Council of the
European Union

Brussels, 22 April 2016
(OR. en)

8235/16
ADD 2

SAN 151

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	22 April 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2016) 130 final
Subject:	COMMISSION STAFF WORKING DOCUMENT on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in 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 2005/62/EC setting standards of quality and safety for human blood and blood components

Delegations will find attached document SWD(2016) 130 final.

Encl.: SWD(2016) 130 final

EUROPEAN
COMMISSION

Brussels, 21.4.2016
SWD(2016) 130 final

COMMISSION STAFF WORKING DOCUMENT

on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in 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 2005/62/EC setting standards of quality and safety for human blood and blood components

{COM(2016) 224 final}
{SWD(2016) 129 final}

Contents

ABBREVIATIONS

Aph. = Apheresis

BE = Blood establishment

EEA = European Economic Area

EU = European Union

EUR = Euro

VUD = Voluntary and unpaid donation

WB = Whole blood

Member States abbreviations*: 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 principle of voluntary and unpaid donation for blood and blood components. The survey was conducted in 2014. Results of a separate survey on the implementation of the blood legislation in general are summarised in a separate Staff Working Document, prepared in parallel with this one. 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.

According to recital (23) the Directive takes account of the definition of the Council of Europe[1] on what is considered voluntary and non-remunerated donation. However, no definitions of the terms compensation, incentive, sufficiency or shortage are defined. To allow for comparable replies, and only for the purpose of this survey, the following definitions were provided:

- Compensation means reparation strictly limited to making good the expenses and inconveniences related to the donation;
- Incentive means inducement/stimulus for donation with a view to seeking financial gain or comparable advantage;
- National self-sufficiency means fulfilling the needs of human blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country's population;
- National sufficiency means fulfilling the needs of blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country and through regional/international cooperation;
- Shortage means a relative deficiency in the supply with blood, blood components and plasma derivatives for medical application, which requires creation of waiting lists or makes a certain therapy temporarily unavailable at national level.

This document aims to map the implementation of the principle of voluntary and unpaid donation (VUD) of blood in the Union. It mainly focuses on practices vis-à-vis donors and collectors (chapter 2.2). It also covers provisions and policies related to VUD (chapter 2.1.) and addresses the efforts to ensure sufficient supply through VUD (chapter 2.3.), as well as the organisation of collection and supply of blood, blood components and derivatives (chapter

1 Recommendation No R(95)14 of the Committee of Ministers to member states on the protection of the health of donors and recipients in the area of blood transfusion, Appendix, Article 2 states "*if the person gives blood, plasma or cellular components of his or her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.*"

.

2.4.). The main findings of this document have been presented to the blood competent authorities during their regular meetings with the Commission.

2. IMPLEMENTATION OF THE PRINCIPLE OF VOLUNTARY AND UNPAID DONATION OF BLOOD AND BLOOD COMPONENTS

2.1. Legislative provisions, guidelines and policies concerning donation

2.1.1. Provisions and guidelines on VUD at national level and their application

The principle of VUD of blood and blood components is recognised in all Member States, albeit enforced to different degrees. The large majority of Member States (25) and Norway reported that VUD of human blood and blood components was mandatory in their country. Due to divergent interpretations of the term "mandatory", it has to be noted that in some of these 25 Member States, the national legal provisions rather "encourage" VUD. On the other hand, VUD may be the common practice or strongly recommended also in those Member States (Czech Republic, Lithuania, and United Kingdom) and Liechtenstein which reported that it was not legally mandated.

Seventeen Member States have defined penalties for infringements of their legislative provisions related to VUD of blood and blood components (AT, BE, BG, CY, EE, EL, ES, FI, FR, HR, IT, LU, NL, PT, RO, SE, UK). The nature of the penalties, the actions for which they are defined and the persons on whom they are imposed (hospital or company managers, legal persons such as hospitals and companies or any individual) vary among these Member States. For instance, there are penalties for collecting blood without consent of the donor or for taking part in blood transactions to make financial gain. Eleven Member States allow the intervention of supervising bodies, for example to revoke or suspend authorisations, 17 Member States have defined fines with maximum amounts from EUR 62 to 25 million euros and 10 Member States allow imprisonment for maximum terms from six months to five years. So far, none of these penalties has ever been imposed.

Nine Member States reported taking additional measures to ensure that donations are voluntary and unpaid (BE, BG, CZ, EE, FI, FR, LT, PL, RO). All of them examine or inspect advertising material provided by blood establishments, collection sites and blood donor associations (flyers, website information etc.). In addition, the Czech Republic and Romania ensure that the principle of VUD is also respected for imported blood and its components. In Bulgaria and Romania, professionals are trained to detect illegal and fraudulent activities.

2.1.2. Recent and planned changes of legislative provisions or guidelines

Since the last survey on VUD of blood and blood components, five Member States (CZ, IE, LV, LT, SK) have implemented binding national rules concerning VUD. The Czech Republic, Latvia and Slovakia have regulated the forms or amounts of compensation for donation of blood that are allowed. Lithuania and Ireland have established rules concerning the promotion of VUD.

Four Member States (EL, IE, RO, SI) mentioned having plans to change their guidelines for the donation of blood and its components in a manner that will further promote VUD. Greece plans new policies such as school education and strategies for social recognition of donors, and for donor registration and maintenance. Furthermore, it wants to improve the distribution of blood and blood components. Ireland is considering implementing guidelines on VUD. Slovenia is considering adopting guidelines for incoming trans-border donors and Romania plans to ask donors about their donations in other countries.

2.1.3. Replacement donors

A replacement blood donor is a person who gives a donation of blood on request, to replace donations that have been used for their family member or friend. A replacement donation is likely to be inconsistent with the principle of VUD. Five Member States (BG, CY, EL, LV, RO) reported being aware of replacement donations in their countries. Bulgaria and Greece indicated that replacement donation often occurred, while Latvia reported occasional occurrence. Romania reported replacement donation on the initiative of family and friends. Cyprus stated that replacement donation only occurred in authorised exceptional circumstances.

Member States seem to have different views on replacement donation. This can partly be explained by the lack of a common definition of this term at the European level:

- In Greece, blood donor programmes make a concerted effort, with a resulting change in hospital practice, in order to convert replacement donors to voluntary blood donors. Also some Romanian replacement donors become repeat or regular donors. Greece and Romania therefore consider replacement donors to be contributing to the national blood supply and to be prospective regular, voluntary and unpaid donors and, consequently, they have dedicated policies or guidelines for this practice;

- Ireland, Spain and the United Kingdom, which are not aware of replacement donors in their countries, have policies that forbid or strongly discourage replacement donation;

- In the Czech Republic, according to a recommendation of the Czech medical society, directed donation for a specific patient is exceptionally acceptable if it bears lower risks for the recipient or if the donation of the specific blood component needed carries increased risks for the donor.

2.1.4. Trans-border donation

Trans-border donors can be described as individuals who donate in a country where they are not living. Five Member States (AT, EE, HU, LU, NL) are aware of individuals who are not living in their countries and who come to their countries to donate blood or blood components. Six Member States (CY, HU, LU, PL, SI, SK) are aware of individuals who are living in their countries and who go to donate blood or blood components outside their country. Among these later ones, Cyprus, Hungary and Luxembourg have reported local shortages within their countries.

In a number of Member States, policies or practices are in place related to trans-border donation.

In 10 Member States (AT, BG, CY, FI, LT, LU, NL, PT, SI, SK), the donor questionnaire is available not only in the native language but also in English, which can significantly facilitate trans-border donation. In Austria, Finland and in some private collection sites in Germany, donor questionnaires are available in additional languages.

Policies or practices which discourage or inhibit donation by persons who are not living in the country of donation are to be found in 16 Member States (CY, CZ, DK, EE, EL, FI, FR, HR, IT, LV, MT, PL, RO, SE, SI, SK) and in Norway:

- In eight Member States (DK, EL, FI, HR, IT, LV, MT, SE), donors must have an identity document issued by the country of donation;

- In Cyprus, the Czech Republic and Romania, donors are usually accepted only if they had been living for some time in the country of donation. This is also the practice in Slovakia and Slovenia, which both pointed out that they accept as donors also their citizens who live and work abroad but donate in their country of origin during their holidays;

- Five Member States (CZ, DK, FR, PL, RO) and Norway pointed out that donors were required to understand the language of the country of donation, at least to a certain level.

Trans-border donation is mainly considered to be an individual practice. Only Hungary and Slovakia reported that, apart from individual trans-border donors, near the border with Austria, there were also organised groups leaving Hungary and Slovakia in order to undergo plasmapheresis donation in Austria. Poland reported that mainly young first time donors who live near to the border with Germany go there to donate plasma in private establishments. Austria and Germany have no further information available on this topic.

2.2. Practices vis-à-vis donors and collectors

2.2.1. Occurrence of practices vis-à-vis donors

The practices vis-à-vis donors vary from one Member State to another (see Figure 1) and there may also be different practices within one country.

It is common practice to give donors refreshments (25 Member States, Liechtenstein and, Norway) and small tokens (such as pins, pens, towels, t-shirts and mugs) (22 Member States, Liechtenstein and Norway). In around half of the Member States, donors are reimbursed their travel costs and get time off work in the public and private sector.

Thirteen Member States (BG, CZ, DE, EE, FI, IE, HU, LT, LU, LV, NL, PL, RO) reported having guiding principles regarding the possibility of giving compensation to donors of blood and blood components. In general, these principles, set out in national laws, decrees or non-binding recommendations, appear to define what form of compensation or other practice is allowed and under which circumstances.

		Refreshments	Food voucher(s)	Small tokens, such as pins, pens, towels, t-shirts, mugs	Free physical check-up (beyond what is required for the donation)	Free or reimbursement of medical costs (e. g. additional medication, etc.)	Reimbursement of costs linked to travel (to and from place of donation)	Time off work - public sector	Time off work - private sector	Compensation linked to loss of earnings	Compensation for the inconveniences related to donation	Fixed sum of money, irrespective of actual costs, established at national level	Fixed sum of money, irrespective of actual costs, established by BE	Other forms
		Maximum value in EUR/donation						Days/donation		Maximum value in EUR/donation				
AT	WB	X		X				1			X		X	
	Aph.	X		X				X			25		25	
BE	WB	X		X										
	Aph.	X		X										
BG	WB	4,09	4,09	3,06			X	2	2			X		
	Aph.	4,09	4.09	3,06			X	2	2			X		
CY	WB	X		X	X									
	Aph.	X		X	X									
CZ	WB	X	X	X			16	<1	<1	X	X		X	
	Aph.	X	X	X			16	<1	<1	X	16-30		16-30	
DE	WB	X		X			27				27		27	
	Aph.	X		X			27				27		27	
DK	WB	1		10										
	Aph.	1		10										
EE	WB	X		X			X	<1	<1					
	Aph.	X		X			X	<1	<1					
EL	WB	1		1	X	X		2						
	Aph.	1		1	X	X		2						
ES	WB	X		X			X							
	Aph.	X		X			X							
FI	WB	X		1.50			X							
	Aph.	X		1.50			X							
FR	WB	X												
	Aph.	X												
HR	WB	3		3				1						
	Aph.	3		3				1						
HU	WB	1,58	X											
	Aph.	X	X											
IE	WB	X		X										
	Aph.	X		X			X							
IT	WB	2.50						1	1					
	Aph.	2.50						1	1					
LT	WB	X		X			X	1	1			12		
	Aph.	X		X			X	1	1			12		
LU	WB							<1	<1					
	Aph.							<1	<1					
LV	WB		1,42					1	1			4.27		
	Aph.		1,42					1	1			28.46		
MT	WB	4		8				<1	<1					
	Aph.	4		8				<1	<1					
NL	WB	2		3.50		X	20	<1	<1	X	X	X	X	X
	Aph.	2		3.50		X	20	<1	<1	X	X	X	X	X
PL	WB	X		X		X	X	1	1	X				
	Aph.	X		X		X	X	1	1	X				
PT	WB	2		2		X								
	Aph.	2		2		X								
RO	WB		15		30		X	1	1					
	Aph.		15		30		X	1	1					
SE	WB	X		X			2/10km				3			
	Aph.	10		10			2/10km				9			
SI	WB	4		8				1	1					
	Aph.	4		8				1	1					
SK	WB	X	2	X	X	X	X	1	1	X				
	Aph.	X	2	X	X	X	X	1	1	X				
UK	WB	X		X										
	Aph.	X		X										
Total EU		25	6	22	4	5	13	16	13	4	5	4	4	1
LI	WB	2.70	2.70	3										
	Aph.	X	X											
NO	WB	X		X										
	Aph.	X		X										

Fig. 1: Practices vis-à-vis donors

Aph.: apheresis, BE: blood establishment, WB: whole blood X: regular or exceptional practice, but value not available or not specified

Note 1: The column 'Free or reimbursement of medical costs' refers only to costs incurred following adverse reactions associated with donation.

Note 2: Where a MS has reported monetary reimbursement or compensation of more than one type, the sums given should not be added together, e.g. for DE, a total of EUR 27 is given.

Note 3: The free physical check-up provided in RO is annual and

		Refreshments	Food voucher(s)	Small tokens, such as pins, pens, towels, t-shirts, mugs	Free physical check-up (beyond what is required for the donation)	Free or reimbursement of medical costs (e.g. additional medication, etc.)	Reimbursement of costs linked to travel (to and from place of donation)	Time off work - public sector	Time off work - private sector	Compensation linked to loss of earnings	Compensation for the inconveniences related to donation	Fixed sum of money, irrespective of actual costs, established at national level	Fixed sum of money, irrespective of actual costs, established by BE	Other forms	Total
		Maximum value in EUR/donation						Days/donation		Maximum value in EUR/donation					
AT	WB	X		X				1			X		X		5
	Aph.	X		X				X			25		25		
BE	WB	X		X											2
	Aph.	X		X											
BG	WB	4.09	4.09	3.06			X	2	2			X			7
	Aph.	4.09	4.09	3.06			X	2	2			X			
CY	WB	X		X	X										3
	Aph.	X		X	X										
CZ	WB	X	X	X			16	<1	<1	X	X		X		9
	Aph.	X	X	X			16	<1	<1	X	30		30		
DE	WB	X		X			27				27		27		5
	Aph.	X		X			27				27		27		
DK	WB	1		10											2
	Aph.	1		10											
EE	WB	X		X			X	<1	<1						5
	Aph.	X		X			X	<1	<1						
EL	WB	1		1	X	X		2							5
	Aph.	1		1	X	X		2							
ES	WB	X		X			X								3
	Aph.	X		X			X								
FI	WB	X		1.50			X								3
	Aph.	X		1.50			X								
FR	WB	X													1
	Aph.	X													
HR	WB	3		3				1							3
	Aph.	3		3				1							
HU	WB	1.58	X												2
	Aph.	X	X												
IE	WB	X		X											3
	Aph.	X		X			X								
IT	WB	2.50						1	1						3
	Aph.	2.50						1	1						
LT	WB	X		X			X	1	1			12			6
	Aph.	X		X			X	1	1			12			
LU	WB							<1	<1						2
	Aph.							<1	<1						
LV	WB		1.42					1	1			4.27			4
	Aph.		1.42					1	1			28.46			
MT	WB	4		8				<1	<1						4
	Aph.	4		8				<1	<1						
NL	WB	2		3.50		X	20	<1	<1	X	X	X	X	X	11
	Aph.	2		3.50		X	20	<1	<1	X	X	X	X	X	
PL	WB	X		X		X	X	1	1	X					7
	Aph.	X		X		X	X	1	1	X					
PT	WB	2		2		X									3
	Aph.	2		2		X									
RO	WB		15		30		X	1	1						5
	Aph.		15		30		X	1	1						
SE	WB	X		X			2/10km				3				4
	Aph.	10		10			2/10km				9				
SI	WB	4		8				1	1						4
	Aph.	4		8				1	1						
SK	WB	X	2	X	X	X	X	1	1	X					9
	Aph.	X	2	X	X	X	X	1	1	X					
UK	WB	X		X											2
	Aph.	X		X											
Total EU		25	6	22	4	5	13	16	13	4	5	4	4	1	
LI	WB	2.70	2.70	3											3
	Aph.	X	X												
NO	WB	X		X											2
	Aph.	X		X											

2.2.2. Values of practices vis-à-vis donors

In most Member States, only fragmented data are available as regards the monetary values of their practices vis-à-vis donors (Figure I). Where values were reported, they were sometimes the same for donation of whole blood and for apheresis donation of blood components. Apheresis donation is not practised in all Member States.

The highest maximum values reported lie between EUR 25 and EUR 30 (AT, CZ, DE, LV, RO). In Bulgaria and the Czech Republic, the maximum values are defined as a percentage of the national minimum wage. The reported maximum values of refreshments and small tokens range between EUR 1 and EUR 10. Food vouchers are available in six Member States (BG, CZ, LV, HU, RO, SK) and in Liechtenstein. The reported maximum values usually lie between EUR 1.4 (Latvia) and EUR 4.1 (Bulgaria). However, in Romania a fixed value of EUR 15 is established for food vouchers.

As regards reimbursement of the costs incurred by the donor to travel to and from the place of donation, in some Member States the actually incurred costs (Finland, Romania) or a certain sum per kilometre (Sweden) are reimbursed whereas other Member States have fixed a maximum value for the reimbursement (Netherlands) or cover it with a maximum lump sum, irrespective of the actually incurred costs (Czech Republic and Germany).

In most Member States where donors get time off work from the public sector, this is also the case for the private sector. In nine Member States, donors are given one day off, in six Member States less than one day or only the time needed for the donation and in two Member States, donors get two days off.

Nine Member States (AT, BG, CZ, DE, LV, LT, NL, PL, SE) reported practices which involve the transfer of money other than for reimbursement of travel or medical costs. Such practices aim at compensating loss of earnings or for the inconveniences related to donation or consist in the transfer of fixed sums of money. These fixed sums are irrespective of the costs actually incurred by the donor for the donation.

In Austria, Bulgaria and Poland, the transfer of money is only allowed under certain circumstances, such as:

- In emergency cases (AT; BG: EUR 23 per donation);
- For donation of rare blood groups (PL);
- For donation through apheresis of plasma and platelets (AT), of platelets (BG: EUR 46 per litre of blood passed through the apparatus), or of anti-D plasma (PL);
- For donations intended for the production of vaccines, sera and immunoglobulins or for research and diagnostic purposes in medicine (BG: EUR 40 per donation).

In the Czech Republic, compensation may exceptionally exceed the demonstrably incurred costs and the maximum value fixed as 5 % of the minimum wage for standard donations. This can be the case if the blood from a specific donor is needed in order to provide individual care to a specific patient, or if special preparation or selection of the donor is required according to the blood group systems of the recipient. In such cases, the maximum is not defined but typically might reach EUR 30.

In 15 Member States, operators or blood establishments are involved in defining the values of what is given to donors (15 Member States: AT, CZ, DE, EE, EL, ES, FI, HU, IE, LT, MT, NL, PL, SE, UK), while national governments are involved in 10 Member States (BG, CY, CZ, IT, LT, LV, PL, PT, RO, SK). Other bodies involved are health insurance schemes (Finland, Croatia, Slovenia), regional and local governments (Italy, Sweden), the Red Cross (Croatia, Liechtenstein) or specific bodies such as the association of local donors in Denmark, a working group on blood in Germany, the hospital transfusion committee in Greece and blood donor associations in Italy. In Luxemburg, there are agreements between employers and employees on the time off work given to donors.

In 10 Member States (CZ, DE, EL, FI, HR, IT, LT, LU, PL, SE), more than one stakeholder is involved in taking the decision on the values of what is given to donors. For example, maximum values can be decided at the national level but the decision on the actual value might be taken on the local level (Czech Republic, Germany, Finland). Other Member States pointed out that different stakeholders agreed on a common decision on the values (EL, IT, HR, LU, SE).

2.2.3. Perception of practices vis-à-vis donors

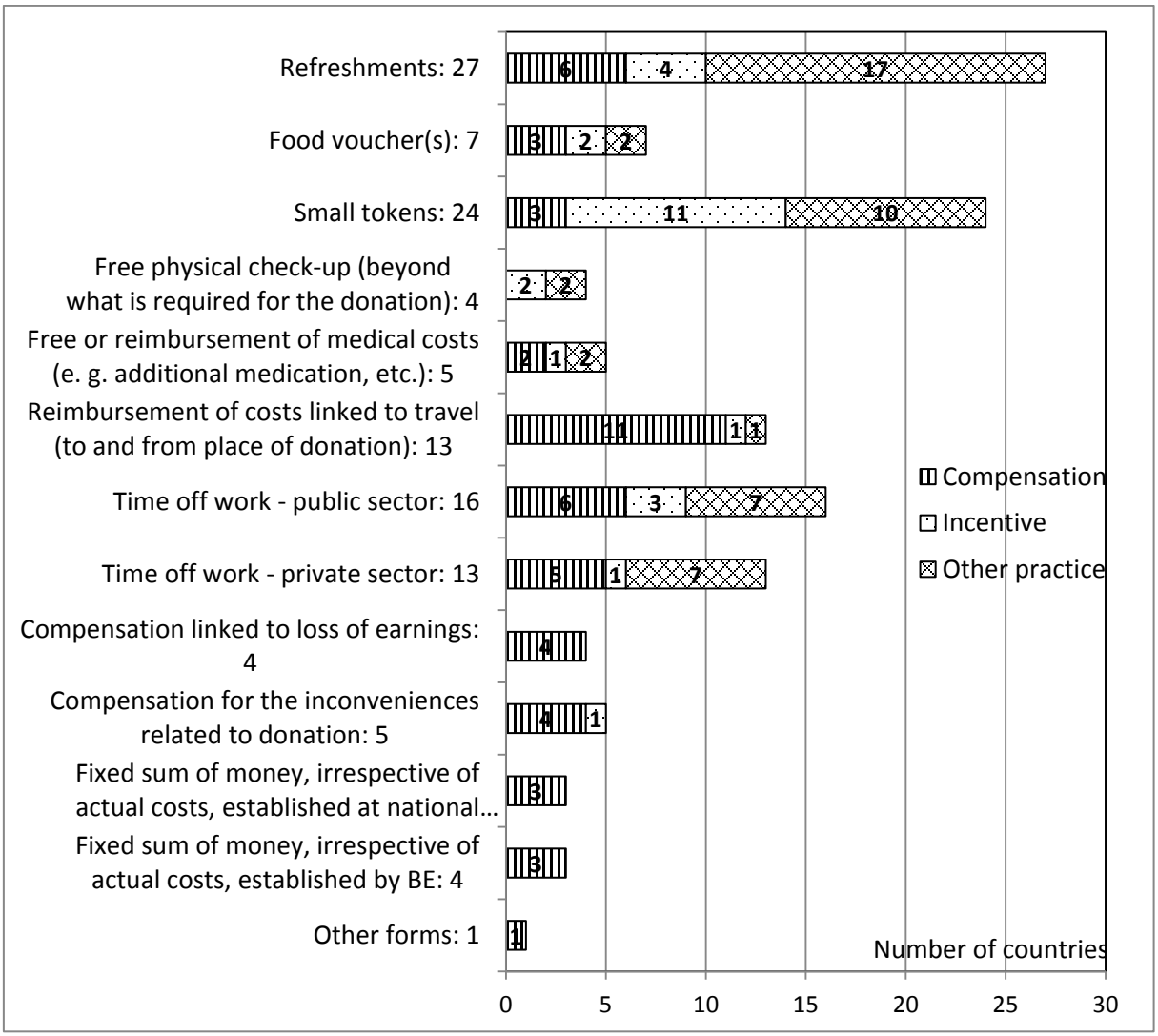

Fig. 2: Perception of practices vis-à-vis donors

Figure 2 shows that the same practice vis-à-vis donors may be classified as compensation by some Member States, as incentive by others and as other practice by a third group. For example, among the countries which chose the option "other practice", 12 explained to give refreshments to donors for medical reasons and seven stated that small tokens were given to express appreciation. These divergent perceptions seem to be linked to different interpretations of the given definitions of compensation and incentive. In addition, there seems to be no common understanding of what practices are compatible with VUD.

2.2.4. Practices vis-à-vis collectors

Ten Member States (DK, EL, HU, IT, LT, LV, PL, PT, SI, SK) reported to provide financial incentives to blood establishments, recruitment organisations or professionals in their Member States for one or more activities related to collection, processing, storage and distribution of whole blood and of blood components (Fig. 3). More Member States provide financial incentives for activities relating to whole blood than for activities relating to apheresis.

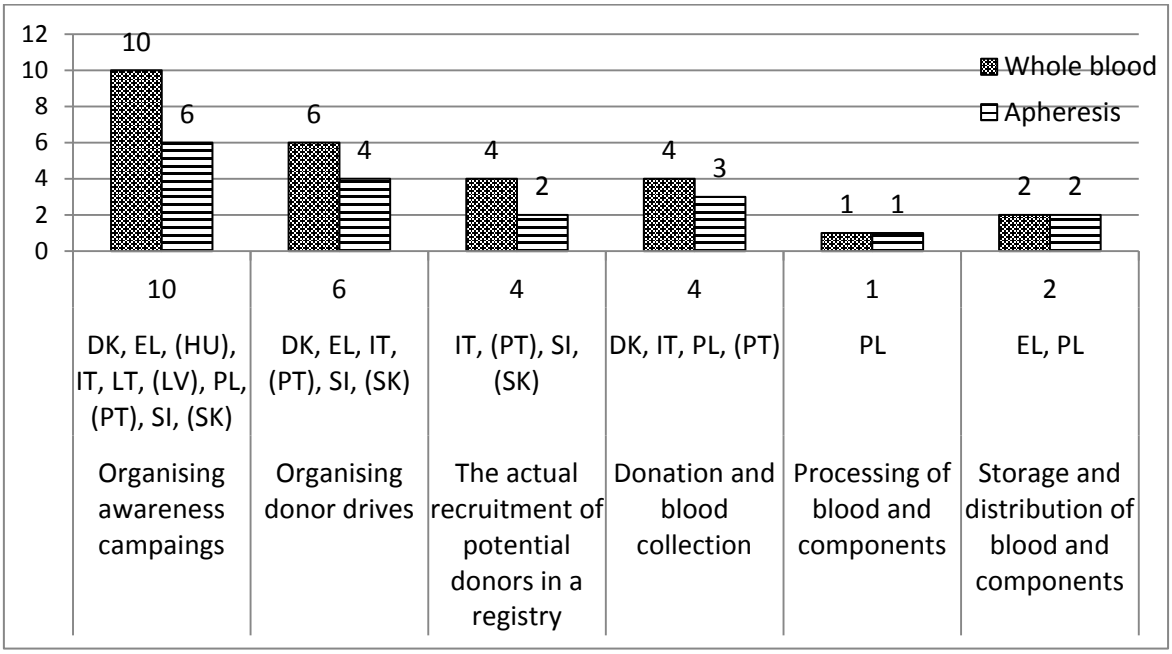

Fig. 3: Activities for which Member States provide financial incentives to blood establishments and others (Member States in brackets provide incentives only for activities related to whole blood).

2.3. Ensuring sufficient supply of blood, blood components and derivatives

2.3.1. Supply of blood, blood components and derivatives

Shortage can be defined as a deficiency in the supply with blood, blood components and plasma derivatives for medical application. Eight Member States (BG, CY, CZ, EL, HU, LV, PT, SE) reported having experienced regular shortage of whole blood, blood components or

plasma fractions (Figure 4). In Slovenia there is a seasonal possibility of shortage of certain blood groups of red blood cells and of platelets.

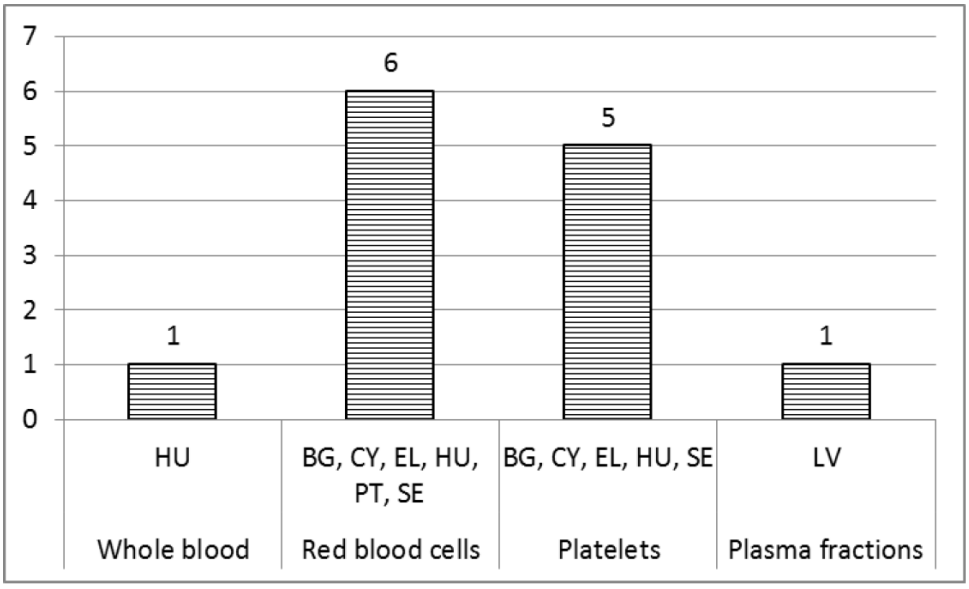

Fig. 4: Regular shortage

Shortage occurs mainly during the summer and other holiday periods, and is mainly due to an insufficient number of donors (seven Member States: BG, CZ, EL, HU, PT, SE, SI) and to high rates of use (three Member States: Bulgaria, Czech Republic and Sweden). Overall, the shortages seem to have no serious impacts on healthcare. In five Member States (BG, CY, EL, HU, PT), as a result of shortage, planned surgeries which were not urgent have been postponed for around four days (Bulgaria, Cyprus, Hungary) up to 20 days in Greece, where summer holidays coincide with the West Nile Virus seasonal activity. The shortages of immunoglobulin (intravenous IgG and anti-D IgG) and fibrinogen in the Czech Republic, which occur only occasionally and the shortage of albumin and immunoglobulins in Latvia seem to have had no impact on healthcare. In Sweden, where shortage occurs in particular in larger cities, it can be covered through collaboration of neighbouring blood establishments. This is also the case in Cyprus. Both Hungary and Sweden reported that in 2014, there has been less shortage than previously.

2.3.2. Policies to promote (self-) sufficiency of blood and derivatives

Member States have set the objectives of self-sufficiency in human blood and blood components and of ensuring that blood and blood components are in so far as possible provided from voluntary and unpaid donations[2].

(Self-) sufficiency can be measured not only at the national, but also at a local or at European Union level. Self-sufficiency at European Union level can be obtained through cooperation of Member States without requiring all Member States to be self-sufficient at their national level.

[2] Recitals 4, 23, 32 and Article 20(1) of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 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, (OJ L 33, 8.2.2003, pp. 30-40).

Twenty-five Member States (all except Austria, Cyprus, Finland) and Liechtenstein and Norway have policies in place to endeavour to achieve self-sufficiency and or sufficiency of blood and blood derivatives. In Cyprus, such a policy was in preparation at the time of this survey. Austria stated that it was self-sufficient in blood and derivatives, Finland declared to be self-sufficient in blood and blood components and to be sufficient in imported plasma products.

In order to achieve (self-) sufficiency, there is a variety of policies in place among the Member States. These policies aim either at increasing the supply of blood, blood components and derivatives, for example through promotion of donation (cf. below chapter 2.3.4.) or through export restrictions or at decreasing the demand, in particular through the promotion of rational or efficient use (cf. below chapter 2.3.5.). Some Member States reported centralisation, in order to have an overview of the national stock, or cooperation of blood establishments within their country. Overall, Member States seem to have more strategies for the promotion of (self-) sufficiency in blood than for the promotion of (self-) sufficiency in derivatives.

These policies appear to be stable over the time. However, some countries are recently increasing their activities in the plasma sector. Four Member States (DK, EL, ES, SK) have launched projects to increase apheresis donations, mainly for plasma, which might also increase in Norway. At the time of the survey, Portugal planned to start a programme to use plasma from whole blood donation via an international tender for the manufacture of plasma derived medicinal products. Greece reported new provisions on the optimisation of clinical use of blood components and, in Norway, there is an initiative to introduce patient blood management.

2.3.3. Promotion of VUD

All Member States and Liechtenstein with the exception of Hungary, the Netherlands and also Norway reported to have taken measures to promote VUD of blood and blood components. Often it was not clear if the reported measures were intended to promote donation of blood and blood components as such or if they focused on VUD. However, since VUD is mandatory in the large majority of Member States, promotion of donation as such is likely to coincide with promotion of VUD.

A variety of different measures are used to promote donation (Figure 5).

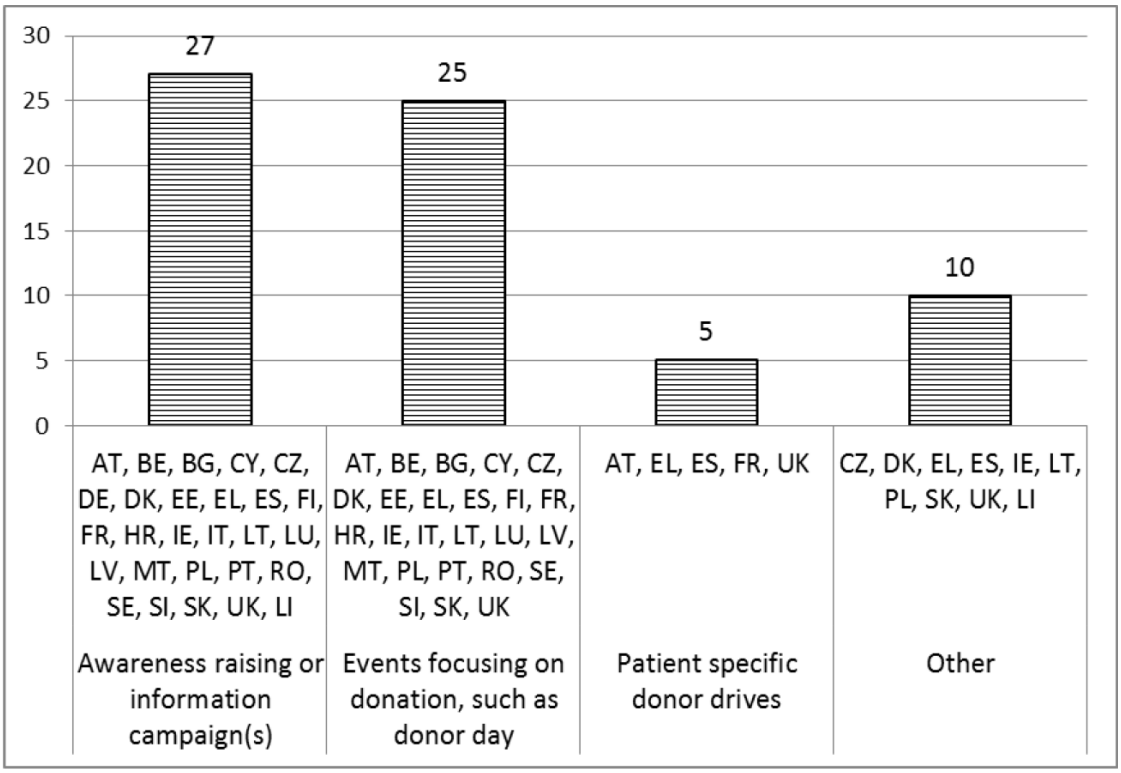

Fig. 5: Measures to promote (voluntary and unpaid) donation

The most common ones are awareness and information campaigns, which are run in 26 Member States and Liechtenstein, as well as events focusing on donation, such as donor days (25 Member States). Fourteen Member States (AT, BG, CZ, EE, ES, HR, IE, IT, LT, LV, PL, PT, RO, UK) and Liechtenstein reported the involvement of the mass media in such campaigns. A large number of Member States noted the importance of honouring frequent donors. Ireland, Italy, Slovenia and the United Kingdom mentioned the use of social media (social networks, smartphone applications). Six Member States (BG, CZ, ES, FR, PL, RO) specified that various stakeholders cooperated in the campaigns, for example governmental institutions, non-governmental organisations and companies.

As regards patient specific donor drives, Greece explained that it carries out campaigns for the promotion of VUD on the International Thalassemia day (8th May). Austria and Ireland noted that registered donors are called if special blood groups or types are urgently needed. The United Kingdom stated that individual patient stories could be used within its marketing and that such patient specific drives tended to be community driven.

Other measures described included, for example, training of staff of blood establishments and of volunteers for promotional measures in Lithuania and Poland.

Among the 26 Member States and Liechtenstein which have taken measures to promote VUD, all but four Member States (Belgium, Czech Republic as regards the national level, Croatia, Malta) have defined specific target groups for these promotion measures (Figure 6).

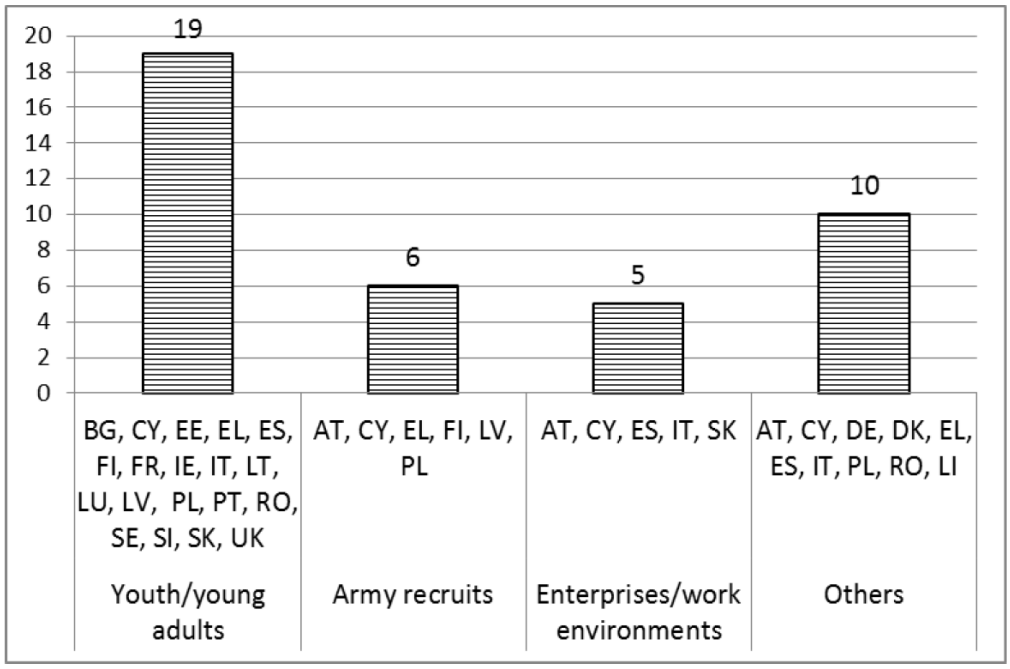

Fig. 6: Target groups for promotional measures

Around two thirds of the Member States target youth and young adults, in particular through promotion measures at schools and universities.

Other target groups are, for example, first time donors in Germany, the rural population in Romania, defined blood groups in Liechtenstein or members of certain professions, such as firemen in Austria and Poland, the public service in Cyprus, athletes in Spain and policemen in Poland. Italy and Spain reported providing training seminars to the media and Spain also medical seminars to general practitioners.

2.3.4. Policies and audits on clinical use of blood, blood components and derivatives as a means to achieve sufficiency

Member States were asked about policies and practices to support appropriate clinical use of blood, blood components and derivatives as these initiatives could support achieving sufficiency through VUD, without relying on importation from countries where the VUD principle might not be followed.

All Member States, and Norway, with the exception of Estonia, Slovakia and Liechtenstein have policies in place to contain or ensure the effective use of blood and blood components for clinical use. Policies to contain or ensure the effective use of plasma derivatives are less common, but 21 Member States have such policies (BE, BG, CY, CZ, DE, DK, EL, ES, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, UK). Most common are national policies and policies on the level of operators and blood establishments (Figure 7). Five Member States (DE, CZ, EL, FR, IT) pointed out that specific bodies were involved in policy-making, such as the German Medical Association (Bundesärztekammer), the French Haute Autorité de la Santé and medical scientific societies in Czech Republic, Greece and Italy.

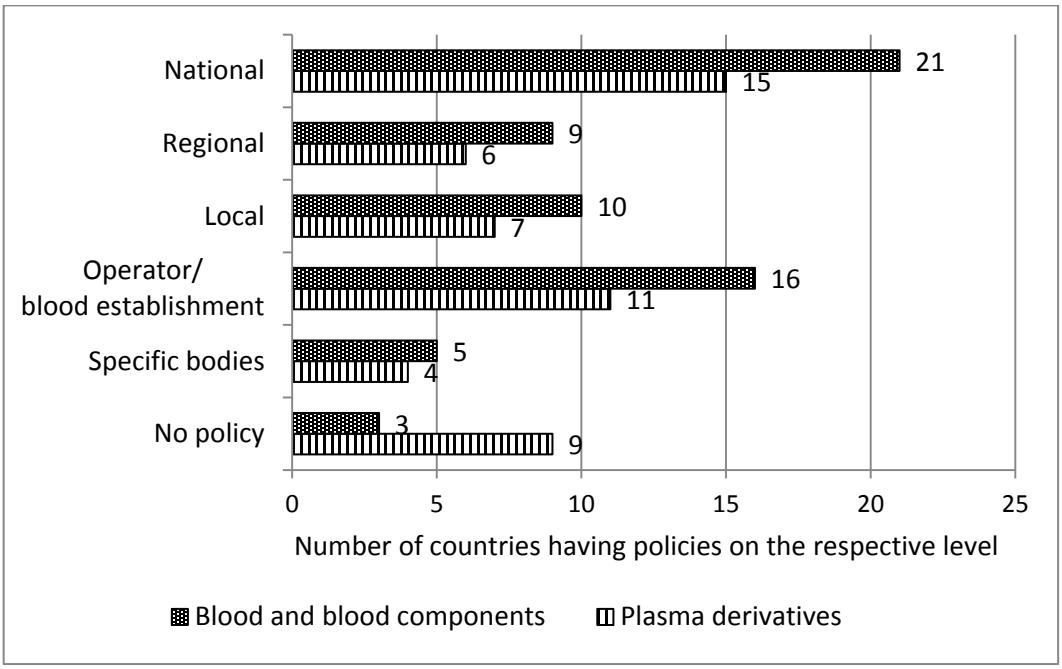

Fig. 7: Policy setting to ensure effective use of blood, blood components and plasma derivatives

Austria, the Czech Republic and Italy stressed the importance of having policies on several levels in order to ensure the effective use of blood, blood components and derivatives and of involving multiple stakeholders, such as patient organisations, health insurance companies, hospitals and single physicians. In order to contain or ensure the effective use of blood and blood components, 17 Member States (AT, BG, CZ, DK, EL, ES, FR, HU, IE, IT, LU, LV, MT, NL, PL, SI, UK) have policies in place on more than one level and 12 Member States (CZ, DK, EL, ES, FR, HU, IE, IT, LU, LV, PL, UK) to contain or ensure the effective use of plasma derivatives.

Examples of such policies are:

- Patient blood management programmes in AT and IT, which contributed, according to Italian data and together with improvement in transfusion practice, to the reduced consumption of red blood cells and fresh frozen plasma in 2013;
- Policies for the use of recombinant factor VIII in EL;
- National clinical guidelines on the appropriate use of blood components for certain indications such as trauma in PT.

Audits on the clinical use of blood, blood components and plasma derivatives can be carried out at national, regional or local level or on the level of hospitals and operators. 16 Member States reported having carried out regular audits on clinical blood use (BE, BG, CY, CZ, DK, EL, FR, HU, IE, IT, LT, LU, MT, PL, PT, UK), but only eight Member States reported carrying out regular audits on clinical use of plasma derivatives (BG, CZ, EL, IE, IT, LU, PL, PT). Audits of clinical blood use take place mainly at the level of hospitals and operators (14 Member States) and at the national level (10 Member States). Audits of clinical use of plasma derivatives are mainly carried out at the hospital or operator level (five Member States) and at the local level (four Member States).

Most Member States that carry out regular audits of clinical use do so on more than one level, both as regards the clinical use of blood and blood components (12 Member States: DK, EL, FR, HU, IE, IT, LT, LU, MT, PL, PT, UK) and of plasma derivatives (six Member States: BG, CZ, EL, IE, IT, LU).

2.4. Organisation of collection and supply

2.4.1. Main collectors and suppliers of blood and blood components

Public national establishments are the main collectors of whole blood in 22 Member States (BG, CY, CZ, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SE, SI, SK, UK) and of plasma in the same Member States with the exception of Latvia and Portugal.

Private national establishments (including not for profit organisations such as the Red Cross) are main suppliers of both whole blood and plasma in seven Member States (AT, BE, CZ, DE, FI, LU, NL, SE) and of plasma in Latvia. Establishments from other countries are also the main suppliers for Ireland as regards solvent/detergent-treated plasma and for the United Kingdom as regards variant Creutzfeldt Jacob disease free plasma.

2.4.2. Plasma fractionation

Twelve Member States (AT, BE, BG, DE, ES, FR, HU, IT, NL, PL, SE, UK) have the capacity for plasma fractionation. The plasma is mainly fractionated by private establishments, which include both for profit organisations (in AT, DE, ES, HU, IT, PL, SE, UK) and non-profit organisations (in Belgium and Netherlands). In Bulgaria and France, plasma is fractionated by public national establishments. The fractionation plant situated in the United Kingdom does not fractionate plasma from within the country, due to risk of variant Creutzfeldt Jacob disease, and was privatised in 2013.

Nine Member States (CZ, EE, EL, FI, LT, LU, LV, SI, SK) and also Liechtenstein and Norway send the plasma collected in their country for fractionation in other Member States, mainly in Austria. Plasma from Denmark is fractionated in Switzerland.

Seven Member States (CY, IE, HR, MT, PT, RO, UK) reported that the plasma collected in their country was not fractionated. Ireland and the United Kingdom explained that this was due to risk of variant Creutzfeldt-Jacob disease. Croatia and Portugal noted that there are plans for plasma fractionation in the future. Lithuania reported an open procedure for contract fractionation.