See annex II table inspection
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	100% (24)
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Satellite: every 2 years. Mobile collection sites: a sample of the total number
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	0%
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	100%
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	0%
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	0%
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	0%
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	-
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	0%. There are no plasma establishments in Spain
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	CAT Foundation and some regional authorities.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	No
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	The experience has been excellent.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	5
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	Specific computer systems
6.1.3. Do you have a single national coding system for blood components?	No
6.1.4. Do you apply an international coding system for blood components?	Yes

6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT-128 (76%)
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Only electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	Specific computer systems
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	Spain is divided in 17 autonomous communities (also called regions). Each of these regions has a competent organization for implementing health policies and for developing regulations. In accordance with this organization, the national network is made up of the HV network of the 17 regions, together with the Haemovigilance Unit. The current system is organized in three levels (see figure): • Local level (level 1): this level is composed by the HBBs and the Blood Establishments BEs. The detection and first analysis of potential adverse events and reactions is responsibility of the HBB and the BE staff. • Regional level (level 2): this level is made up by the Regional Haemovigilance Networks. Within this level, tasks that involve collecting information from BE and HBB depending on each regional authority and the coordination with the Ministry of Health are developed. The responsible person is the Regional Haemovigilance Coordinator. • National level (level 3): this is the place where we can find the Haemovigilance Unit that is responsible for the coordination of the 17 regions and for the relationship with the European Commission. This Unit gathers the information related to the events registered by the regional networks and it prepares an annual report.
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.2.1. If no, what template do you use (please specify)? If possible, please upload template.	A similar template to the one developed for the annual reporting is use for gathering the SAEs. A more complete template than the EC one is used for reporting SARs.
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	A procedure was made in 2004. It includes common definitions, templates for reporting SAREs and a general reporting framework.
6.2.6.1. If yes, please provide a brief description.	A procedure was made in 2004. It includes common definitions, templates for reporting SAREs and a general reporting framework.
6.2.7. Do you perform root cause analyses of the SARE?	Yes
6.2.7.1. If yes, in which cases?	In all cases. Templates use for reporting SARs at HBBs include questions intended to evaluate their possible cause. The root cause analyses for SAEs is made by BEs

6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	No
6.2.8.2. If no, why not.	Because we were waiting for data of SAR/E recorded at EU level to be more consolidated and for an official and public report from the EU.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	Information only available at regional level.
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	The NCA and the responsible person in every BEs are in touch by e-mail and phone. A mail distribution list is made and it is continually updated. We also are working in a system called e-Room which is expected to be an alert system. This system is quite similar to the CIRCA BC platform.
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	The NCA and the responsible person in every BEs are in touch by e-mail and phone. A mail distribution list is made and it is continually updated. We also are working in a system called e-Room which is expected to be an alert system. This system is quite similar to the CIRCA BC platform.
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	Communicable diseases and other threats to health Medical devices
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	Blood components are not imported for transfusion
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	Jurisdiction of the Spanish Agency for Drugs and Medical Devices (Agency) The importing pharmaceutical laboratory must be authorized by the Agency to import, store, and analyze Plasma as raw material of biological origin (Biomat)
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Equivalent standards (bilateral agreements) If it was necessary, equivalent standards verification would be applied.
7.3.1. If others, please specify.	IVO: If a BE is in a situation that they have to import blood or blood components they have a responibility to ensure that the place where they import from has the same quality standard as the national. (e.g EU legislation) MPA: För plasma for fractionation, the compliance with the EU-standards is documented in Plasma Master Files, which is scrutinized before approval of the PMF and of the corresponding plasma derived medicinal products. A reassessment of the PMF, as updated, is thereafter made annually. PMFs are certified by EMA in a EU-centralised procedure
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of	Yes

Directive 2002/98/EC?	
7.4.1. If yes, please specify.	In the event that it was necessary, application of NAT technology in minimum markers would be required, detection of Chagas` disease, as well as the application of procedures of leukodepletion and/or viral inactivation
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.5.1. If yes, please provide this data per component and by country of origin.	No components for transfusion were imported.
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No. Jurisdiction of the Spanish Agency for Drugs and Medical Devices (Agency)
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	Jurisdiction of the Spanish Agency for Drugs and Medical Devices (Agency)
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	Not applicable
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.10.1. If yes, please provide this data by country of destination.	= 0
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	Yes No We do not understand this question.
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	Yes
8.2.1. If yes, please specify.	
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	There is a protocol of actions from the National Epidemiological Surveillance Network that establishes the bases of surveillance and the public health measures to control communicable diseases that must be reported in Spain, and those diseases that must be monitored in the framework of the European Union, including WNV. 1st. As described in the Protocol, (updated in April 2013) active epidemiological surveillance in humans begins when viral circulation in animals (birds or horses) and/or vectors is detected. These criteria are adjusted depending on the epidemiological situation. The epidemic territory is defined according to the circulation and dynamics of the infection of the virus and in it the recommended public health measures will be applied. In areas where have already been detected human cases, active surveillance is

	reactivated at the beginning of each season of activity of the vector. If, at any time, a doctor or laboratory detects a case of infection by this virus, it notifies by urgent and compulsory way this fact to the epidemiological surveillance of the corresponding autonomous community service, and from here to the central level. Public health measures Preventive measures Broadly, the prevention of human infection is based on preventing mosquito bites and to increase transfusion and transplantation safety. In human outbreaks that have occurred in our environment, surveillance of WNV outbreaks in horses has been a fundamental element to delimit the epidemic territory, so it is essential to have up-to-date and GEO-referenced information from these foci. Notifiable diseases protocols: http://www.isciii.es/ISCIII/es/contenidos/fd-servicios-cientifico-tecnicos/fd-vigilancias-alertas/fd-procedimientos/protocolos.shtml Preventive measures of transmission by blood: Recommendations of the Scientific Committee on Transfusion Safety (November 2010) after the Spanish outbreak is available in: http://www.msssi.gob.es/profesionales/saludPublica/medicinaTransfusional/acuerdos/docs/Virus_Nilo.pdf.
8.5. Which other communicable diseases are of relevance to you?	No
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No X (But currently it is not clear (platelets rich plasma))
8.6.1. If no, which is the applicable legal framework and the competent national authority?	It depends on the type of product, as well as the form of obtaining
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	RPP, autologous eyes drops
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Any plasma with industrial treatment (Example: SD inactivated plasma).

A.1.29. Survey response Sweden

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Health and Social Care Inspectorate (IVO)
1.1.2. Address of NCA 1:	Inspektionen för vård och omsorg (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 possible)	Blood and blood components Tissues and cells Human organs
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	Yes
1.2.1. Name of National Competent Authority 2:	Medical Product Agency
1.2.2. Address of NCA 2:	Läkemedelsverket Box 26 SE-751 03 Uppsala Sweden
1.2.3. Telephone (central access point):	+46 18 17 46 00
1.2.4. E-mail (central access point):	registrator@mpa.se
1.2.5. Website:	www.lakemedelsvarket.se
1.2.6. What are the role/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Other
1.2.6.1. If other, please specify.	Pharmaceuticals (including blood deriatives) and Medical devices
1.3. National Competent Authority 3?	Yes
1.3.1. Name of National Competent Authority 3:	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. What are the roles/tasks of the NCA? (more than 1 answer possible)	Other
1.3.6.1. If other, please specify.	Legislation, knowledge
1.4. 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.).	Health an Social Care Inspectorate: Independent CA with assignment from the govenment to supervise and authorize health and social care in Sweden. Total numbers of staff approx 500 localized as six regional offices and one central office. Tha staff consists of various expertise depending on the area for supervision, accordingly the staff consists of health care personell, social workers and legal advisers. 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, tissue and cells and organs. Medical Product Agency: Independent CA responsible for regulation and surveillance of the development, manufacturing and sale of medicinal products and for the surveillance of medical devices. Approximately 750 people work att the agency; most are pharmacist and doctors. The agency is divided into four departments; Development, Licensing, Supervision and Usage. The agency is actively involved in EU matters in the field of pharmaceuticals and medical devices. The National Board of Health and Welfare: Independent CA with assigment from government to perform follow up, national guidelines, issue bylaws and keep national registries in the areas of Health and Social care. Total numbers of staff is approximaltely 400 divided into three departments; Regualtions and Licences, Statistics, Monitoring and Evaluation and Knowledge-based Policy and Guidance.
1.5. 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

1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	NA
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	MPA: 91 IVO:28 See 4.7 for explanation
2.1.2. How many of the BEs are satellite sites?	94. incl certain satellites, used with low frequency, included in the authorisation of a regular BE
2.1.3. How many of the BEs are mobile sites?	13
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	247549
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	247549
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	NA
2.1.7. Do you experience cross-border movement of donors into/from your country?	No
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	484755
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	9929
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	700
2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	NA
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	NA
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	NA
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	23
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	se answer 2.1.15
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is not standardised at national/regional level
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	By inspections
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	If a donor for some reason after donation no longer want the BE to use his/her blood they have a possibility to give notice to BE and they cannot ask why. If this is happening the blood and blood components will be registrered with a code in the IT system and no components will be used. When this donors occures in a BE he/she will be checked up before donate again.
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	All criteria are relevant but some of them have to be evaluated on a national level because of the actual situation in the country.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or	Section 2.1, Sexual behaviour: We have encountered interpretation difficulties concerning “permanent deferral” and “high risk”.

least reliable to verify?	
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	Yes
2.2.3.1. If yes, please specify (additions/deletions/replacements, …).	In Annex III section 2.1 of the Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components there are the following permanent deferral criteria for donors of allogeneic donations: Sexual behavior Persons whose sexual behavior puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood A deferral period would be more reasonable and enable these persons to donate blood or blood components, if a reasonable time frame could be set to rule out the risk of transferable diseases. To clarify such an interpretation, the directive should be amended as follows: The above mentioned lines in section 2.1 on sexual behavior are omitted. Instead, an amendment of section 2.2.2 Exposure to risk of acquiring a transfusion-transmissible infection under 2.2 Temporary deferral criteria for donors of allogeneic donations is done by inserting a new line as a third paragraph: Sexual risk behavior Defer for 12* months after cessation of risk behaviour (*appropriate time period may be a subject of discussion)
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	No
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	There is several risky behaviours that should be taken into account when You have to consider donor deferral. Most important is to identify high risk sexual behaviours in the the interwiew with the potential donor.
2.2.6. Are there national guidelines for the assessment of vCJD?	No
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	The population in Sweden travelling a lot and therefor it is very common with temporary deferral for that reason. Even tattooes are very common and gives a period of deferral.
2.2.9. Do you have a system of centralised collection of data on deferrals?	No
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	No
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	No
2.2.11.1. If no, what other deferral criteria would you suggest for derogation? Would you have other suggestions on the usefulness and set-up of such temporary derogations?	NA
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	It is mandatory by legislation only to use accredited laboratories. Analyses of the mandatory documentation is requested from all BEs and they have to show which laboratory they use for donor testing (and have a written agreement applicable). The accreditation by SWEDAC is publicly available and the laboratory holds an accreditation licence. MPA: the laboratories must be inspected and comply with the Codes of statutes LVFS 2006:16.
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	No
3.1.2.2. If no, please specify the main barriers to implement NAT testing?	Epidemiological data in Sweden does not motivate a legal obligation to perform NAT testing. The National Board of Helath and Welfare and the Swedish Institute for Communicable Disease Control have the responisibility to follow and perform risk assessments of these diseases and for the moment we have no indications that NAT

	testing will be mandatory. As a voluntary measure applied by BEs, blood components are collected only from repeat tested donors in Sweden which means that a first time donor will not be allowed to give blood.
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	HIV 1 o 2 Ag, Anti HBc, anti-HTLV- I o II Treponema Pallidum
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	Anti HBc, anti-HTLV- I o II Treponema Pallidum
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	No
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	No
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Some of the BE in Sweden is using pathogen inactivation techniques for platelets but it is not mandatory and the BE itself has consider if they want to use that technology.
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Most of the BEs have other have a limited numbers of persons that may perform parts of the activities under Article 9 (1) by delegations but the overall responsability is a task for the responible person. MPA: limited number of trained persons may perform parts of quality assurance but the overall responsibility of the release of plasma for fractionation is within the remit of the responsible person.
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Inspections of the site/centre - Analysis of the mandatory documentation
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	It is mandatory in national legislation to have a quality system in place and it is for BE most common to have that also complying with the GMP regulations.
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Inspections of the site/centre - Analysis of the mandatory documentation
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Electonic archives or on paper
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Every BE has to comply with the requirerments in Directive 2002/98, annex IV and 2005/62/EC and that is mandatory to document in the BE's quality system. Due inspections there a follow up to ensure that.
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is	Due inspections.

rendered anonymous so that the donor cannot be identified (Article 23)?	
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	No
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA give (more than 1 answer possible)?	Authorisation Licensing
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	MPA: 91 IVO: 28 See 4.7
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	All BEs has to use a accreditated laboratory and The Swedish Board for Accreditation and Conformity Assessment (SWEDAC) is responsible for that in Sweden. www.swedac.se Medical Products Agency: For BEs authorised for the collection of plasma for fraction, laboratories must be authorised by MPA.
4.6. How many laboratories performing donor testing are active within your country?	23
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	In Sweden BE and hospital blood banks are within the same organization. The "main BE" in a region or organization, are responsible for a couple of units linked to them. In Sweden there are 28 "main BE" and all of them are situated at a hospital. Most main BE has responsibility for a couple of other hospital blood banks and have also satellite and mobile centers in the same organization. IVO gives authorization for the main BE and the hospital blood banks linked to every BE. If they also collect plasma for fractionation they have to be authorized by Medical Products Agency. According to the MPA regulations, in turn complying with the guidelines issued for PMF by EMA/CHMP, all collection centers (albeit not including satellites used at a low frequency) are classified as BEs. Therefore the different figures reported by the two CAs is a matter of classification. See also point 2.1.1.
4.8. How many hospital blood banks are active within your country?	...
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	Octapharma Stockholm
4.10.2. If yes, please state the responsible authority within your country.	Medical Products Agency
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Health and Social Care Inspectorate: Responsible for inspections (both regular and in the event of SAR/E) according to Directive 2002/98/EC Article 8 (1-4) in the field of blood and blood components for transfusion. Medical Products Agency: Department of inspection

5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	MPA: 2 IVO: 2
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Tissues and cells Pharmaceuticals (including plasma derivatives) Advanced therapies Hospitals
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	MPA and IVO: See 5.4.1
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	IVO: 15 desk-board revision and 21 at site inspection
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	MPA: 45 IVO: 34 the routine inspections is a combination of general system-oriented and thematic
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	MPA: 0, IVO: 0
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	MPA: 0, IVO: 0
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	IVO: A risk based approach is in use both for the regular and other inspecions. The common approach is to use all reported SAR/E for the actual BE/hospital blood bank as a compliment to the ordinairy template for regular inspection. The ordinairy template is also revised annually on a national level after analyses of findings in former inspecions nationwide. MPA: No
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	Yes
5.5.3. How many BE have been inspected at least twice in the last 3 years?	MPA: 40 IVO: all 28 main BE has been inspected twice
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	IVO: The main BE/hospital blood bank is inspected every second year but not all including units (other hospital blood banks/BE in the same organization). They will be inspected at least every fourth year and the responsible person for main BE has to responsible for all units all time. If there is a possibility both CAs are trying to coordinate inspections so both CAs inspect at the same time. MPA:Every second year
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	MPA: 0, IVO: 3
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	MPA: 45, IVO: 31
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	MPA: 0, IVO:0
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	MPA: 0, IVO: 0
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	MPA: 0, IVO: 0
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	NA
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	1

5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	Se answer 5.5.4
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	IVO: This CA has responibilty for supervision of health care in order to patient safety on national level and the organisation in Sweden of BE/hospital blood banks gives opportunity to inspect the whole chain "from vein to vein". MPA: no
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
5.10.1. If yes, what is your experience with this Guide?	Helpful
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	Yes
5.11.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (not important) – 2 (sufficient) – 3 (good) – 4 (very good) to 5(essential)	4
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	No
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	MPA and IVO
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	All components
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Granulocytes
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	By inspections on sites
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	SAR snd SAE are reported directly to the coordinators at the CA close to the event/reaction and in addition an annual report of all SAr and SAE should follow the annual report for the activity of BE. The coordinators collect the reports, evaluate the suggested/performed actions and the reports according to classification that should be reported later to EC. If needed the coordinators may ask for additional actions that has to be completed before the report is closed.

6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	Yes
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	50-69%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	Yes
6.2.6.1. If yes, please provide a brief description.	Not applicable because of the national organisation of BE/hospital blood banks in Sweden. The hospital blood banks and BE are in the same organisation and of course they have mandatory procedure for reporting SAR/SAE in place. Se answer to 6.2.1.1
6.2.7. Do you perform root cause analyses of the SARE?	No
6.2.7.2. If no, why not?	The response for SAR/E is the BE and they have to do the root cause analysis and send report to CA who has to approve or not.
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Every second year, Health and Social Care Inspectorate (former Swedigh National Board of Health and Welfare) invites all BE to a meeting where one point in the agenda is to give feed-back regarding SAR/E recorded at EU level.
6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	MPA: 1. IVO: 1
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	The Swedish National Board of Health and Welfare have a function with a 24-hours service that provide all other CA with information if there is a rapid alert in the field of blood and blood components, Tissue and cells ,organs. (all kinds of rapid alerts under the Swedish Ministry of Health and Social affairs responsibility is reported to this function). The person in duty has to inform responsible CA as soon as the alert is actual so they have to consider what to do and if there is a need to contact BE/hospital blood banks. The coordinators at IVO have contact list covering all BE's and an e-mail is sent out together with an alert on our public website. MPA: no
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Se answer 6.2.11.1
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Pharmacovilance Medical devices Communicable diseases and other threats to health
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	6.2.11.1 MPA: OMCL, EMA (both rarely)
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	NO
7. Import - export (Art 21 Directive 2002/98/EC)	

7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	National law on blood safety 2006:496 and the CAs Codes of statutes
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	National law on blood safety 2006:496, National law on pharmaceuticals 1992:859 and the MPAs Codes of statutes LVFS 2006:16, LVFS 2004:7
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	IVO: If a BE is in a situation that they have to import blood or blood components they have a responibility to ensure that the place where they import from has the same quality standard as the national. (e.g EU legislation) MPA: För plasma for fractionation, the compliance with the EU-standards is documented in Plasma Master Files, which is scrutinized before approval of the PMF and of the corresponding plasma derived medicinal products. A reassessment of the PMF, as updated, is thereafter made annually. PMFs are certified by EMA in a EU-centralised procedure
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	Yes
7.6.1. If yes, please provide this data by country of origin.	Proprietary info in PMF dossiers
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	All BEs in Sweden, that are releasing plasma for fractionation, are inspected and authorised according the same national legislation as applies for use of the plasma in Sweden
7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	..
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	Yes
7.12.1. If yes, for which blood components (more than 1 answer possible)?	Plasma
7.12.2. If yes to Q. 7.12., what do you do with the surplus of blood or blood components?	BEs sell the plasma to fractionation(pharmaceutical) companies
7.12.3. If yes to Q. 7.12., would you be interested in concluding bilateral agreements with other MS in order to address the surplus?	MPA: No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What	MPA: We have encountered problems related to the import to the EU of blood components collected in third country (e.g. red blood

specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	cells) used as a reagent (not starting material) in the manufacture of a medicinal product, which has a marketing authorisation in Sweden (granted previous to the implementation of the Blood directives). The company is not willing to ensure that the RBCs comply with the criteria of 2004/33/EC, neither that the BE is inspected and approved according to the Blood directives. It is not in the remit of the Inspectorate of Sweden to inspect, becasue the MS of import, likewise the MS responsible of survey of the manufacturer of the medicinal product, does not require that the BE is inspected according to the Blood directives.
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	When we receive alerts from ECDC abouts outbreaks of WNV in some of the Member States all CAs in Sweden in the field of blood and blood components will consider if we have to forward this alert to BE immidiately or not. The BEs has to introduce 28 days of quarantine for donors who has visited the actual area.
8.5. Which other communicable diseases are of relevance to you?	All blood transfusion transmitted communicable diseases will have relevance.
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	Yes
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Overlap / classification problems concerning the survey of establishments collecting blood cells to be used as a basis for cell derived products. Would cells be derived from a sample taken at a medical care centre and then be further processed, for example in the preparation of an autologous cell therapy product, the traceability might be at risk of becoming non-sufficient.
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Preparation of a product for an individual patient is out of scope of the pharmaceutical legislation (2001/83/EC Art 3.2 and 3.6) but any product starting with a pooling of plasma for further processing would be considered to fall under the scope of the pharmaceutical legislation.

A.1.30. Survey response United Kingdom

1. Public information	
1.1. Name of National Competent Authority (NCA) 1:	Medicines and Healthcare Products Regulatory Agency
1.1.2. Address of NCA 1:	151 Buckingham Palace Road London SW1W 9SZ
1.1.3. Telephone (central access point):	020 3080 6000
1.1.4. E-mail (central access point):	info@mhra.gsi.gov.uk
1.1.5. Website:	www.mhra.gov.uk (moving to www.gov.uk during 2014)
1.1.6. The NCA is responsible for? (more than 1 answer possible)	Blood and blood components Pharmaceuticals (including blood derivatives) Medical devices
1.1.7. What are the roles/tasks of the NCA? (more than 1 answer possible)	Designation, authorisation, accreditation, licensing of BEs Inspection Haemovigilance
1.2. National Competent Authority 2?	No
1.4. 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 Competent Authority (MHRA) is a government department affiliated to the UK Department of Health. MHRA also fulfils the duties of Competent Authority for medicines and medical devices. With respect to the number of staff responsible for performing the duties relating to the blood competent authority, this is as follows: Inspectors – 6 senior inspectors, 3 accredited inspectors (multi-skilled, performing blood and pharmaceutical inspections) Haemovigilence – 3 Regulatory / EU affairs – 1 Administrative staff (processing of authorisation applications etc) – 4 (multi-skilled, processing blood and pharmaceutical applications) http://www.mhra.gov.uk/Aboutus/index.htm
1.5. 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
1.6. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies):	N/A
2.1. Collection	
2.1.1. Please provide the number of BEs in your country recorded at 31/12/2012.	13
2.1.2. How many of the BEs are satellite sites?	There are approximately 10 satellite collection sites operated under the responsibility of a nearby main blood establishment
2.1.3. How many of the BEs are mobile sites?	4 blood establishment authorisation holders (the main UK Blood Services) operate mobile collection activities. This accounts for the majority of blood establishment collections in the UK
2.1.4. Could you please provide the number of donors active in 2012 (01/01-31/12/2012).	1,376,013
2.1.5. Could you please provide the number of repeat donors active in 2012 (01/01-31/12/2012).	670,716 (England, Scotland & Northern Ireland)
2.1.6. Could you please provide the number of first time donors active in 2012 (01/01-31/12/2012).	198,526
2.1.7. Do you experience cross-border movement of donors into/from your country?	Yes
2.1.7.1. If yes, please explain (from/to which other countries, plasma/blood donations, estimated magnitude, explaining factors, …).	From Republic of Ireland, blood donations less than 1% of 63,000 donors FFP for transfusion in UK children is sourced from Austria
2.1.8. For whole blood donations, could you please provide the number of whole blood donations in 2012 (01/01-31/12/2012).	2,256,736
2.1.9. For whole blood donations, could you please provide what is the standard or average volume of a whole blood donation in your country (in ml per donor).	450-495ml
2.1.10. For plasma donations by apheresis, could you please provide the number of plasma donations in 2012 (01/01-31/12/2012).	Nil
2.1.11. For plasma donations by apheresis, could you please provide what is the standard or average volume of a plasma donation in your country (in ml per donor).	N/A

2.1.12. For platelet donations by apheresis, could you please provide the number of platelet donations in 2012 (01/01-31/12/2012).	148,012
2.1.13. For platelet donations by apheresis, could you please provide what is the standard or average volume of a platelet donation in your country (in ml per donor).	197-231 mls single platelet donation
2.1.14. Could you please provide the number of other donations by apheresis in 2012 (01/01-31/12/2012).	Nil
2.1.15. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for whole blood donations.	7
2.1.16. Could you please provide the number of laboratories performing donor testing at 31/12/2012 for plasma donations.	N/A
2.1.17. What measures are in place to ensure that donors are provided with the appropriate information, as required under Art. 16 and Annex II, Part A of Directive 2004/33? (more than 1 answer possible).	Only trained personnel is allowed to provide such information Information for donors are standardised at national/regional level Other
2.1.17.1. If other, please specify.	This information is on the Donor Welcome Pamphlet which every donor receives on arrival and is required to read prior to signing their informed consent statement. This is/can be reinforced verbally by BSQR trained staff when required (Wales). Donor information leaflet is provided at each session. Consent statement requires donor to say that they have read and understood it. All publications available on website. Audio versions available for visually impaired donors (Scotland). Information provided in written format (leaflet) and may be followed up verbally by trained staff as appropriate (Northern Ireland).
2.1.18. What methods are in place to ensure that donors provide the appropriate information, as required by Art. 17 and Annex II, Part B of Directive 2004/33? (more than 1 answer possible).	Information is collected through a personal interview with a medical doctor Information is collected through a personal interview with a health care professional that is not a medical doctor Information is collected through a donor evaluation/selection form that is standardised at national level. Information is collected through a donor evaluation/selection form that is standardised at regional level Other
2.1.18.1. Please provide a copy of the donor evaluation/selection form standardised at national level (in English if possible).	Sample attached
2.1.18.3. If other, please specify.	All new donors are interviewed with greater depth by a registered nurse in a personal donor interview. Repeat donors who have not donated in the previous two years are also interviewed by registered nurses (Scotland) Information is collected through a personal interview with a healthcare professional who may or may not be a medical doctor and is collected through a donor healthcheck questionnaire which is standardised at national level (Northern Ireland)
2.1.19. How do you ensure that the donor evaluation and testing procedures are documented and any relevant abnormal findings are reported to the donor (Art. 18(2) of Directive 2002/98)?	All donor deferrals and relevant comments are recorded in eProgesa. If required additional information can be sought from the donor's own doctor using a medical referral form on session. This would be managed by Donor Carer Doctors and the donor would be notified in writing or by telephone call of the outcome. Any relevant comments or derferral codes would be recorded in e Progresa. The donor would be notified of any abnormal test results by a doctor in line with Scotland's national policies and SOPs (Scotland) Procedures contained in Quality Management Systems and SOPs are in place in Northern Ireland
2.1.20. Do you have a system for the self-exclusion by a donor?	Yes
2.1.20.1. If yes, please describe (bar code, etc.).	Wales: No, except non-attendance Northern Ireland: Yes, Healthcheck, Website information Scotland: Not a formal system, but the literature offers the donors the opportunity to leave the session without explanation. England: No
2.2. Deferral (Directive 2004/33/EC)	
2.2.1. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most relevant? Please explain.	In general the guidance is too broad and not specific enough and does not give any real rationale. The guidance is very much a minimum standard and could be better evidence-based than

	currently. It is also largely silent on some key areas.
2.2.2. Which of the eligibility/deferral criteria provided in Annex III of Directive 2004/33/EC do you find most difficult to implement or least reliable to verify?	Travel associated risk
2.2.3. Would you suggest changes in eligibility/deferral criteria in Annex III of 2004/33/EC?	No
2.2.4. Are there national guidelines for the assessment of risky sexual behaviours as required under Annex III of Directive 2004/33/EC?	Yes
2.2.5. Please specify which risky sexual behaviours are considered during donor deferral.	IV Drug use Sex with partners from high prevalence countries MSM Female sex with a man who has had sex with a man Sex with sex workers Sex workers Persons who believe their partner has or may be HIV positive, HTLV positive or be a carrier or Hep B or C Persons who have sex with injectable drug users
2.2.6. Are there national guidelines for the assessment of vCJD?	Yes
2.2.7. With ageing population, is there a need to change the current age acceptance criteria (point 1.12 of Annex III of 2004/33/EC)?	No
2.2.8. What have been the main causes leading to deferrals in your country? Can you provide information on the frequency of donor deferral along the different deferral/eligibility criteria. Which criteria are most/least leading to donor deferral?	Travel or medication (Northern Ireland & Wales) Low blood pressure 3%, medical 2.3%, infections 1.4% and travel 0.5% (England) Hb failure 2.48%, awaiting medical test results 1.04%, WNV risk 1%, age assessment 0.55%, tattoo and body piercing 0.52%, malaria 0.47%, unhealed wounds 0.37%, endoscopy 0.36%, dental 0.29& and D&V 0.29% (Scotland)
2.2.9. Do you have a system of centralised collection of data on deferrals?	Yes
2.2.9.1. If yes, please specify.	Wales: Local database based on donation outcomes, numbers only recorded Northern Ireland: Local database based on donation outcomes, numbers only recorded Scotland: Deferrals recorded in e-Progesa England: PULSE (main donor database)
2.2.9.2. If yes, how many deferrals have been recorded in 2012 (01/01-31/12/2012)?	Wales: 2,176
2.2.10. In 2009, Commission Directive 2009/135/EC was adopted to allow Member States temporary derogations to ensure blood supply during time of potential crisis. Was this derogation effectively applied by BEs in your country?	Yes
2.2.11. In case of future crisis, would temporary derogation of the deferral criteria in Commission Directive 2009/135/EC (Hgb levels and deferral window after flu-like symptoms) be the most efficient to maintain supply?	Yes
3.1. Testing	
3.1.1. How do you ensure, as CA, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art 5(2)?	MHRA inspections and CPA
3.1.2. Do you use NAT technology for routine testing blood or blood components in your Member State?	Yes
3.1.2.1. If yes, please specify how and how often NAT technology is used?	Every donation, pools of 24 donations
3.1.3. The basic testing requirements for donations are specified under Annex IV of Directive 2002/98/EC. In your country, are additional tests performed on a routine basis?	Yes
3.1.3.1. If yes, please specify whether these are mandatory under national legislation for whole blood donations.	Syphilis, HTLV & HCV are mandatory
3.1.3.2. If yes, please specify whether these are mandatory under national legislation for plasma donations.	N/A
3.1.4. Would you suggest changes in basic testing requirements for donations as specified under Annex IV of Directive 2002/98/EC?	No
3.1.5. Do you have a system of centralised collection of data with test results?	Yes
3.1.5.1. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for HIV:	15 confirmed positive results
3.1.5.2. If yes, could you provide the number of positive test results	70 confirmed positive and 1 non determinate results

in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis B:	
3.1.5.3. If yes, could you provide the number of positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) for Hepatitis C:	69 confirmed positive results
3.1.5.4. If yes, could you provide the number of 'other' positive test results in 2012 (on donations between 1/1/2012 and 31/12/2012) as well as specify which ones:	Syphilis 76 confirmed positive results HTLV 10 confirmed results Bacteria 3
3.1.6. Do you have any additional comments on testing (e.g. international accreditation systems for testing laboratories)?	All labs perform NEQAS (Scotland)
3.1.7. Are pathogen reduction/inactivation techniques used in your Member State?	Yes
3.1.7.1. If yes, please describe the processes used and the blood components concerned.	Bacterial Monitoring of Platelets (Wales, Northern Ireland) Methylene blue treatment of plasma (England, Northern Ireland)
3.2. Processing	
3.2.1. Has every BE designated a responsible person, which fulfils the minimum conditions of formal qualification and practical experience (Article 9 (2))?	Yes
3.2.2. Are tasks under Article 9 (1) delegated to other persons qualified by training and experience to perform such tasks?	Yes
3.2.2.1. If yes, please specify.	Responsibilities defined in job descriptions During periods of leave to suitably qualified or experienced personnel During periods of leave and via a BECS IT platform
3.2.3. How do you ensure that personnel in BEs and hospital blood banks is qualified and trained (Article 10 and Article 6)?	Relevant qualifications, by maintaining CPD and formal training to SOPs with regular competency assessments Annual assessment of registration, training matrix, training budget and policy and through top management commitment to budget allocation
3.2.4. Have BE and hospital blood banks a quality system for blood establishments based on the principles of good practice (Article 11 and Article 6)?	Yes
3.2.4.1. If yes, please specify.	As inspected by MHRA BE based on principles of ICHQ10
3.2.5. How do you ensure that BEs and hospital blood banks maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms (Article 12 and Article 6)?	Through MHRA inspection
3.2.6. Do BE maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d) and are these records kept for a minimum of 15 years (Article 13)?	Yes
3.2.6.1. If yes, please specify how.	Paper and computer archives
3.2.7. Is there a system in place to ensure that storage, transport and distribution conditions of blood and blood components in BEs and in hospital blood banks comply with the requirements referred to in Directive 2002/98, Annex IV, and Directive 2005/62/EC?	Yes
3.2.7.1. If yes, please specify.	Inspections Annual Blood Compliance Reports from HBBs Quality management systems
3.2.8. How do you ensure that all data, including genetic information, collected within the scope of this Directive by BEs and hospital blood banks and to which third parties have access is rendered anonymous so that the donor cannot be identified (Article 23)?	Data security systems
3.2.9. Do BEs and hospital blood banks in your country use a bar code based system for the distribution of blood and blood components?	Yes
3.2.9.1. If yes, is this system mandatory?	Yes
3.2.10. Do your BE's use the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	Yes
3.2.10.1. If yes, what is your experience with this Guide?	Helpful Being integrated in Quality management systems Note: Yes, but there is also the UK Red Book (Guide for blood transfusion services in the UK)
4. Designation, authorisation, accreditation and licensing (Art 5 Directive 2002/98/EC)	
4.1. For the collection of blood or blood components, does your CA	Authorisation

give (more than 1 answer possible)?	
4.2. How do you ensure that BE comply with the requirements laid down in Art. 5 Directive 2002/98/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) (more than 1 answer possible)?	Inspections of the site/centre Desk-based analysis of the mandatory documentation
4.3. Have all BEs been designated, authorised, accredited or licensed by the competent authority/ies?	Yes
4.3.1. If yes, how many BEs have been authorised by [please provide date of record]?	14 by 31 March 2014
4.4. Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5(5) Directive 2002/98/EC)?	No
4.5. Which national authority is responsible for the accreditation, designation, and authorisation or licensing of laboratories performing donor testing?	MHRA; although standalone labs are not holders of a BEA.
4.6. How many laboratories performing donor testing are active within your country?	There are no standalone labs in the UK. All donor testing labs are associated with BEs performing collection and processing.
4.7. Which national authority is responsible for authorisation (accreditation, designation, licensing) and oversight of hospital blood banks?	The MHRA has oversight of hospital blood banks
4.8. How many hospital blood banks are active within your country?	433
4.9. Are there additional rules governing hospital blood banks than those laid down in provisions covering articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC?	No
4.10. Are there plasma fractionation facilities in your country?	Yes
4.10.1. If yes, please provide a list with details of the sites (location, products, capacity, owners' name (public/private), import/export, …).	Bio Products Laboratory (BPL), Elstree. http://www.bpl.co.uk/ They manufacture a full range of plasma derived medicinal products.
4.10.2. If yes, please state the responsible authority within your country.	MHRA
5. Inspections (Art 8 Directive 2002/98/EC)	
5.1. Is there a system in place for organising inspections and control measures of BEs?	Yes
5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections.	Medicines Inspectorate, Inspection, Enforcement & Standards Division, MHRA
5.1.2. If yes, please specify staffing (how many inspectors (full time equivalents) are responsible for inspecting BEs?).	6 inspectors, part time with other duties, equivalent to approximately 2 full time equivalents to inspect both hospital blood banks and blood establishments.
5.2. Does the inspection scheme interact or overlap with the inspection scheme for other activities, e.g. pharmaceuticals, tissues and cells etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.2.1. If yes, please specify which one(s) (more than 1 answer possible).	Pharmaceuticals (including plasma derivatives) Advanced therapies Medical devices
5.3.1. Number of inspections by type: Please specify the number of general system-oriented inspections on-site .	43 Blood Establishment inspections and 51 hospital blood bank inspections.
5.3.2. Number of inspections by type: Please specify number of thematic/limited inspections on-site.	Three inspections of limited scope; these were performed ‘for cause’ based on a range on intelligence sources.
5.4.1. Number of inspections by cause: Please specify number of routine inspections of BEs conducted in 2012 (01/01/2012 to 31/12/2012).	Please see response to 5.3.2
5.4.2. Number of inspections by cause: Please specify number of inspections of BE following SARE or a suspicion thereof in 2012 (01/01/2012 to 31/12/2012).	None as a sole trigger for inspection. SARE information considered as risk indicators when planning and scheduling inspections
5.4.3. Number of inspections by cause: Please specify other type of inspections that were conducted and how many (e.g. due to a whistle-blower).	Please see response to 5.3.2. None due to a whistle-blower
5.5.1. Frequency of inspections: Is there a risk based approach in the planning of inspections?	Yes
5.5.1.1. If yes, please explain.	Risk indicators such as previous inspection compliance, SARE reports, other intelligence (e.g. relating to the healthcare organisation

	operating the site) is considered in the risk based scheduling of inspections. Risk is also used to determine those functions to be reviewed (and the depth of such review) during the inspection. For example, donor viral screening is considered a higher risk activity.
5.5.2. Do you find it difficult to comply with the 2-year requirement for intervals for inspecting BEs required by Article 8(2) Directive 2001/83/EC?	No
5.5.2.1. If no, why not?	Adequate resources are assigned to inspect the number of UK Blood Establishments. The fixed minimum 2-year requirement does place a challenge upon the full implementation of a risk based scheduling system. However, a fixed interval legislative requirement makes it difficult to fully implement a risk based approach for highly compliant sites where, in the pharmaceutical sector, interval between inspections may be extended.
5.5.3. How many BE have been inspected at least twice in the last 3 years?	All Blood Establishment sites performing authorised functions as defined in the Directive are inspected every 2 years.
5.5.4. How regularly are mobile and satellite collection sites inspected in your country?	Satellite (fixed location) sites are inspected every 2 years, at the same time as their 'parent' main site. Mobile collection sessions are inspected on a risk based sampling basis during the inspection of their 'parent' main site.
5.6.1. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where no shortcomings were observed?	Where no shortcomings are identified, compliance is confirmed as being generally acceptable, and the competent authority continues to support site activities.
5.6.2. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where minor shortcomings were noted?	Deficiencies classified as 'other' (minor in nature, as per EMA Compilation of Community Procedures for Pharmaceuticals) were identified at most inspections. In all cases, compliance was considered to be generally acceptable for continued support of site activities.
5.6.3. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) where major shortcomings were noted?	Deficiencies classified as 'major' are usually able to be addressed to a satisfactory level following inspection, such that a final decision of general compliance (and continued support for site activities) can be achieved.
5.6.4. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by suspension of authorisation?	There were no suspensions of Blood Establishment Authorisations in this period.
5.6.5. What was the outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012) which were followed by closure of the blood establishment?	N/A
5.6.6. Please specify any other outcome of the inspections carried out in the BEs in 2012 (01/01/2012 to 31/12/2012).	N/A
5.7. Please specify the number of plasma establishments inspected in 2012 [a site for collection of plasma].	16 plasmapheresis inspections, performed in third countries
5.8. Are all NCA officials empowered to inspect blood establishments as well as facilities of any third parties on its own territory, take samples for examination and analysis, and examine any documents relating to the object of the inspection? (Art. 8(3) Directive 2002/98/EC)	Yes
5.9. Is a system in place for inspecting hospital blood banks?	Yes
5.9.1. If yes, please describe.	UK law requires each hospital blood bank to submit a compliance report annually. These submissions are assessed to identify risk factors to trigger inspections 'for cause'.
5.9.2. If yes, are you as blood NCA involved in inspecting hospital blood banks?	Yes
5.9.2.1. If yes, please specify.	See response to 5.9.1
5.10. Do you use at national level the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components?	No
5.10.2. If no, which guidelines/regulations are used for inspections at national level?	In 2012, EUGMP and annex to Directive 2005/62/EC. The UK transposition of the Blood Directives is also used as an inspection standard.
5.11. Did you (do you intend to) send your inspectors to the trainings organised by EU-funded projects (e.g. EUBIS, CATIE)?	No
5.11.2. If no, why not?	The UK has experience of inspecting blood establishments in the

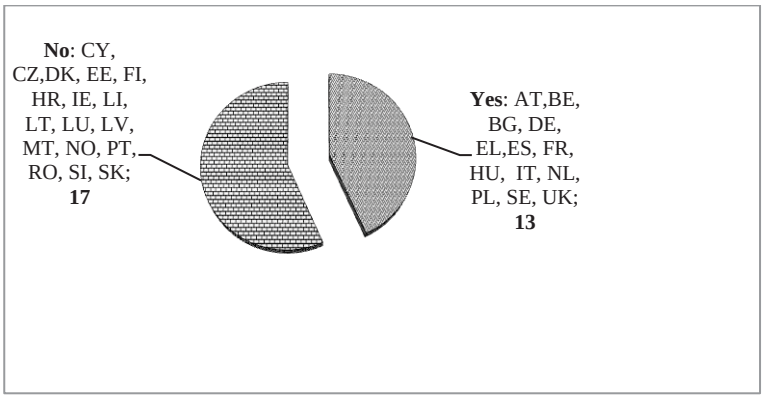
	UK and third countries since a change in UK law in 1992.
5.12. Has there been any international collaboration on inspections with other MS, such as an inspection of a BE in another MS, an inspection of a BE in your country, or a request by another MS on the results and control measures of your inspections?	Yes
6.1. Traceability (Article 14 Directive 2002/98/EC, Directive 2005/61/EC)	
6.1.1. Was a donor identification system (Art. 14(1)) implemented in your country?	Yes
6.1.2. Which is the CA for ensuring traceability in your Member State?	MHRA
6.1.3. Do you have a single national coding system for blood components?	Yes
6.1.3.1. If yes, for which blood components?	All
6.1.4. Do you apply an international coding system for blood components?	Yes
6.1.4.1. If yes, which coding system (ISBT, Eurocode, …)?	ISBT 128, Codabar for product codes
6.1.4.2. If yes, for which blood components (more than 1 answer possible)?	Platelets Plasma Red Blood Cells Wholeblood Others
6.1.4.2.1. If other, please specify.	Pooled Cryo, pooled Buffy coas
6.1.5. How is the data storage for traceability purposes organised in your BEs (Art 8(4) Directive 2002/98)?	Both paper records and electronic forms
6.1.6. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/86/EC, Art 9)?	IT systems, data retention policy, retention and disposal schedule
6.1.7. Do you consider 30 years an adequate time-frame for data storage?	Yes
6.1.8. Do the same rules on traceability that apply to BE also apply to hospital blood banks?	Yes
6.2. Notification of serious adverse events and reactions (Article 15 Directive 2002/98/EC, Directive 2005/61/EC)	
6.2.1. Do you have a national vigilance system in place (for the reporting of SAR/E (Article 15(1))?	Yes
6.2.1.1. If yes, please give a short description of the system.	SABRE is an online reporting system designed to allow BEs, HBBs and other reporting establishments to report SAEs and SARs to meet their statutory obligations. It is based on the requirements of the Annexes to Directive 2005/61/EC
6.2.2. Do you use the SAR/E templates developed for the Annual reporting to the EC (Dir. 2005/61, Article 5 and 6) also at national level?	Yes
6.2.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level?	Yes
6.2.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all BEs?	No
6.2.4.1. If no, why not?	There is a team of two
6.2.5. How many BE provided in 2012 the SAR/E data as requested (please provide the % from the total number of BEs authorised in your country) (only 1 answer possible)	100%
6.2.6. Do you have a mandatory procedure for hospital blood banks when reporting SAR/SAE to the BEs which distributed the blood and blood components (Art 5.1)?	No
6.2.6.2. If no, how do you ensure that SAR/E are reported from Hospital Blood Banks to BEs?	HBB are not required to report SAR/E to BEs, but to the Competent Authority. HBB report SARs to BEs if they are related to the quality and safety of the blood. The UK Blood Safety and Quality Regulations require the reporting of SAR/E.
6.2.7. Do you perform root cause analyses of the SARE?	No
6.2.7.2. If no, why not?	Not required
6.2.8. Do you give feedback to the BEs regarding SAR/E recorded at EU level?	Yes
6.2.8.1. If yes, please specify.	Mentioned in presentations of National data

6.2.9. Do you require your BEs to have recall procedure?	Yes
6.2.10. How many recalls related to safety & quality of blood/blood components were issued in your country in 2012? Please provide a list (you may upload one), specifying the causes and which blood components were recalled.	This information is not held by MHRA
6.2.11. Do you have in place a system/procedure to notify BEs in case of a national rapid alert?	Yes
6.2.11.1. If yes, please give a short description of the system/procedure.	MHRA would issue alerts by email
6.2.12. Do you have in place a system/procedure to notify BEs when a rapid alert is issued via the Rapid Alert System for blood at European level (CIRCA-BC)?	Yes
6.2.12.1. If yes, please give a short description of the system/procedure.	Relevant information is sent to the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)
6.2.13. Do you notify alerts communicated via the blood national vigilance system also to other national vigilance/alert systems?	Yes
6.2.13.1. If yes, which of the following systems are usually contacted (more than 1 answer possible)?	Tissues and cells Organs Pharmacovilance Medical devices Communicable diseases and other threats to health Other
6.2.13.1.1. If other, please specify.	All options available but usually Pharmacovigilance and Devices via internal MHRA communications
6.2.14. Do you also receive alerts via other national vigilance/alert systems, such as for tissues and cells, organs, or medical devices?	Yes
6.2.14.1. If yes, please specify.	All options apply
6.2.15. Do you have any additional comments on traceability and SAR/E reporting?	The MHRA's Haemovigilance team has incorporated its own categorisation to existing Directive categories to assist analysis of data received. We further break down the Event categories "Other", and "Storage" and the Specification category "Human error". Since introducing these categories and providing specific and targeted data analysis, SAE reports have reduced by nearly 18 %
7. Import - export (Art 21 Directive 2002/98/EC)	
7.1. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for transfusion from EU Member States or third countries?	The Blood Safety and Quality Regulations 2005 as amended
7.2. Which rules and conditions exist for the authorisation and control of the import of blood and blood components for fractionation from EU Member States or third countries?	The Blood Safety and Quality Regulations 2005 as amended
7.3. Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? (only 1 answer possible)	Others
7.3.1. If others, please specify.	The responsibility is placed upon importing BEs to demonstrate equivalence with EU/UK requirements. The systems in place to make this assessment are periodically assessed for their suitability during inspection of the BE.
7.4. Do you foresee requirements for the testing requirements for import of blood and blood components from third countries that go beyond the minimum requirements provided in Annex IV of Directive 2002/98/EC?	No
7.5. Do you have data on the numbers of blood components imported for transfusion from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.6. Do you have data on the numbers of plasma imported for fractionation from third countries (outside the EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.7. Which rules exist for the authorisation and control of the export of blood and blood components for fractionation to EU Member States or third countries?	In the UK, no blood / blood components for fractionation are exported / used for fractionation, due to vCJD risks in the population

7.8. Which rules exist for the authorisation and control of the export of blood and blood components for transfusion to EU Member States or third countries?	In the UK, no blood / blood components for fractionation are exported for transfusion, due to vCJD risks in the population
7.9. Do you have data on the number of blood components exported for fractionation from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.10. Do you have data on the number of blood components exported for transfusion from your Member State to third countries (outside EU) in 2012 (01/01/2012 to 31/12/2012)?	No
7.11. Is there a regular shortage of blood or blood components in your MS?	No
7.12. Is there a regular surplus of blood or blood components in your MS?	No
7.13. Are you aware of any significant changes in 2013 which may invalidate the 2012 data on imports/exports between your country and other third countries?	No
8. Sanctions and general comments	
8.1. Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
8.1.1. If yes, have penalties already been imposed?	No
8.1.2. If yes, what were the reasons for imposing the penalties? Please describe.	N/A
8.1.3. If yes, how many penalties have been imposed in 2012 (01/01/2012 to 31/12/2012)?	N/A
8.1.4. If yes, what kinds of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty, etc.)	N/A
8.2. Have you introduced or maintained more stringent measures than those foreseen under the Directive?	No
8.3. What difficulties were encountered by the Member State in the transposition or implementation of the Blood Directives? What specific issues would need to be addressed by the Commission in the course of a potential revision of Directive 2002/98/EC?	None specific to the Blood Directives
8.4. During the last years there have been outbreaks of West Nile Virus in different EU Member States. Are there any preventive measures of West Nile Virus transmission by blood in place in your country?	Yes
8.4.1. If yes, please provide us with detailed information.	Donor eligibility criteria, targeted donor screening
8.5. Which other communicable diseases are of relevance to you?	vCJD, and those addressed by the EU Donor eligibility / mandatory screening requirements
8.6. Do you consider bed-side techniques of collection, processing and application of blood or blood components (e.g., platelet rich plasma) to fall under the EU blood legislation within your country?	No
8.6.1. If no, which is the applicable legal framework and the competent national authority?	Medical practice legislation if the procedure is conducted within the immediate environment of the patient and there is no off-site processing.
8.7. Are there other techniques/components used within your country on which you have doubts whether they fall under the scope of Directive 2002/98/EC?	Possibly monocytes/dendritic cells
8.8. Can you specify which industrial processes, when applied on blood components, make you consider that these components would fall under the pharmaceutical legislation? (e.g., level of pooling, inactivation techniques, …)	Scale of activity but MHRA would need to consider each case on its own merits. Some guiding principles which would apply across all EU National Competent Authorities would be welcome

Annex 2: Fractionation Facilities

Thirteen countries reported having fractionation facilities within their borders.



Country	**AT**	**BE**	**BG**	**DE**	
Fractionator	Baxter, Vienna Octapharma, Vienna	C.A.F. – D.C.F. Baxter, Nivelles	Bul Bio - National Center of Infectious and Parasitic Diseases Ltd. (BB-NCIPD Ltd.) (public)	Biotest AG, Landsteinerstr. CSL Behring GmbH	
Country	**ES**	**EL**	**FR**	**HU**	
Fractionator	Laboratories Grifols (private)	The National Plasma Fractionation Centre ''Elias Politis'' [23]	- LFB Biomédicaments (public) Octapharma – (private)	Human Bioplasma Ltd belongs to Kedrion. (private)	
Country	**IT**	**NL**	**PL**	**SE**	**UK**
Fractionator	Kedrion Biopharma SpA, Baxter (private)	Sanquin	BIOMED Lublin SA - Lublin Factory of Sera and Vaccines. Production of anti D immunoglobulin and anti HBs only. (private)	Octapharma Stockholm (private)	Bio Products Laboratory (BPL), Elstree

[23] Note that this fractionation facility was not mentioned in the survey on the application of the principle of voluntary unpaid donation

Annex 3: Number of positive test results in 2012 for HIV, hepatitis B and hepatitis C and the number of laboratories performing donor testing

	HIV	Hepatitis B	Hepatitis C	Ratio positive tests (HIV, HBV, HCV) over donations WB and plasma	Number of laboratories performing donor testing for WB donations	Number of laboratories performing donor testing for plasma donations
AT	-	NA	NA		24	2
BE	10	60	18	0,01%	6	6
BG	5	851	86	0,56%	6	6
CY	8	19	19	0,08%	4	4
CZ	9	30	111	0,01%	52	
DE	114	510	358	0,01%	141	92
DK	0	5	4	0,00%	5	5
EE	6	13	32	0,09%	5	5
ES	142	474	252	0,22%	24	24
FI	1	2	15	0,00%	1	1
FR	NA	NA	NA	0,00%	14	14
GR	21	432	86	0,02%	92	
HR	7	14	6	0,02%	10	0
HU	4	12	111	0,03%	2	2
IE	1	1	2	0,00%	3	
IT	143	868	351	0,04%	174	174
LI	0	NA	NA	0,00%	1	
LT	29	167	482	0,85%	6	1
LU	0	3	0	0,01%	1	1
LV	12	52	205	0,48%	1	
MT	0	0	2	0,01%	1	1
NL	2	19	4	0,00%	1	1
NO	0	4	2	0,00%	19	19
PL	52	731	557	0,11%	23	23
PT	33	55	32	0,03%	22	0
RO	66	2.612	422	0,78%	42	42
SE	NA	NA	NA	0,00%	23	23
SI	2	12	4	0,02%	3	2
SK	2	24	25	0,03%	47	14
UK	15	70	69	0,01%	7	Not applicable