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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Health Law and International

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Summary Table of Responses from Competent Authorities for Blood and Blood Components

Questionnaire on the transposition and implementation of the European regulatory framework blood and blood components

In preparation of the fourth meeting of competent authorities on blood and blood components on 29 January 2009, competent authorities were invited to complete a questionnaire covering the transposition and implementation of Directives 2002/98/EC[1], 2004/33/EC[2], 2005/61/EC[3] and 2005/62/EC[4] into their national law.

This table presents responses regarding the situation from the Member States, candidate countries (Croatia, Former Yugoslav Republic of Macedonia, and Turkey) and EFTA countries (Iceland, Liechtenstein, Norway, Switzerland) as of January 2009.

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[1] OJ L 33, 8.2.2003, p. 30

[2] OJ L 91, 30.3.2004, p. 25

[3] OJ L 256, 1.10.2005, p.32

[4] OJ L256, 1.10.2005, p.41

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1. PUBLIC INFORMATION

AUSTRIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Federal Ministry of Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Radetzkystrasse 2, A-1030 Wien, Austria
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	no
1.7.1 Please indicate the website or provide us with the report.	www.bmg.gv.at
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Federal Ministry of Health
1.9 Is the competent authority(ies) responsible for human tissues and cells?	yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	yes
1.13.1 Please specify these other fields	veterinary issues; public health
BELGIUM	

1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Federal Agency for Medicines and Health Products
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Eurostation II, Place Victor Horta 40/40, 1060 Brussels, Belgium
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	Soon
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Agency under the authority of the Minister of Health
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Directorate-General for Healthcare facilities organization of the Federal Public Service Health, Food Chain Safety and Environment Health
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
BULGARIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Bulgarian Drug Agency
1.3 Address. If there are multiple authorities, please indicate the address of each one.	26 Yanko Sakazov blvd, Sofia 1504
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes

1.7.1 Please indicate the website or provide us with the report.	I am going to send my annual report to the Ministry of Health. It is their responsibility to send a copy of the report to the EC.
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	BDA is a national Competent Authority on pharmaceuticals, medical devices and is at the Minister of health
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	Transplantation Executive Agency
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Transplantation Executive Agency
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	Clinical trials, stakeholders, GMP
CROATIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	MoHSW (Ministry of Health and Social Welfare Agency for Quality and Accreditation in Healthcare
1.3 Address. If there are multiple authorities, please indicate the address of each one.	MoHSW (10 000 Zagreb, Ksaver 200a) AQAH (10 000 Zagreb, Vončinina 2)
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.hztm.hr
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	MoHSW is competent authority for authorisation and inspection of blood, tissue establishment: Therefore new Department for inspection and blood, tissue and cells monitoring within MoHSW is formally designated in December 2008. Agency for quality and Accreditation
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes

1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	MoHSW - Department for special healthcare programs and transplantation
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	Agency for medicals and Medical Devices (AMMD)
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	Agency for medicals and Medical Devices (AMMD)
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
CYPRUS	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	MEDICAL AND PUBLIC HEALTH SERVICES, MINISTRY OF HEALTH
1.3 Address. If there are multiple authorities, please indicate the address of each one.	GIORGHIO, PRODROMOU 1 & CHILONOS 17, 1449 NICOSIA, CYPRUS
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	No
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	DEPARTMENT IN THE MINISTRY OF HEALTH
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	PHARMACEUTICAL SERVICES [DEPARTMENT IN THE MINISTRY OF HEALTH]
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes

1.13.1 Please specify these other fields	The Medical and Public Health Services of the Ministry of Health are responsible for a wide spectrum of activities that concern the protection of consumer's health. In brief the responsibilities of the Public Health Services apart, from the food safety th
CZECH REPUBLIC	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Ministry oh Health of the Czech Republic, some competencies delegated to State Institute for Drug Control (SUKL)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	MoH: Palackeho nam. 4, 128 00 Prague, Czech Republic SUKL: Srobarova 48, 100 00 Prague, Czech Republic
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	MoH / Department of pharmacy (legal framework, regulation, export / import licensing etc.)
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	MoH: health care
DENMARK	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Danish Medicines Agency and National Board of Health

1.3 Address. If there are multiple authorities, please indicate the address of each one.	1 Axel Heides Gade, DK 2300 Copenhagen S 67 Islands Brygge, DK 2300 Copenhagen S
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	Available for 2007 on www.dkma.dk. (In Danish only)
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Danish Medicines Agency and National Board of Health belong to the Ministry of Health and Prevention
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	Advanced Therapies Products
FINLAND	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	National Agency for Medicines
1.3 Address. If there are multiple authorities, please indicate the address of each one.	P.O.Box 55 (Mannerheimintie 103b) FI-00301 Helsinki, FINLAND
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	According to the national legislation blood establishment shall give the annual report to the competent authority; this report has also confidential data. The annual report (public) of Finnish Red Cross Blood Service is published on the their webpage

1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The National Agency for Medicines (NAM) is supervising, competent authority which is situated organisationally under the Ministry of Social Affairs and Health. Director General is leading NAM. NAM is divided into 5 Departments; Administration, Enforcement
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	The competent authority is the National Supervisory Authority for Welfare and Health (est. 1.1.2009)
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
FRANCE	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Direction générale de la santé (DGS) French Health Products Safety Agency, Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps))
1.3 Address. If there are multiple authorities, please indicate the address of each one.	DGS: 14 avenue Duquesnes 75350 Paris 07 SP Afssaps: 143/147 Boulevard Anatole France F-93285 SAINT DENIS Cedex
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	The annual report on the activities of the blood establishments is the report of the French national blood service (Etablissement français du sang); this report isn't that of the French competent authority, the Afssaps. The haemovigilance data are detailed in a specific annual report of the Afssaps. Annual report of the French National Blood Service: www.efs.sante.fr Annual report of haemovigilance: www.afssaps.sante.fr
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The law of 1st July 1998 created the French Health Products Safety Agency –Afssaps – within a global context of reinforcing health monitoring and control of all products for human use.

1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	Gene therapy products, ancillary therapeutic products, insecticides and other anti-parasite products for human use, health food products intended for medical use, cosmetics.
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Ministry of Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Government of the Republic of Macedonia Ministry of Health 50 divizija no 6, 1000 Skopje Macedonia Institute of transfusione medicine Vodnjanska 17 1000 Skopje Macedonia
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	Website: www.ITM.ORG.MK
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	

1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	THE WHOLE HEALTH SYSTEM IN THE COUNTRY
GERMANY	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Paul-Ehrlich-Institut (PEI), 32 regional GMP inspection services of the "Laender"
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Paul-Ehrlich-Institut, D-63225 Langen Adresses from the Laender authorities to obtain at: Zentralstelle der Länder für Gesundheitsschutz bei Arzneimittel und Medizinprodukten (ZLG), Medicinal Products Department - Central Coordination Unit Sebastianstrass
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.pei.de
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	PEI is an independent higher federal authority within the portfolio of the German Federal Ministry of Health Regional GMP inspection services are competent authorities of the federal states ("Laender")
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Please see questionnaire for tissues and cells
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes

1.13.1 Please specify these other fields	PEI: marketing authorization of plasma derivatives and its recombinant analogues, blood components, vaccines, allergens, tissues; vigilance for these products, IVD vigilance, OMCL for batch release, contract laboratory for IVD batch release, GCP licenses
GREECE	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Ministry of Health and Social Solidarity 1) National Blood Centre (EKEA) 2) Hellenic Centre for Diseases Control and Prevention (HCDCP) Hellenic Coordinating Haemovigilance Centre (SKAE)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	EKEA, 7 Olympioniki Mantika st, Acharnes 13671, Greece HCDCP- SKAE, 10 Averof st, 10433 Athens, Greece
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	The report will be send in due course.
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The Ministry of Health and Social Solidarity has the exclusive competence and responsibility for the organization of the blood transfusion system in compliance with Directive 2002/98/EC. For this purpose, EKEA, which is a Legal Entity of Public Law, has b
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	Hellenic Transplant Organization (HTO)
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Hellenic Transplant Organization (HTO)
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	National Organization for Medicines (EOF)
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	National Organization for Medicines (EOF)
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	The Hellenic Centre for Diseases Control and Prevention (HCDCP) cooperates with the National Blood Centre (EKEA) for haemovigilance, traceability, look back for HIV infection and other blood transmissible infections as well as for the epidemiological surveillance of transfused transmitted infections. HCDCP's main activities are prevention and control of communicable diseases and protection and promotion of public health.

HUNGARY	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	NATIONAL INSTITUTE OF PHARMACY (ORSZÁGOS GYÓGYSZERÉSZETI INTÉZET)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	3. ZRÍNYI str, BUDAPEST, 1051-HUNGARY
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.ovsz.hu
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	THE COMPETENT INDEPENDENT STATE-OWNED GOVERMENT AUTHORITY ESTABLISHED UNDER SUPERVISION of THE HEALTH MINISTRY
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	NATIONAL PUBLIC HEALTH and MEDICAL OFFICER SERVICE;
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	AUTHORITY FOR MEDICAL DEVICES OF THE OFFICE OF HEALTH, AUTHORIZATION AND ADMINISTRATIVE PROCEDURES (ENGEDÉLYEZÉSI és KÖZIGAZGATÁSI HIVATAL ORVOSTECHNIKAI IGAZGATÓSÁG)
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	IT IS RESPONSIBLE FOR THE REGISTRATION OF MANUFACTURERS AND DEVICES ACCORDING TO ARTICLE 14 OF THE MDD DIRECTIVE AND ARTICLE 10.6 OF THE IVD DIRECTIVE
IRELAND	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Irish Medicines Board

1.3 Address. If there are multiple authorities, please indicate the address of each one.	Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Ireland
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	Can be provided at Competent Authorities Meeting.
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Independent State Body which reports to the Department of Health and Children
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	No Competent Authority assigned in Ireland yet.
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	Herbals & Cosmetics
ICELAND	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Ministry of Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Vegmúla 3 IS 150 Reykjavík Iceland
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	No
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Ministy of Health, Office Pharmaceutical Affairs

1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	
ITALY	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Ministry of Welfare - National Blood Centre Regional Health Authorities (n. 21) - Regional Blood Centres
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Ministry of Welfare - Dept of Prevention - Blood and Transplant Section Via G. Ribotta, 5 - 00144 Rome, Italy Italian National Blood Centre Via Giano della Bella, 27 - 00162 Rome, Italy
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The Ministry of Welfare has legislative and general planning tasks. The National Blood Centre is the technical body of the Ministry of Welfare responsible for co-ordination and technical and scientific control of all transfusion medicine issues ruled by national laws and European provisions; it also co-ordinates the Regional Blood Centres which work as a national network.
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	Ministry of Welfare - National Transplant Centre. Note: Cord blood cells are in charge of the National Blood Centre in collaboration with the National Transplant Centre)
1.10 Is the competent authority(ies) responsible for human organs?	No

1.10.1 If no, Please specify which regulatory authority is responsible	Ministry of Welfare - National Transplant Centre
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	Ministry of Welfare - Italian Medicine Agency (AIFA). Note: The National Blood Centre is responsible for planning the national collection of plasma to be manufactured into plasma products and for plasma product self-sufficency policies; it is also directly involved (together with AIFA) in the control of quality and safety of plasma products.
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	Ministry of Welfare
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
LIECHTENSTEIN	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Amt für Gesundheit (= Office of Health)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Äulestrasse 51, 9490 Vaduz Liechtenstein
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	No
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Office within the Liechtenstein administration
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	

1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	insurance, Public health affairs
LITHUANIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	1. Ministry of Health 2. State Service of Accreditation for Health Care Activities under the Ministry of Health 3. State Medical Audit Inspectorate under the Ministry of Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	1. 33 Vilniaus str., Vilnius, Lithuania 2. 92 Zalgirio str., Vilnius, Lithuania 3. 5 A. Smetonos str., Vilnius, lithuania
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	Report in Lithuanian available on request www.lsic.lt
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The competent authorities are responsible for implementing of the blood directives
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	National Bureau on transplantation
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	National Bureau on transplantation
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	State Medicines Control Agency under the Ministry of Health
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
LATVIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Health Statistics and Medical Technologies State Agency is the Competent Authority in Latvia

1.3 Address. If there are multiple authorities, please indicate the address of each one.	12/22 Duntes Street, Riga, LV -1005, Latvia
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	in progress
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Due to the national legislation in the process of supervision of the Blood establishments, Blood Centre and Hospital Blood Banks takes part Health Statistics and Medical Technologies State Agency, which is under the supervision of the Ministry of Health.
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	State Medicine agency
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	Confirms the technologies for the blood and blood components preparations and use
LUXEMBOURG	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Minister of Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Villa Louvigny Allée Marconi L-2120 Luxembourg
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.croix-rouge.lu

1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Ministry of Health
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	
1.13.1 Please specify these other fields	
MALTA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Directorate General for Public Health Regulation within the Ministry for Social Policy. http://www.sahha.gov.mt/pages.aspx?page=942 The Superintendent of Public Health is the Licensing Authority for the purposes of the Human Blood and Transplant Act (Cap
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Address: The Director General for Public Health Regulation Ministry for Social Policy 15, Palazzo Castellania, Merchants Street, Valletta, VLT 2000 Telephone: +356 2299 2426 Fax: +356 2124 2884
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	Webpage: http://www.health.gov.mt/nbts/index3.htm Summary Statistics: http://www.health.gov.mt/nbts/statistics.htm
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The Superintendent of Public Health is the Licensing Authority for the purposes of the Human Blood and Transplant Act (Cap.483). http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_15/Chapt483.pdf). Currently, the Director General of Public Health

1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Not Applicable
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	However - the Superintendent of Public Health is the Licensing Authority responsible for pharmaceuticals, as stipulated under the Medicines Act (Cap.458). http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_14/Chapt458.PDF
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	The regulatory authority responsible for medical devices is the Malta Standards Authority within the Ministry of Finance, the Economy and Investment. http://www.msa.org.mt/rad/medicaldevices/index.htm
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	The Director General also performs the duties of Chief Government Medical Officer and Superintendent of Public Health in terms of law. http://www.sahha.gov.mt/pages.aspx?page=942
NETHERLANDS	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Minister of Health, Welfare and Sport
1.3 Address. If there are multiple authorities, please indicate the address of each one.	P.O. Box 20350 2500 EJ Den Haag The Netherlands
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.Sanquin.nl
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Minister of Health, Welfare and Sport

1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	
NORWAY	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Norwegian Directorate of Health (for authorisation) Norwegian Board of Health Supervision & Norwegian Medicines Agency, both for inspection and control measures)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Norwegian Directorate of Health PO Box 7000 St Olavs plass N-0130 Oslo, Norway
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	http://www.hemovigilans.no/docs/28652_Blodtrans_webutgave.pdf
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Directorate
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	Norwegian Medicines Agency

1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	
POLAND	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Mrs. Ewa Kopacz - Minister of Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	15 Miodowa str. Warszawa
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	At the moment the last report available is for 2007.
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Ministry of Health
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	Medical materials
PORTUGAL	

1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Autoridade para os Serviços de Sangue e Transplantação (ASST)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Av. João Crisostomo, 14 1049-62 Lisboa Portugal
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Department in the Ministry of Health
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P (Infarmed)
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	Infarmed
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
ROMANIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	MINISTRY OF HEALTH
1.3 Address. If there are multiple authorities, please indicate the address of each one.	No. 1-3, CRISTIAN POPISTEANU STREET 010024 BUCHAREST
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	The english version will be sent to gabriella.csoka@ec.europa.eu

1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Ministry of Health is organised according with Governmental Decision no 1718/2009. Ministry of Health was nominated Competent Authority for blood and blood components trough Law no282/2005. At MOH level, responsibility for authorisation has be
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	ROMANIAN DRUG AGENCY
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	PUBLIC HEALTH, PREPAREDNESS AND RESPONSE, TRAINING, OTHER
SLOVAKIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	The Ministry of Health - The Ministry of Health as a central body of state administration in the healthcare sector within its authority (for example State Institute for Drug Control) State Institute for Drug Control - The State Institute for Drug Control
1.3 Address. If there are multiple authorities, please indicate the address of each one.	The Ministry of Health – Limbová 2, 837 52 Bratislava 37, Slovakia State Institute for Drug Control – Kvetná 11, 825 08 Bratislava 26, Slovakia
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.mzsr.sk
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Ministry of Health - Organizational Rules of the Ministry of Health of the Slovak Republic is a basic internal organisational regulation of the Ministry of Health of the Slovak Republic.
1.9 Is the competent authority(ies) responsible for human tissues and cells?	
1.9.1 If no, Please specify which regulatory authority is responsible	

1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	/
SLOVENIA	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Agency for Medical Products and Medical Devices of the Republic of Slovenia.
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Ptujska ulica 21, 1000 Ljubljana, Slovenia
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	For year 2008 not yet (It will be prepared till 30th March, 2009). For year 2007 it is on the website www.ztm.si
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Agency for Medical Products and Medical Devices of the Republic of Slovenia is competent authority for medicines for human and veterinary use, medical devices, and also for blood and tissues/cells.
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Institute for transplantation of Organs and Tissues of the Republic of Slovenia is the central national institution responsible for human organs
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	

1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	OMCL
SPAIN	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	1. Ministry of Health:Directorate General for Public Health: Dr. Ildefonso Hernandez Aguado 2. Autonomous Communities:Regional Departments of Health (17)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	1. Ministry of Health:Directorate General for Public Health: Dr. Ildefonso Hernandez Aguado Paseo del Pardo 18-20. Madrid 28071 Teléf:915962062 mail: dgsps@msc.es
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	1. The annual report: "Estadística Estatal de actividad de los Centros y Servicios de Transfusión" is directly available for the blood establishments directors through the computer application eRoom system 2. and also available for general public in the W
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	1.Ministry of Health. Directorate General for Public Health: chair of the Blood Transfusion Advisory Committee (CNH), coordinating body for the all 17 Autonomous Communities. 2. Blood Safety Scientific Committee (CCST), advisory body for the Directorate G
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	Dirección General de Terapias avanzadas y trasplantes-Organización Nacional de Trasplantes
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Dirección General de Terapias avanzadas y trasplantes-Organización Nacional de Trasplantes
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	Agencia Española de Medicamentos y Productos Sanitarios
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	Agencia Española de Medicamentos y Productos Sanitarios
1.13 Is the competent authority(ies) responsible for other fields?	Yes

1.13.1 Please specify these other fields	Sanidad Exterior (Health through the borders);Sanidad ambiental y laboral (Environmental and working health);Promoción de la salud y epidemiología (Epidemiology and health Promocion);Centro de coordinación de Alertas y Emergencias (Coordinating Centre for
SWEDEN	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	National Board of Health and Welfare, Medical Products Agency
1.3 Address. If there are multiple authorities, please indicate the address of each one.	National Board of Health and Welfare SE-106 30 Stockholm Sweden, Medical Products Agency SE-751 03 Uppsala Sweden
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	The Annual report (in Swedish) is attached to the questionnaire.
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The National Board of Health and Welfare is an independent authority under the Ministry of Health and Social Affairs. The Government determines the policy guidelines for our work, which among others include develop and publish regulations based on legislations and to supervise for compliance.
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	The National Board of Health and Welfare is the responsible authority for supervising health and medical care in Sweden. The two competent authorities described in 1.8 above, are covering the defined responsibilities in Sweden.

SWITZERLAND	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	1) Swissmedic, Swiss Agency for Therapeutic Products 2)Federal Office of Public Health
1.3 Address. If there are multiple authorities, please indicate the address of each one.	1)Hallerstrasse 7, CH-3000 Bern 9 2)Seilerstrasse 8, CH-3011 Bern
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	http://www.blutspende.ch/de/forms/bestellformular_fuer_Jahresbericht.php
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Swissmedic is the central Swiss supervisory authority for therapeutic products (human and veterinary medicines together with medical devices). It is linked to the Federal Department of Home Affairs (FDHA). Swissmedic's administrates the Swiss Law on Therapeutic Products (LTP). The Federal Office of Public Health (FOPH), as the national authority in health matters, is part of the Federal Department of Home Affairs and represents Switzerland in international organisations and in dealings with other countries. It is responsible - together with the cantons - for public health and the development of national health policy including monitoring transmissible diseases, radiological protection, regulations governing the basic and advanced training of doctors, dentists, pharmacists and veterinary surgeons and for legislation on biological safety, research on humans, stem cell research and transplantation medicine. It is drafting the laws and regulations and supervises the implementation.
1.9 Is the competent authority(ies) responsible for human tissues and cells?	Yes
1.9.1 If no, Please specify which regulatory authority is responsible	
1.10 Is the competent authority(ies) responsible for human organs?	Yes
1.10.1 If no, Please specify which regulatory authority is responsible	
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	Yes
1.13.1 Please specify these other fields	See answer to question 1.8:licensing medicines granting authorizations for the procurement of blood, the manufacture and distribution of medicines (including blood and blood components) inspections mainly in the field of biologicals and coordination of the

TURKEY	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Department of Ministry of Heath of Turkey, Curative Services Directorate General, Unit of Blood Service.
1.3 Address. If there are multiple authorities, please indicate the address of each one.	No.
1.7 Do you have an annual report on the activities of blood establishments in your Member State?	Yes
1.7.1 Please indicate the website or provide us with the report.	www.saglik.gov.tr
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Department of Ministry of Heath of Turkey, Curative Services Directorate General
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	Unit of tissue and cell under the Directorate General of Curative Services
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Unitof organ under the Directotare General of Curative Services
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	No
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	No
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	
UNITED KINGDOM	
1.2 Name of the designated competent authority(ies) (Art. 4 (1) Directive 2002/98/EC) If there are multiple designated competent authorities, please indicate each one.	Medicines and Healthcare products Regulatory Agency (MHRA)
1.3 Address. If there are multiple authorities, please indicate the address of each one.	Market Towers 1 Nine Elms Lane London SW8 5NQ

1.7 Do you have an annual report on the activities of blood establishments in your Member State?	No
1.7.1 Please indicate the website or provide us with the report.	
1.8 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The MHRA is the UK competent for medicinal products, medical devices and the safety and quality of blood and blood components
1.9 Is the competent authority(ies) responsible for human tissues and cells?	No
1.9.1 If no, Please specify which regulatory authority is responsible	Human Tissue Authority (HTA) & Human Fertilisation and Embryology Authority (HFEA)
1.10 Is the competent authority(ies) responsible for human organs?	No
1.10.1 If no, Please specify which regulatory authority is responsible	Human Tissue Authority
1.11 Is the competent authority(ies) responsible for pharmaceuticals?	Yes
1.11.1 If no, Please specify which regulatory authority is responsible	
1.12 Is the competent authority(ies) responsible for medical devices?	Yes
1.12.1 If no, Please specify which regulatory authority is responsible	
1.13 Is the competent authority(ies) responsible for other fields?	No
1.13.1 Please specify these other fields	

2. TRANSPOSITION

AUSTRIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
BELGIUM	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
BULGARIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes

2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	Not yet.
CROATIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
CYPRUS	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
CZECH REPUBLIC	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes

2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	no
DENMARK	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	No
FINLAND	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	New Administrative Regulations (given by NAM) into force the 1st of January 2009. Technical quality and safety requirements for blood and blood components 1/2008 Quality system for Blood Establishments 2/2008
FRANCE	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes

2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	no
GERMANY	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
GREECE	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes

2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	New regulations for the organization and the functions of the National Blood Centre (EKEA) are drafted in the frame of a new law "Regulations for the organizations of the Ministry of Health and Social Solidarity and other provisions". This is under discussion in Parliament.
HUNGARY	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
IRELAND	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	

2.5 Additional comments on transposition	Directives transposed into Statutory Instruments 360 of 2005, 547 of 2006 and 562 of 2006.
ICELAND	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
ITALY	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	The transposition of the Directive 2002/98/EC, originally performed in Aug 2005, has been updated in Dec 2007.
LIECHTENSTEIN	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	

2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
LITHUANIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
LATVIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
LUXEMBOURG	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	

2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
MALTA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	The Laws of Malta through the Human Blood and Transplants Act (Cap.483). http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_15/Chapt483.pdf Directive 2002/98/EC was further transposed through the Blood (Quality and Safety) Regulations (LN272/06). http://www.doi.gov.mt/EN/legalnotices/2006/11/LN272.pdf These Regulations implement the requirements of the following EU Directives: - Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components; and - 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. 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 has been transposed into the Laws of Malta through the Blood (Quality and Safety) Regulations (LN272/06). http://www.doi.gov.mt/EN/legalnotices/2006/11/LN272.pdf Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events was transposed into the Laws of Malta through the Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations (LN273/06). http://www.doi.gov.mt/EN/legalnotices/2006/11/LN273.pdf Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments was transposed into the Laws of Malta through the Blood (Quality and Safety) Regulations (LN272/06). http://www.doi.gov.mt/EN/legalnotices/2006/11/LN272.pdf
THE NETHERLANDS	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes

2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
NORWAY	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
POLAND	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
PORTUGAL	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes - Decreto lei 267/2007
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes- Decreto lei 267/2007

2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes - Decreto lei 267/2007
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes- Decreto lei 267/2007
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
ROMANIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
SLOVAKIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	/
SLOVENIA	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes

2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
SPAIN	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
SWEDEN	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
SWITZERLAND	
2.1- Has Directive 2002/98/EC been transposed into national law?	No
2.1.1 If no, when is the transposition expected?	Switzerland is not a Member State of the European Union. But the regulations in Switzerland are equivalent to the Directive 2002/98/EC.

2.2- Has Directive 2004/33/EC been transposed into national law?	No
2.3.1 If no, when is the transposition expected?	Switzerland is not a Member State of the European Union. But the regulations in Switzerland are equivalent to the Directive 2004/33/EC.
2.3- Has Directive 2005/61/EC been transposed into national law?	No
2.2.1 If no, when is the transposition expected?	Switzerland is not a Member State of the European Union. But the regulations in Switzerland are equivalent to the Directive 2005/61/EC.
2.4- Has Directive 2005/62/EC been transposed into national law?	No
2.4.1 If no, when is the transposition expected?	Switzerland is not a Member State of the European Union. But the regulations in Switzerland are equivalent to the Directive 2005/62/EC.
2.5 Additional comments on transposition	Reference is made here to the discussions between Switzerland and EC in the framework of the health acquis.
TURKEY	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	
2.5 Additional comments on transposition	
UNITED KINGDOM	
2.1- Has Directive 2002/98/EC been transposed into national law?	Yes
2.1.1 If no, when is the transposition expected?	
2.2- Has Directive 2004/33/EC been transposed into national law?	Yes
2.3.1 If no, when is the transposition expected?	
2.3- Has Directive 2005/61/EC been transposed into national law?	Yes
2.2.1 If no, when is the transposition expected?	
2.4- Has Directive 2005/62/EC been transposed into national law?	Yes
2.4.1 If no, when is the transposition expected?	

2.5 Additional comments on transposition	

3. AUTHORISATIONS (ART. 5 DIRECTIVE 2002/98/EC)

AUSTRIA	
3.1- How many blood establishments are there in your country?	16 blood establishments & 14 plasmapheresis centres
3.2- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	yes
3.2.1 If no. Today, how many blood establishments have received authorisation?	
3.2.2 If no, When will this approval process be completed? What is (are) the reason(s) for the delay in the approval process?	
3.3 Are there plasma fractionation facilities in your country?	yes
3.3.1 How many are there?	2
3.3.2 Are these public or private facilities?	private
3.3.3 Is the product used nationally and/or is it exported?	both
3.3.4 Please describe the authorisation process	An manufacturing authorization (establishment licence) is granted by the Federal Office for Safety in Health Care if the national provisions (Austrian Medicines Act with ordinances) and EU directives with GMP guidelines with annexes, e.g. qualified person, facilities, personnel, Quality Assurance Systems, GMP/GDP, etc. are met and verified by an inspection of the AGES PharmMed inspectors. The authorisation process is the same as for pharmaceutical companies.
BELGIUM	
Number of blood establishments?	6
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	

Are there plasma fractionation facilities?	Yes
How many?	2
Public or private?	private
National use or export?	
describe 3.3.4	The authorisation process is the same as for any pharmaceutical plant
BULGARIA	
Number of blood establishments?	There are 5 big Blood Establishments (called Regional Blood Collection Centres) and 28 smaller (Hospital based blood collection departments)
All authorised by the comp auth?	No
If no, how many authorised?	All of the 28 hospital based blood establishment and 1 regional blood centre have been accredited.
When full authorisation completed?	I suppose, this process will have been completed by the end of the 2009.
Are there plasma fractionation facilities?	Yes
How many?	2
Public or private?	public
National use or export?	Their products are intended for national market only.
describe 3.3.4	According to the Bulgarian drug Law all plasma-derived medicinal products are subject to national marketing authorization procedure
CROATIA	
Number of blood establishments?	17(16+1)
All authorised by the comp auth?	No
If no, how many authorised?	Only 1 (one)
When full authorisation completed?	The approval process is planed to be partially completed in 2009. The reason for delay is establishment of CA (setting up a new Department within ministry)
Are there plasma fractionation facilities?	Yes
How many?	1
Public or private?	Mostly public
National use or export?	Nationally and exported
describe 3.3.4	Products must be registered in AMMD.
CYPRUS	

Number of blood establishments?	ONE
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
CZECH REPUBLIC	
Number of blood establishments?	79 (SUKL 01012009)
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
DENMARK	
Number of blood establishments?	In the 5 regions there are 13 blood centres and 59 donation sites. Testing and separation into blood components are centralised. At present 10 sites do fractionation and 8 sites perform testing.
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	

describe 3.3.4	
FINLAND	
Number of blood establishments?	1 Blood Establishment with 17 sites.
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
FRANCE	
Number of blood establishments?	17 regional establishments performing 158 collection activities, 17 processing activities, 17 testing activities and 152 distribution activities
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	two
Public or private?	one public and one private (LFB, Octapharma)
National use or export?	The both
describe 3.3.4	Manufacturing authorisation (according to article 40 of Directive 2001/83/EC) has been delivered for each manufacturing site
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
Number of blood establishments?	ONE
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	

Public or private?	
National use or export?	
describe 3.3.4	
GERMANY	
Number of blood establishments?	84 blood establishments with 140 production sites; 5 private organisations which exclusively collect plasma for fractionation with several collection centres each
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	3
Public or private?	private
National use or export?	The products are used nationally and are exported.
describe 3.3.4	Facilities obtain GMP license by the regional GMP inspection services. Marketing authorization for blood products is given by the PEI.
GREECE	
Number of blood establishments?	14
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	One, named "Elias Politis" branch of the National Blood Centre (EKEA). This fractionation centre produces precipitated plasma which is further processed and fractionated into albumin 20% by CLB-Sanquin. Following this procedure albumin is imported from the CLB to "Elias Politis" for local distribution.
Public or private?	Public.
National use or export?	Nationally.

describe 3.3.4	An official contract between the National Centre for the Production of Blood products "Elias Politis" and CLB is in compliance with the regulations of the National Organization for Medicines (EOF) that are based on the CPMP/BWP/269/95 and other updated EU GMP's and the relevant Dutch legislation. Law 3402/2005 "For restructuring of blood transfusion" authorizes EKEA and thus its unit "Elias Politis" to coordinate the collection of plasma at national level.
HUNGARY	
Number of blood establishments?	SEVEN (7) BLOOD ESTABLISHMENTS AND 16 BLOOD BANKS LIKE AS HOSPITAL BLOOD BANKS THAT ARE ALSO BELONGING TO THE HUNGARIAN NATIONAL BLOOD TRANSFUSION SERVICE.
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	ONE (1)
Public or private?	PRIVATE, IT IS INDEPENDENT FROM THE BLOOD SERVICE
National use or export?	BOTH
describe 3.3.4	THE NATIONAL INSTITUTE OF PHARMACY IS RESPONSIBLE FOR IT, ACCORDING TO THE GMP DIRECTIVE.
IRELAND	
Number of blood establishments?	Five. (5)
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	

ICELAND	
Number of blood establishments?	
All authorised by the comp auth?	
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
ITALY	
Number of blood establishments?	In Italy there is no distinction between "Blood Establishment" and "Hospital Blood Bank". Blood Transfusion Services (BTSs) are by law only public hospital-based services. The overall number of BTSs is 326 (2005 survey).
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	2 (Kedrion Biopharmaceuticals, Baxter)
Public or private?	Private
National use or export?	Both
describe 3.3.4	Authorisation process performed by the Italian Medicine Agency (AIFA), complying with European provisions
LIECHTENSTEIN	
Number of blood establishments?	2
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	

Public or private?	
National use or export?	
describe 3.3.4	
LITHUANIA	
Number of blood establishments?	4
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
LATVIA	
Number of blood establishments?	11
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
LUXEMBOURG	
Number of blood establishments?	one
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	

Public or private?	
National use or export?	
describe 3.3.4	
MALTA	
Number of blood establishments?	Malta has one blood establishment.
All authorised by the comp auth?	No
If no, how many authorised?	Not Applicable
When full authorisation completed?	The Competent Authority has organised an inspection of this only blood establishment with a view to license. Approval is due to be granted in the very near future.
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
THE NETHERLANDS	
Number of blood establishments?	1
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	one
Public or private?	private
National use or export?	both
describe 3.3.4	fractionation facility is licensed by the Minister of Health
NORWAY	
Number of blood establishments?	36
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	

Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
POLAND	
Number of blood establishments?	23
All authorised by the comp auth?	No
If no, how many authorised?	22
When full authorisation completed?	The approval process will be completed in the next few weeks. The lack of compliance with the requirements was the reason for the delay of the approval of the one blood establishment. This blood establishment had already improved its standard and passed the authorisation audit.
Are there plasma fractionation facilities?	Yes
How many?	1
Public or private?	private
National use or export?	nationally
describe 3.3.4	The authorisation for blood establishments is granted by the Minister of Health. This decision is based on the audit report prepared and presented by the Institute of Haematology and Blood Transfusion. This authorisation is not applicable for source plasma. The authorisation for blood establishments concerning source plasma is in competence of Main Pharmaceutical Inspector and need the other audit report prepared by the competent, accredited pharmaceutical inspection.
PORTUGAL	
Number of blood establishments?	26
All authorised by the comp auth?	No
If no, how many authorised?	Two
When full authorisation completed?	31th October 2009
Are there plasma fractionation facilities?	No

How many?	
Public or private?	
National use or export?	
describe 3.3.4	
ROMANIA	
Number of blood establishments?	41 BEs + 1 BE of The Ministry of Defence
All authorised by the comp auth?	No
If no, how many authorised?	None.
When full authorisation completed?	All 41 BEs have authorisation to function as an institution, for the sanitary and hygienic conditions, released by the County Public Health Directorates, which are subordinated to the Competent Authority (MOH). According to the Law 282/2005 and Minister's of Health Order 1225/2006, authorization to perform activities in the transfusion field should be released by the Public Health Authority of the MoH, based on the assessment report elaborated by the Regional Institute of Public Health, on institution request. The institutions which have to follow this procedure to be authorised to perform activities in the transfusion field are as follows: blood establishments, National Institute of Blood Transfusion (currently still named National Institute of Transfusion Hematology) and hospitals using transfusion therapy (authorisation for the Blood Banks). So far, all of the 41 BEs are in evaluation process according to this procedure. Order 1225 regarding requirements for the authorisation does not state minimal standards to get the authorisation and conditions for suspending/withdrawing it, therefore it has to be revised and completed in 2009.
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
SLOVAKIA	
Number of blood establishments?	44
All authorised by the comp auth?	Yes
If no, how many authorised?	

When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
SLOVENIA	
Number of blood establishments?	There are three authorised blood establishments. One of these blood establishments has also 2 departments on different locations. One of those two blood establishment-departments has been inspected and authorised, the other one is planed to be authorised in the next three months. There are also 7 Blood establishments which are in reorganisation phase and they will become departments of one of the already authorised blood establishments.
All authorised by the comp auth?	No
If no, how many authorised?	Three.
When full authorisation completed?	We are planning that the approval will be completed till the end of the year 2009. The other blood establishments in Republic of Slovenia which are not yet authorised are still in reorganisation phase to become compliant with the legislation and to join one of establishments which has already been authorised.
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
SPAIN	
Number of blood establishments?	There are 25
All authorised by the comp auth?	Yes
If no, how many authorised?	

When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	There is one facility
Public or private?	It is a private facility
National use or export?	Both of them: nationally and exported used
describe 3.3.4	The authorization is granted by the "Agencia Española de Medicamentos y Productos Sanitarios"
SWEDEN	
Number of blood establishments?	32 transfusion centres (organizations) is a combination of blood establishments and hospital blood bank. The organizations often consist of more than one centre and can also include hospital blood banks. All in all there are 82 inspection sites and a number of blood collecting units.
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	One
Public or private?	Private
National use or export?	Both
describe 3.3.4	A Plasma Master File certificate, according to Directive 2003/63/EC, is granted for the plasma used as source material for medicinal products. Marketing authorisation is granted for medicinal products, as defined in Directive 2001/83/EC, according to the procedures of this directive.
SWITZERLAND	
Number of blood establishments?	54 Establishment licenses for blood establishments which perform collection and/or processing activities, and 50 Establishment licenses for establishments which perform serology testing. These establishment licenses may cover multiple sites (e.g. for collection).
All authorised by the comp auth?	Yes
If no, how many authorised?	

When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	1
Public or private?	Private
National use or export?	Both
describe 3.3.4	An authorization (establishment licence) is granted if the legal provisions, e.g. responsible person, facilities, personnel, Quality Assurance Systems, GMP/GDP, etc. are met and verification through an inspection is performed. The authorisation process is the same as for all pharmaceutical companies.
TURKEY	
Number of blood establishments?	1 -name is Turkish Red Crescent
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	No
How many?	
Public or private?	
National use or export?	
describe 3.3.4	
UNITED KINGDOM	
Number of blood establishments?	14
All authorised by the comp auth?	Yes
If no, how many authorised?	
When full authorisation completed?	
Are there plasma fractionation facilities?	Yes
How many?	1
Public or private?	Public
National use or export?	Both
describe 3.3.4	Manufacturing authorisation & marketing authorisations

4. HOSPITAL BLOOD BANK

AUSTRIA	
4.1- How many Hospital Blood Banks are in activity?	150
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	yes
4.2.1 If YES, please describe	hospital act implementing 2002/98/EC; authorised by local authorities
BELGIUM	
4.1- How many Hospital Blood Banks are in activity?	112
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	There are rules governing the hospital blood banks for the provisions mentioned. In addition hospital blood banks must be authorised by the competent authority (at Community level)
BULGARIA	
4.1- How many Hospital Blood Banks are in activity?	56
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
CROATIA	
4.1- How many Hospital Blood Banks are in activity?	16

4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
CYPRUS	
4.1- How many Hospital Blood Banks are in activity?	SIX
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
CZECH REPUBLIC	
4.1- How many Hospital Blood Banks are in activity?	56 (SUKL 01012009)
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	GMP inspections
DENMARK	
4.1- How many Hospital Blood Banks are in activity?	There are 61 Hospital Blood Banks (storage of released blood components.
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
FINLAND	
4.1- How many Hospital Blood Banks are in activity?	54
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes

4.2.1 If YES, please describe	The requirements of the Blood Directives concerning especially hospital blood banks are transposed in the national legislation (Blood Service Act 197/2005). According to the national legislation hospital blood banks are part of the hospital organisations and are supervised mainly by another competent authority.
FRANCE	
4.1- How many Hospital Blood Banks are in activity?	705 Hospital Blood Banks are in activity
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	The rules governing the Hospital blood banks were updated by the decree published at the French Official Journal on September 9, 2007, and in particular the provisions relating to the authorisation and the inspection of these establishments.
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
4.1- How many Hospital Blood Banks are in activity?	22
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
GERMANY	
4.1- How many Hospital Blood Banks are in activity?	Approximately 800
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
GREECE	
4.1- How many Hospital Blood Banks are in activity?	81. This regulation does not apply for another 5 hospital blood banks

4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	Collection of blood in cooperation with the National Blood Centre is performed by the hospital blood banks (Law 3402/2005 Article 10B, Paragraph 1)
HUNGARY	
4.1- How many Hospital Blood Banks are in activity?	24
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	YES, 60/2003 (X.20.) DECREE OF HEALTH MINISTRY
IRELAND	
4.1- How many Hospital Blood Banks are in activity?	Fifty-five (55) Hospital Blood Banks in operation.
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	All Hospital Blood Banks are required to submit an Annual Report to the Competent Authority which provides details of the systems that it has in place to ensure compliance with the requirements of the Irish Legislation and including a declaration that these systems are appropriate and in place. All Hospital Blood Banks are also required to be compliant with International Standard ISO 15189 - Medical Laboratories - Particular requirements for quality and competence.
ICELAND	
4.1- How many Hospital Blood Banks are in activity?	One
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	

ITALY	
4.1- How many Hospital Blood Banks are in activity?	In Italy there is no distinction between "Blood Establishment" and "Hospital Blood Bank".
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	National blood laws.
LIECHTENSTEIN	
4.1- How many Hospital Blood Banks are in activity?	only one blood depot
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	Our national provisions are according to the Swiss Law on Therapeutic Products is applicable.
LITHUANIA	
4.1- How many Hospital Blood Banks are in activity?	102
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
LATVIA	
4.1- How many Hospital Blood Banks are in activity?	49
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	
LUXEMBOURG	
4.1- How many Hospital Blood Banks are in activity?	9

4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	règlement grand-ducal
MALTA	
4.1- How many Hospital Blood Banks are in activity?	Four hospital blood banks are currently in activity.
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
THE NETHERLANDS	
4.1- How many Hospital Blood Banks are in activity?	about 115??
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
NORWAY	
4.1- How many Hospital Blood Banks are in activity?	A few. These are authorised as part of the authorisation of blood establishments
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes; in addition to the provisions mentioned, general laws regulating the health care sector, including hospitals in general, laws on patient rights, laws governing medical records etc apply
4.2.1 If YES, please describe	
POLAND	
4.1- How many Hospital Blood Banks are in activity?	533
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes

4.2.1 If YES, please describe	The Decree of Minister of Health from 2005 provides more detailed requirements for the organisation of transfusion service in hospitals, inclusive blood banks.
PORTUGAL	
4.1- How many Hospital Blood Banks are in activity?	
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
ROMANIA	
4.1- How many Hospital Blood Banks are in activity?	345
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	Provisions covered by the above mentioned articles of Directive 2002/98/EC have been transposed in Law 282/2005.Other requirements regarding organisation, location, personnel, technical requirements for minimal equipment and testing , etc. are stated in the Minister's Order 1224/2006. Requirements on quality management system, as they are in Directive 2005/62/EC , have been extended to the hospital blood banks and clinical services (with regards to the transfusion activities), by the endorsement of Minister's Order 1132/2007.
SLOVAKIA	
4.1- How many Hospital Blood Banks are in activity?	It is not so clear, because The hospital blood banks did not need the authorisation.
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
SLOVENIA	

4.1- How many Hospital Blood Banks are in activity?	Three
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	Hospital blood banks are ruled by legislation on health activities (Health Activities Act).
SPAIN	
4.1- How many Hospital Blood Banks are in activity?	There are 341 hospital blood banks (Hospital transfusion Services). 250 out of these 341 hospital blood banks belong to Public Hospitals and carry out the 95% of all transfusions in the country. Hospital blood banks do not take part in the preparation of blood components
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	1.Compulsory establishment of Quality Systems in every hospital blood bank. (Art.32 del RD 1088/2005), and 2. Compulsory establishment of Transfusion Committees (Art. 40 del RD 1088/2005)
SWEDEN	
4.1- How many Hospital Blood Banks are in activity?	82 (see question 3.1)
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
SWITZERLAND	
4.1- How many Hospital Blood Banks are in activity?	Approximately 100 (Authorisation for the storage of blood components (only if there are no other activities regarding blood) is issued by the cantonal authority, therefore, as federal authority we do not know the actual number of establishments holding an authorisation issued by the cantonal authorities)

4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	Hospital blood banks are required to have a cantonal establishment license. Some basic requirements (e.g. archiving of documents) which are comparable to the EU provisions are laid down in the national Law on Therapeutic Products. In addition, cantonal regulations exist for hospital blood banks.
TURKEY	
4.1- How many Hospital Blood Banks are in activity?	368
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	No
4.2.1 If YES, please describe	
UNITED KINGDOM	
4.1- How many Hospital Blood Banks are in activity?	390
4.2- Are there rules governing the Hospital blood banks? (for provisions not covered by articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 of Directive 2002/98/EC)	Yes
4.2.1 If YES, please describe	Hospital blood banks are required to submit to the competent authority an annual report of their compliance with the relevant provisions of the Directives. When necessary, the competent authority will carry out inspections to assess the compliance status of hospital blood banks

5. INSPECTIONS

AUSTRIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	yes
5.1.1 If yes, Please describe	inspectorate of AGES PharmMed on behalf of Federal Office for Safety in Health Care with the mandate for enforcing Federal Medicines Act, Federal Blood Safety Act, etc. which are based on 2001/83/EC and 2002/98/EC including all daughter directives.The inspections are imbedded in the pharmaceutical inspection system of the AGES PharmMed Institute for Inspections, Medical Devices and Haemovigilance (acting on behalf of the Federal Office for Safety in Health Care) because blood as well as tissues and cells are defined as medicinal products in the Austrian Medicines Act.
5.2 Have blood establishments already been inspected?	yes
5.2.1 If yes, How many regular inspections were done in 2008?	12
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	GMP inspectors specialised on blood
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	yes
5.4.1 If yes, Please describe	AGES PharmMed inspects and Federal Office for Safety in Health Care authorises
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	yes
5.5.1 If yes, Please describe	Inspections of Hospital blood banks are performed by regional or local authorities including medical officers according to a checklist issued by the Federal Ministry of Health.
5.5.2 If no, Please describe	

5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
5.6.1 If yes, Please describe	
BELGIUM	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Organised by the Inspection department of the Federal Agency for Medicines and Health Products
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	24
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Officials of the Federal Agency for Medicines and Health Products or the FPS Health and designated by the King
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The Minister of Health is granting the accreditation.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Organised by the Regional Ministries of Public Health.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
BULGARIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	According to articles 38 and 39 of LBBDBT and Regulation 26 (on the terms and conditions for inspections of blood establishments) BDA must inspect BE and HBB on regular basis every year.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	60
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	We have done 1 inspection following a suspected serious adverse reaction, but the reaction has not been confirmed.
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Bulgarian Drug Agency
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The accreditation is done by an accreditation committee, a specialized body of the Ministry of Health. An Expert commission, nominated by an order of the Minister of Health makes an assessment following the criteria and indexes, included in the regulation and prepares report.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	In development. There is not enough qualified staff at the agency.
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	The 5 Big Blood establishments (so called Regional blood transfusion centres) provide source plasma for fractionation for national manufacturers of plasma-derived products. So, according to the Directive 2001/83/EC this is a step of manufacturing process and we perform joined inspections with Bulgarian GMP inspectors.
CROATIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	No

5.1.1 If yes, Please describe	
5.2 Have blood establishments already been inspected?	No
5.2.1 If yes, How many regular inspections were done in 2008?	
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	GMP pharmaceutical inspectors
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	The same authority is granting authorisation and inspecting the blood establishment
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	A new system for inspection is currently under development (setting up new department within MoHSW)
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	The same inspectors team will inspect blood, tissue and cells establishments
CYPRUS	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	No
5.1.1 If yes, Please describe	
5.2 Have blood establishments already been inspected?	No
5.2.1 If yes, How many regular inspections were done in 2008?	
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Officials from the Pharmaceutical Services will be carrying the inspections

5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The Pharmaceutical Services is a different Department from the Department of Medical and Public Health Services. Both departments belong to the Ministry of Health.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	no commends can be provided
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
CZECH REPUBLIC	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	GMP Inspection planning principles are laid down by internal document PN-INS-018-1: For example: "6.1.3. Follow-up inspection A follow-up inspection shall mean an inspection conducted at blood establishment pursuant to Section 11, paragraph 5, of Decree no. 143/2008 Coll. A follow-up inspection shall be conducted in the maximum interval of 24 months ± 3 months. The interval may be shortened 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 inspection shall always be 12 months or less. A follow-up inspection may be conducted either as an inspection notified in advance or, where such notice could pose a risk of failure to identify the actual situation, as an inspection without prior notice."
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	45 inspections of blood establishments and 8 inspections of blood banks

5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	none
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Inspectors of State Institute for drug control, specialized on blood/blood components. The minimum qualification according section 22, paragraph 2, Act no 378/2007 Coll., on Pharmaceuticals and Amendments to Several Related Acts (comparable with requirement for responsible person - see art. 9 par. 2 directive 2002/98/EU); training for inspections in blood establishments and blood banks.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	According Section 13 of Act no 378/2007 Coll., on Pharmaceuticals the State Institute for Drug Control issues manufacturing authorisations for transfusion products and raw materials for further production (paragraph 2, letter a) 2.) and inspects, at the premises of operators and other persons handling pharmaceuticals, adherence to this Act (paragraph 2, letter g))
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Inspection planning principles are laid down by internal document PN-INS-018-1, in principle very similar to the system for blood establishments
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
DENMARK	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Site and inspection frequency are entered into the database LOS, which then indicates the coming inspection date.
5.2 Have blood establishments already been inspected?	Yes

5.2.1 If yes, How many regular inspections were done in 2008?	41 inspections.
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	None
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Trained inspectors, all with academic degrees.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	The Department for Inspection, Laboratories and Statistics is issuing authorisations and perform inspections. Two separate sections within the Department are the acting units.
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	All Hospital Blood banks are operated by Blood Establishments (Centres). Inspection of HBB is performed as part of the inspection of BE´s.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	Inspectors trained for the different topics form part of the inspection team. Separate inspection reports are issued.
FINLAND	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Blood establishments have been inspected in Finland since the year 1996. Inspections are conducted by the inspectors of the National Agency for Medicines on a regular basis.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	9

5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	Procedures to handle SAEs and SARs are inspected as a part of normal inspections. Until now there has been no need for specific SAE /SAR inspections.
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Inspections are carried out by the inspectors of the National Agency for Medicines. Inspectors shall be qualified and certified to inspect blood establishments.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	The same authority is licensing and inspecting.
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	National Agency for Medicines does not inspect hospital blood banks. According to the national legislation hospital blood banks are part of hospital organisations and are mainly supervised by another competent authority.
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	NAM Inspectorate has a common quality system, so the training system and inspection procedures are similar.
FRANCE	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	- The system in place for organising inspections was set up in France since 1994 and is based on regularly performed inspections according to French good transfusion practices. - An external quality control of blood and blood components was performed in France since 1996. This external quality control is carried out according to an annual program.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	81 inspections concerning 121 blood activities

5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	Only one
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Inspectors of the Afssaps
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	By the same authority but by two different departments
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	The inspections of these hospital blood banks are carried out at the regional level by the regional inspectorate
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	No
5.1.1 If yes, Please describe	
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	NONE
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	NONE
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	BURREAU FOR MEDICINES MINISTRY OF HEALTH OF MACEDONIA
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	THERE IS A LEGISLATIVE COMLPLIANCE

5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	THERE WAS AN OLD INSPECTION SYSTEM WITH THE EXPERTS FROM ITM(Institute of transfusione medicine)
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	
GERMANY	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Inspections of blood establishments are in the responsibility of regional GMP inspection services according to the German Medicinal Products Act (Art. 64) and are in general performed together with authorized experts from PEI. Vigilance inspections (Medicinal Products Act Art. 63b para. 5a and Art. 63c para. 5) and inspections prior to marketing authorization (Medicinal Products Act Art. 25 para. 5, and 8) have to be organized by authorized experts from PEI and are performed in consultation with inspectors of the regional GMP inspection services.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	Total number performed by regional GMP inspection services is not centralised registered. In 2008, 118 inspections have been performed together with PEI at production sites for allogeneic blood compon
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	3 within one establishment
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Inspectors from regional GMP inspection services of the “Laender”, mostly accompanied by authorized experts from PEI.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	

5.4.2 If no, Please provide comments	• Blood establishment licensing according to the German Medicinal Products Act (Art. 13) is performed by regional GMP inspection services in consultation with authorized experts from PEI.
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	see above
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	In general, all kinds of inspection activities are regulated in comparable manner by the German Medicinal Products Act. Therefore, depending on the structure of the regional GMP inspection services it is possible that same inspector teams are responsible for different tasks. Training, education and other common duties of regional inspection services are harmonized by ZLG (specific "Laender" authority).
GREECE	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Blood establishments are inspected and controlled by authorized personnel of the National Blood Centre (EKEA)(Law 3402/2005 article 4, paragraph 4 and 5). Inspections are performed regularly in order to secure quality and safety for the collection, testing, processing, storage and distribution of blood and blood components. The competent authority (EKEA) organizes inspection and other control measures as appropriate in the event of any serious adverse event or reaction or a suspicion thereof. In specific events, the National Inspectors Body organizes inspections to the blood establishments and if necessary proposes control measures to EKEA through the Ministry of Health.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	One inspection took place in only 5 of the blood establishments.

5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	2 inspections.
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	EKEA's authorized personnel is for inspections is comprised by a physician, a biologist and a technician. Respectively, the specialized personnel of the National Body of Inspectors includes all fields of expertise (i.e physicians, lawyers, mechanics)
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	No, except for specific events where the National Body of Inspectors is called upon
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	At a first level the hospital blood bank is inspected by its supervising Regional Blood Centre. At a second level the competent authority (EKEA) is inspecting the hospital blood banks in the same away as with the blood establishments.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	Yes, only in specific events by the National Inspectors Body
HUNGARY	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	THE INSPECTORATE OF NATIONAL INSTITUTE OF PHARMACY ONCE/2 YEARS, SINCE 2002. THE HEADQUARTERS OF THE HUNGARIAN NATIONAL BLOOD TRANSFUSION SERVICE IS INDEPENDENT FROM THE ROUTINE BLOOD BANK PROCESSES, IT COORDINATES THE STRUCTURE AND FUNCTION OF THE BLOOD ESTABLISHMENTS AND THEIR QUALITY ASSURANCE SYSTEM AND AUDITS THEIR WORK AS WELL THE BLOOD DRIVE ACTIVITIES (ACCORDING TO THE DIRECTIVES AND NATIONAL LAW) OF THE HOSPITAL BLOOD BANKS ARE IN CONTRACTUAL CONNECTION WITH THE SERVICE.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	TWO (2)
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	NO
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	A. ALL PROCESS AND DOCUMENTATION HAD BEEN CONTROLLED BY THE INSPECTORS.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	NATIONAL PUBLIC HEALTH AND MEDICAL OFFICER SERVICE CONTROL THE BUILDINGS, THE PERSONNEL'S, ETC., BUT THE CLINICAL LABORATORY TECHNIQUES ARE INSPECTED BY THE EXPERTS OF TRANSFUSION.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
IRELAND	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	On site inspections were performed at all Blood Establishments in 2006 and 2007 prior to authorisation. Once authorised, all Blood Establishments were placed on a routine inspection schedule and will be inspected on-site at least every two years
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	Four (4) routine inspections were performed at one Blood Establishment. This Blood Establishment is the sole supplier of allogeneic blood in Ireland.
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	None
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Blood and Tissues Inspectors
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	The Management Committee of the Irish Medicines Board approves the authorisation of blood establishments following inspections and recommendations from the Blood and Tissues Inspectors.
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Inspections of Hospital Blood Banks have been performed on the basis of information provided in the Annual Reports that each Hospital Blood Bank submits to the Competent Authority. 30 inspections performed in 2007 and 22 inspections performed in 2008.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	The inspections only overlap in that the same inspectors may perform inspection of blood establishments, tissues establishments and hospital blood banks.
ICELAND	

5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	The Icelandic Medicines Agency (IMCA) has performed inspection by the assistance of Danish trained inspectors
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	2
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Inspectors from IMCA cf. 5.1
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	At the moment yes. The Ministry issues the authorization based upon inspection carried out by the IMCA and a paper based inspection carried out by the Chief Medical Officer
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	The Hospital Blood Bank will be inspected regularly every second year
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	i.a. pharmaceuticals and/or pharmaceutical production
ITALY	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	Inspections are in charge of Regional Health Authorities which have to comply with nationally established authorisation requirements and regionally established accreditation requirements. The latter shall have to comply with national guidelines issued by the National Blood Centre. Work is in progress for updating and homogenizing the inspection system. All blood establishments are authorised complying with pre-existing national and regional provisions.
5.2 Have blood establishments already been inspected?	No
5.2.1 If yes, How many regular inspections were done in 2008?	
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	To be determined within the new inspection system. Regional inspection teams shall be integrated by National Blood Centre's auditors.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	See 5.3.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	In Italy there is no distinction between "Blood Establishment" and "Hospital Blood Bank".
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	Cooperative teams are managed by the National Blood Centre and the National Transplant Centre for inspection of stem cell transplantation programs and cord blood banks
LIECHTENSTEIN	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	The Office of Health has a contract with Swissmedic to conduct the inspections.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	none
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	none
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	official inspectors of Swissmedic with the qualification according to ISO 17020 QM as inspectors for blood establishments
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The Office of Health is granting the license, but is delegating the inspections to Swissmedic.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	The inspections are performed by the same inspectorate.
LITHUANIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	According to the order of the Ministry of Health, inspections and control measures of blood establishments shall be organised on the regular basis. The interval between two control measures shall not exceed two years.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	4
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0

5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Specialists from State Medical Audit inspectorate
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	State Service of Accreditation for Health Care Activities is granting the authorisation State Medical Audit inspectorate is inspecting the blood establishments
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
LATVIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	The conformity of assessment of the Blood establishments was done by experts of the Agency due to the Rule of the Cabinet of Ministers Nr.1037,,Standards of quality for the collection, testing, processing, storage and distribution of human blood and blood components"
5.2 Have blood establishments already been inspected?	No
5.2.1 If yes, How many regular inspections were done in 2008?	
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	The officials inspect blood establishments as well as facilities, examine any documents relating to the object of the inspection
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No

5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	The conformity of assessment of the Hospital Blood Banks was done by experts of the Agency due to the Rule of the Cabinet of Ministers Nr. 1037,, Standards of quality for the collection, testing, processing, storage, distribution of human blood and blood components"
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
LUXEMBOURG	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	(Law 1979) a medical officer nominated by the minister of health is in charge of these inspections
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	regular
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	organized by the director general of health (règlement grand-ducal)
5.5.2 If no, Please describe	

5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
MALTA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	The inspection of the blood establishment is carried out by the Medicines Authority within the Ministry for Social Policy on behalf of the Licensing Authority.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	One inspection of the only blood establishment that exists in Malta was carried out in 2008.
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	Nil
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Trained inspectors within the competent authority are responsible for carrying out such inspections.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The Director General for Public Health Regulation (as the Competent Authority) issues a license based on the recommendations of the Medicines Authority (Inspectorate).
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	Although a formal system for the regular inspection of blood banks does not exist yet, in the case of a serious adverse event or reaction, an investigative root cause analysis would be carried out.

5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	The inspectorate team inspecting the blood establishment has common members from within the inspectorate team inspecting pharmaceuticals.
THE NETHERLANDS	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Four blood banks (big establishments) are responsible for the collection of blood/plasma. The blood banks have central management and central storage/testing facilities. The blood banks have more than one location where blood/plasma is actually donated. Every two years each blood bank and all fixed blood establishments are inspected. The mobile collection sites are excluded from this frequency. The inspections of mobile sites are chosen at random.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	1 Every 2 years each blood establishment is inspected. Two of the four big blood establishments. In 2009 the other two will be inspected.
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	none
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Competent inspectors and an inspectorate officer.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	Minister is competent authority but in practise: granting is Ministry of Health and inspecting is Inspectorate
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes

5.5.1 If yes, Please describe	There is a decree "kwaliteitseisen ziekenhuisbloedbanken"which is related to the law "kwaliteitswet zorginstellingen". This encloses the hospital blood banks and will be inspected in general hospital settings. The inspection division blood&tissues doesn't have a systematic inspection system to monitor the part of the blood chain in the hospitals.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
NORWAY	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	System in place at the Norwegian Board of Health Supervision and at the Norwegian Medicines Agency
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	30
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Officials from the CAs: Norwegian Board of Health Supervision and the Norwegian Medicines Agency
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	Authority granted by the Norwegian Directorate of Health. Inspections carried out by the Norwegian Board of Health Supervision and the Norwegian Medicines Agency
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	System in place at the Norwegian Board of Health Supervision and at the Norwegian medicines Agency

5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
POLAND	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	According to the Public Transfusion Service Act, each blood establishment has to be inspected by the Institute of Haematology and Blood Transfusion at least once in two years.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	15
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Institute of Haematology and Blood Transfusion in Warsaw
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The accreditation is granted by the Minister of Health.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Hospital Blood Banks are inspected by the Regional Centres for Transfusion Medicine (independent establishments from the hospitals).
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes

5.6.1 If yes, Please describe	Main Pharmaceutical Inspectorate inspects blood establishments as source plasma producers. The inspection spectrum overlaps the inspection realized by Institute of Haematology and Blood Transfusion.
PORTUGAL	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	According to the law 267/2007 ASST is responsible for inspections on blood establishments and hospital blood banks. The inspections are organised and done, by 3 Institutions, in cooperation - ASST(2 inspectors) , Portuguese Institute of Blood (1inspector) and Inspecção Geral de Saúde (2 inspectors), under the responsabilty of ASST. Two experts are also part of the team.
5.2 Have blood establishments already been inspected?	Yes (until now we perform 11 inspections - Jan and Feb 2009)
5.2.1 If yes, How many regular inspections were done in 2008?	0
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Autoridade para os Serviços de Sangue e Transplantação (ASST) Inspecção Geral para as Actividades em Saúde (IGAS) and Portuguese Institute of Blood (IPS).The inspections are organised and done, by these 3 Institutions, in cooperation - ASST(2 inspectors), IPS (1inspector) and IGAS (2 inspectors), under the responsabilty of ASST. Two experts are also part of the team. Blood establishments and Hospital Blood banks are inspected at the same time, if both exist in the same hospital.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes -Autoridade para os Serviços de Sangue e Transplantação (ASST) Inspecção Geral para as Actividades em Saúde (IGAS) and Portuguese Institute of Blood (IPS) in coopertaion, under ASST responsability, and at the same time.
5.4.1 If yes, Please describe	The inspections are performed by two authorities Autoridade para os Serviços de Sangue e Transplantação (ASST) and Inspecção Geral para as Actividades em Saúde (IGAS) and IPS. Only ASST can authorise blood establishment and blood banks.

5.4.2 If no, Please provide comments	The inspections are done in cooperation but only ASST can give legal authorisation to the blood establishment and blood banks.
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Autoridade para os Serviços de Sangue e Transplantação (ASST) Inspecção Geral para as Actividades em Saúde (IGAS) and Portuguese Institute of Blood (IPS).The inspections are organised and done, by these 3 Institutions, in cooperation - ASST(2 inspectors), IPS (1inspector) and IGAS (2 inspectors), under the responsabilty of ASST. Two experts are also part of the team. Blood establishments and Hospital Blood banks are inspected at the same time, if both exist in the same hospital.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	Part of the inspection team is the same
ROMANIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	According to Law 282/2005, Sanitary State Inspection, structure of the MOH (Competent Authority) is responsible with inspections on blood and blood components, performed both in blood establishments and hospital blood banks. Sanitary State Inspection plans, organises, coordinates and monitors inspections performed by inspectors working at the regional and county branches level .A common checklist is used for the inspections all-around the country. Inspection reports are submitted to the Sanitary State Inspection (MOH).
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	1/BE
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	NONE

5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	INSPECTORS
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	The Competent Authority is the MINISTRY OF HEALTH. Its responsibility to authorise has been assigned to the Directorate of PUBLIC HEALTH AUTHORITY. The responsibility of inspections has been assigned to the SANITARY STATE INSPECTION, another structure, with different management. Between the 2 structural units of the MOH a collaborative relationship is set up.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	According to Law 282/2005, transposing Directive 2002/98/EC, Sanitary State Inspection has the responsibility and authority to perform inspections in the hospital blood banks, too.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
SLOVAKIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	State Institute for Drug Control organising inspections and control measures of blood establishments.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	18
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	0

5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	General, entrance, continuous, pointed inspection
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	Ministry of Health (MH) does not provide the inspection. Ministry of Health granting the authorisation. State Institute for Drug Control inspecting the blood establishment.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	No
5.5.1 If yes, Please describe	
5.5.2 If no, Please describe	Each hospital in Slovakia has probably the Hospital Blood Bank. These Hospital Blood Banks did not need the authorization for their activities. If the organization doesn't have the authorization, the State Institute for Drug Control can not be the inspection.
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
SLOVENIA	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	According to the rules on criteria how to authorised blood establishments in Republic of Slovenia are laid down in national legislations "Pravilnik o postopku izdaje in preklica dovoljenja za opravljanje dejavnosti preskrbe s krvjo" ((Official gazette of RS, 06/08), it is obligatory for the CA to verify blood establishments before authorisation and perform regular inspection periodically every 2 years.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	One

5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	NONE
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Pharmaceutical inspectors from the competent authority Agency for Medical Products and Medical Devices of the Republic of Slovenia with the same competencies as described in Medical Product Act (Official gazette of RS, No. 31/2006)
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	Agency for Medical Products and Medical Devices of the Republic of Slovenia has Sector for Pharmaceutical inspection divided into two departments. Granting authorisations and services inspecting blood establishments belong to different departments.
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	YES, but Agency for Medical Products and Medical Devices of the Republic of Slovenia is not responsible for that inspection. Hospital blood banks are ruled by legislation on health activities (Health Activities Act) and are also inspected by Ministry of Health Administrative Inspection and supervised by Chamber of Medicines.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	The same inspectors team conduct inspection on blood (blood establishments) and in the field of tissues/cells (tissue establishments, tissue banks, donors centres,..).
SPAIN	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	1. By the Autonomous Communities (regional health authorities), which are the competent authorities for granting the authorisations/licences. 2. By the Scientific Societies (SETS and AEHH): conducted by the "Comité de Acreditación en Transfusión (CAT)"
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	6 inspections in 2007 (2008 final data not yet available)
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	Data are not available.
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	1. Autonomous Communities (regional health authorities): inspectors from the Regional Departments of Health, jointly with an expert in transfusion medicine 2. Accreditation Systems conducted by Scientific Societies: experts in transfusion medicine
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	For the authorisation (Authorisation by regional health authorities): YES; for the accreditation: NO
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Regional authorities are establishing systems for inspecting in a gradual way. 35% of the inspections have been conducted by them and the 65% by the Scientific Societies
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	Scientific Societies Accreditation Committee also carry out inspections in tissue banks
SWEDEN	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	The National Board of Health and Welfare: As for all supervision of health and medical care, including the area of blood, inspectors for conducting audits are situated regionally. Standard for supervision have been designed and used. These standards are not only based on the EC-directives but also regulations for quality and patient's safety, which all supervision in Sweden is based on. The Medical Products Agency performs inspections every second year based on the directives as well as GMP.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	The National Board of Health and Welfare: 27 The MPA: 46
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	None
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Experienced officials from the authorities. At the Medical Products Agency its pharmaceutical inspectors that perform the inspections.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	The National Board of Health and Welfare: The responsibility for authorisation and inspections lies under different units within the organisation. Medical Products Agency both inspects and grants authorisations.
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	See 5.1.1
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	
SWITZERLAND	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes

5.1.1 If yes, Please describe	The Division Inspectorates of Swissmedic conducts these inspections and has a quality management system and accreditation according to ISO 17020 for their activities.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	46 regular inspections in blood establishment and testing laboratories were performed in 2008.
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	There was no inspection just related to serious adverse events in 2008.
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Official employees of Swissmedic with the ISO 17020-QM-controlled qualification as inspectors for blood establishments.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	An authorisation request is treated by the same department at Swissmedic which is performing the inspections in blood establishments. The final result of an inspection is a formal proposal by the lead inspector with regard to granting/maintaining/suspending an establishment license. This proposal is taken into consideration when assessing an authorisation request.
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Inspections of Hospital blood banks are performed by cantonal authorities.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes

5.6.1 If yes, Please describe	The inspection of blood establishments is performed by the same inspectorate at Swissmedic. The inspectors involved have a special qualification to perform blood establishment inspections. Depending on the qualification the same inspector team may perform different types of inspections. All inspection activities are integrated into the same quality management system which is accredited as an inspection body according to ISO 17020.
TURKEY	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Ministry of Health
5.2 Have blood establishments already been inspected?	No
5.2.1 If yes, How many regular inspections were done in 2008?	
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Authorities of Ministry of Health
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	Yes
5.4.1 If yes, Please describe	Authorities of Ministry of Health of Turkey inspects Turkish Red Crescent
5.4.2 If no, Please provide comments	
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Due to new legislation is just harmonized, these work are taken into consideration by the competent Authorities of Ministry of Health under new arrangements to be enforced future.
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	No
5.6.1 If yes, Please describe	

UNITED KINGDOM	
5.1 Is a system in place for organising inspections and control measures of blood establishments?	Yes
5.1.1 If yes, Please describe	Blood establishments and fixed collection sites are inspected by the MHRA on a rolling 2 year cycle. Interim 'for cause' inspections may be carried out if required. Mobile collection sites are inspected on a sampling basis during the 2 yearly inspection of the controlling blood establishment.
5.2 Have blood establishments already been inspected?	Yes
5.2.1 If yes, How many regular inspections were done in 2008?	4
5.2.2 If yes, How many inspections were done following serious adverse events or reactions or a suspicion thereof in 2008?	None for blood establishments
5.3 What type of officials carry out inspections? (Art. 8.3 Directive 2002/98/EC)	Pharmaceutical GMP inspectors, with specialist training in blood inspections.
5.4 Is the authority/service granting the authorisation different from the authority/service inspecting the blood establishment?	No
5.4.1 If yes, Please describe	
5.4.2 If no, Please provide comments	MHRA conducts inspections and grants authorisations
5.5 Is a system in place for inspecting Hospital Blood Banks?	Yes
5.5.1 If yes, Please describe	Hospital blood banks are required to submit to the competent authority an annual report of their compliance with the relevant provisions of the Directives. These reports are risk assessed and when necessary, the competent authority will carry out inspections to assess the compliance status of hospital blood banks
5.5.2 If no, Please describe	
5.6 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example tissues, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	Yes
5.6.1 If yes, Please describe	GMP inspectors inspect sites manufacturing medicinal products as well as blood establishments and hospital blood banks

6. DONORS ELIGIBILITY CRITERIA

AUSTRIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Federal Blood Safety Act (1999 by the Blutsicherheitsgesetz) and Ordinance for Donor Testing and Release criteria (Blutspenderverordnung = Blood donor ordinance) Rational: The ordinance includes heterosexuals and homosexuals with frequent change of partners and sexual practices which may lead to breaching the skin and/or mucosa barrier enhancing the contamination with sexually transmittable infectious agents.
BELGIUM	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes

6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Law of July 5, 1994 concerning blood and blood derivatives of human origin (art. 14): Before every donation an information folder about AIDS must be given systematically to the donor. This folder must state what risk behaviour is. The examining doctor must assure oneself that the notion of risk behaviour was well understood. The doctor must ask clear questions that will enable him/her to defer donors with such behaviour. Furthermore the donor must have the possibility to ask that the collected product would not be used
BULGARIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	No
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
CROATIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	You cannot donate blood if you:
CYPRUS	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Guidelines of October 1985: permanent deferral of donors who had experienced MSM
CZECH REPUBLIC	

6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Resolution CM(Res (2008)5 of the Council of Europe is taken as a basis: - men having sex with another men - sex for money or drug (incl. sex workers and their clients) both based on actualised epidemiological data on HIV / HBV / HCV
DENMARK	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Donor has to sign that (s)he has read and understood a leaflet published by the National Board of Health (http://www.sst.dk/publ/Publ2006/KOT/Transfusion/blodpjece.pdf). In this leaflet the following is stated: Important announcement to all blood donors concerning viral infection from bloodMust be read prior to donation of bloodYou cannot donate blood if you:- suspect that you might be infected with HIV or hepatitisOr if, within the last 6 months, you:- have had sexual contact with someone who has been exposed to infection in any of the ways described in this leaflet- have had sexual intercourse with someone who is infected with HIV or carries hepatitis- have had sexual intercourse with someone from geographical areas in which HIV or hepatitis B occurs widely in the population. This includes Asia, South and Central America and the whole of Africa- have been pierced or tattooedYou cannot donate blood if, at some point in your life, you:- as a man, have had sexual contact with another man- are or have been a prostitute- use or have used intravenous drugs- share or have shared a syringe with others- have been treated for haemophilia before 1988
FINLAND	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes

6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
FRANCE	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Arrêté publié le 18/01/2009 - Rapport(s) sexuel(s) non protégé(s) avec un partenaire occasionnel Contre-Indication (CI) de quatre mois après le dernier rapport sexuel non protégé - Multi partenariat sexuel : plus d'un partenaire dans les quatre derniers mois CI de quatre mois après la fin de la situation de multi partenariat - Homme ayant eu des rapports sexuels avec un homme CI permanente - Rapports sexuels non protégés avec un nouveau partenaire depuis moins de deux mois CI de quatre mois après le dernier rapport sexuel non protégé
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
GERMANY	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Rational: epidemiological data from GermanyPermanent deferral of persons at risk for acquiring HIV-infection and other infectious diseases by contact is part of the national transfusion guideline at least since its 1985 edition. Permanent deferral of persons with increased risk for acquiring HIV-, HCV- or HBV- infections are explicitly listed as "homo- and bisexual men, intravenous drug dependents, prostitutes" first time in the 1996 edition of the national transfusion guideline.

GREECE	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
HUNGARY	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	#NAME?
IRELAND	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	No
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
ICELAND	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Or if, within the last 6 months, you:
ITALY	

6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	#NAME?
LIECHTENSTEIN	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	#NAME?
LITHUANIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	- have had sexual intercourse with someone from geographical areas in which HIV or hepatitis B occurs widely in the population. This includes Asia, South and Central America and the whole of Africa
LATVIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
LUXEMBOURG	

6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	#NAME?
MALTA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	You cannot donate blood if, at some point in your life, you:
THE NETHERLANDS	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	- as a man, have had sexual contact with another man
NORWAY	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	national guideline and questionnaire used by all blood establishments, adopted 11/2006. MSM, women having sex with MSM, prostitutes and persons having sex with prostitutes are all excluded
POLAND	

6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	#NAME?
PORTUGAL	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	#NAME?
ROMANIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	- have been treated for haemophilia before 1988
SLOVAKIA	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	No
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
SLOVENIA	

6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	The rules on criteria for blood donors are laid down in national legislation. It is obligatory to ask blood donors about their sexual behaviours and to test every blood unit. National rules are: - Pravilnik o obveznem testiranju krvi in component krvi (Official gazette of RS, No. 9/07). - Pravilnik o strokovno medicinskih pogojih za odvzem krvi (Official gazette of RS, No. 9/07).
SPAIN	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Important announcement to all blood donors concerning viral infection from blood
SWEDEN	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	Detailed regulations, according to directive, adopted December 2006.
SWITZERLAND	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes

6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	The criteria are defined by the Blood Transfusion Service of the Swiss red cross (BTS SRC), based on legal requirements (Law on therapeutic products, (LTP) Ordinance on establishment licenses) and on the (legally binding) Recommendations of the Council of Europe (Guide to the preparation, use and quality assurance of blood components).
TURKEY	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	No
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	
UNITED KINGDOM	
6.1 Are there national guidelines for the assessment of at risk sexual behaviours? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.2.2 of Directive 2004/33/EC)	Yes
6.1.1 If yes, Please describe (including dates of adoption/review(s) and rational)	The Guidelines for the Blood Transfusion Services in the UK - 7th Edition October 2005 - as amended ("The Red Book") Long-standing requirement (excerpt from UK donor selection guidelines below). Obligatory Information must be provided so that those at risk do not donate. The Department of Health Blood Safety Entry on donor self-exclusion must be understood. It states: You must not donate if: you think you need a test for HIV/AIDS, HTLV or hepatitis You must never donate if: you are HIV positive you are HTLV positive you are a hepatitis B carrier you are a hepatitis C carrier you are a man who has ever had oral or anal sex with another man, even if you used a condom or other protective you have ever received money or drugs for sex you have ever injected, or been injected with, drugs; even a long time ago or only once. This includes body-building drugs. You may be able to give if a doctor prescribed the drugs. Please ask. You must not donate for at least 12 months after sex (even if you used a condom or other protective) with: a partner who is, or you think may be: HIV or HTLV positive; a hepatitis B carrier; a hepatitis C carrier. (If you are a woman): a man who has ever had oral or anal sex with another man, even if they used a condom or other protective. a partner who has ever received money or drugs for sex. a partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes body-building drugs. You may be able to give if a doctor prescribed the drugs. Please ask. a partner who has, or you think may have been, sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa.

7. VIGILANCE - SERIOUS ADVERSE EVENTS AND REACTIONS

AUSTRIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	yes
7.1.1 Please give a short description of the system	The reporting of serious events and reactions is mandatory.A 24 hours service of the Vergiftungszentrale (Emergency Centre of Poisoning) run by the Federal Institute for Health Care (ÖBIG/GÖG) is established since 2003 where doctors can report and receive help in emergency events by specialists of transfusion medicine. The reports are based on a score card to allow the doctors to classify the reports in the hospital. Giving a score of 6 the event has to be reported via the hospital blood bank. The reports are graded into immediate reports and annual reports. Reporting is performed with defined standard forms (downloads from the BASG Homepage) issued by Federal Office for Safety in Health Care (BASG). The reports are collected in the AGES PharmMed Institute "Inspection" and immediate actions are taken via a rapid alert letter to the regional health care offices if indicated. The annual data for the report to DG SANCO will be cumulated by AGES PharmMed and reported by the Federal Office for Safety in Health Care (BASG).
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	yes
7.2.1 If yes, Please describe	defined standard form by Federal Office for Safety in Health Care; further adaptation through EUSTITE vigilance arm
7.3 Is there a link with the national/European pharmacovigilance system?	yes
7.3.1 If yes, Please describe	AGES PharmMed is also operatively active in collection and handling of pharmacovigilance issues. Recalls are authorised by Federal Office for Safety in Health Care
7.4 Is there a link with a national vigilance system for medical devices?	yes
7.4.1 If yes, Please describe	a medical device registry is in place

7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	yes
7.5.1 If yes, Please describe	Early warning system is in place in the Federal Ministry of Health. Early warnings related to blood product's transmittable agents are forwarded to a responsible person in the Federal Ministry of Health
BELGIUM	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Standard notification forms (electronic transmission) and instructions were distributed. Contact persons, responsible for reporting, were appointed by hospitals and blood establishments. Notifications to the Belgian haemovigilance centre started in November 2005. To ensure confidentiality, names of patient, donor or staff involved must remain disclosed. Reportable incidents include serious adverse reactions during or after transfusion, incorrect blood components transfused and near misses, and in blood establishments serious donor complications and serious events covering the chain from donation to distribution.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	Notifications that concern the national biovigilance system are systematically forwarded to that system and vice versa.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	Notifications that concern the national pharmacovigilance system are systematically forwarded to that system and vice versa. Link with the European pharmacovigilance system through the national system.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	Notifications that concern the national vigilance system for medical devices (including medical devices for in vitro diagnostic use) are systematically forwarded to that system and vice versa.

7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	A link with the national contact person for the EWRS was established.
BULGARIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	No
7.1.1 Please give a short description of the system	
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	Unfortunately, I am not in charge of this, so I could not give you any details about it.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	We are working together with the department for medical devices.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	National vigilance system for communicable diseases has a website and they make public all the information about it and at the same time they send us the information.
CROATIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	There is a obligation to report SAE and SAR to HBB, HBB report to CITM, and CITM report to MoHSW
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No

7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	There is a obligation of reporting communicable diseases to Croatian institute for public health
CYPRUS	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	No
7.1.1 Please give a short description of the system	
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	Close contact is established with the section of the Public Health Services of the Department of Medical and Public Health Services, of the Ministry of Health. Their scope is the adoption of preventive measures in a wide spectrum of the Environmental Health sector.
CZECH REPUBLIC	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Serious adverse events and reactions are reported to SUKL in a manner compatible with EU Commission Directive 2005/61/EC (rapid notification – analyses, corrective measures – confirmation notification – annual report).

7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	The competency is delegated to the State Institute for Drug Control, who is responsible for system of vigilance for human blood and blood components an also for human tissues and cells. Both systems are operated separately.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	The competency is delegated to the State Institute for Drug Control, who is responsible for system of vigilance for human blood and blood components an also for human tissues and cells. Both systems are operated separately.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	The competency is delegated to the State Institute for Drug Control, who is responsible for system of vigilance for human blood and blood components an also for human tissues and cells. Both systems are operated separately.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	Different competent authority is responsible for this system - major public health officer within MoH. The head of this authority can influence regulation of blood and blood components in case of the risk. Moreover any case of HIV, HBV, HCV is investigated for possible post-transfusion origin in cooperation of BTS / SUKL and public health service
DENMARK	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	In accordance with Executive Orders formats are available from our web site www.dkma.dk (in Danish only). The formats are in accordance with the Directives.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes

7.2.1 If yes, Please describe	Yes, for tissues and cells. Formats are available from our website www.dkma.dk (in Danish only). The formats are in accordance with the Directives.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	The Danish Medicines Agency receive reports on serious adverse events seen in recipients of blood or/blood components. The DKMA will on a yearly basis submit to the Commission an annual report on the notification of serious adverse events and reactions received. Besides this the DKMA will, when considered safety relevant, immediately report information on serious adverse events to other countries
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	The manufacturer or his authorised representative shall notify the National Competent authority about any adverse events/serious incident and/or field safety corrective actions on the market when the reporting criteria are met (MEDDEV 2.12-1 rev 5). The manufacturers are recommended to use the report forms stated in Annex 3 and Annex 4 in the section 10 of EU Commission's Guidelines on a medical devices vigilance system MEDDEV 2.12-1 rev 5. These report forms can also be found on our website http://www.medicaldevices.dk/1024/visArtikel.uk.mu.asp?artikelID=3889 The Danish medicines Agency also obliges professional users and other healthcare professionals to report adverse incidents. They can also report via our website http://www.medicinskudstyr.dk/1024/visArtikelBred.mu.asp?artikelID=12647 . There is no legal requirement within the directive obliging users to report incidents. However, user reporting is vital for the vigilance system to operate successfully.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	Department of Epidemiology, The State Serum Institute, is the Danish contact for Epidemic And Pandemic Alert and Response (EPR), i.e. the IHR (2005) and communicates information to and from the WHO system. DKMA will be informed by SSI of all cases involving blood, tissues and cells.
FINLAND	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	According to the Blood Service Act (197/2005) blood establishments and health care units have to keep register of all adverse events and reactions related the quality and safety of human blood and blood components. Health care units have to notify the serious events and reactions to the blood establishment. Blood establishment has to notify these serious events and reactions to the competent authority in accordance with the procedure and notification format referred in the Blood Directives and national legislation (Decree 258/2006).
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	NAM oversees also the safety and quality of human tissues and cells. Same inspectors are responsible for haemovigilance and tissue vigilance systems.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	NAM oversees also the pharmacovigilance; close cooperation between these vigilance systems.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	NAM oversees also the national vigilance system for medical devices; close cooperation between these vigilance systems.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
FRANCE	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	The French system of haemovigilance was set up since : - January 24, 1994 to collect, supervise and evaluate all the adverse reactions occurring at the patients, - May 7, 2007 to collect, supervise and evaluate the serious adverse reactions occurring at the blood and blood components donors, - May 7, 2007 to collect, supervise and evaluate the serious adverse events related to the collection, testing, processing, storage, distribution/issuing and transfusion of blood and blood components. - 2007 installation of the National Haemovigilance Committee - Commission Nationale d'Hémovigilance (CNH) - and its working parties - composed of external scientific experts. They participate in the evaluation process conducted by the Afssaps The French haemovigilance system is organised by the Afssaps in a network integrating different levels: national levels (haemovigilance service of the French national blood establishment, haemovigilance service of the Army blood center, national haemovigilance committee), regional levels (regional coordinators) and local levels (correspondents of hospitals and blood establishments). The epidemiological follow-up of blood donors is carried out by the French institute for public health surveillance. Each reporting establishment (hospital and/or blood establishment) notifies the Afssaps its adverse reactions, occurring at the patients, directly on a secure online reporting system (e-FIT). For the serious adverse reactions occurring at the blood and blood components donors, and the serious adverse events related to the transfusion chain, the reporting system is currently non electronic. However, the Afssaps projects a rapid integration, of the reporting of these events and reactions, on its e-FIT system. Also, the Afssaps coordinates vigilance activities relating to different health products. There is a link between French haemovigilance system and the European Haemovigilance Network (EHN)
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	There is a link between the haemovigilance and the biovigilance systems, but only at the national level
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	There is a link between the haemovigilance and the pharmacovigilance systems, but only at the national level.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	There is a link between the haemovigilance and the medical devices (used during collection, testing, processing of blood and blood components) vigilance systems at the national level and in co-operation with the European Haemovigilance Network (EHN)

7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	There is a rapport form by the Bureau of Medicines for every adverse effect of a medicine or biologics
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	Ministry of Health
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	
GERMANY	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Blood establishments as marketing authorization holders of blood components are legally obligated to notify any suspicion of SAE and SAR with a possible impact on quality and safety of the blood component to the PEI within 15 days. In case of blood components without marketing authorization like autologous blood establishments have to notify to the regional GMP inspection services (Medicinal Products Act Art. 63c). Physicians are legally obligated to notify without delay any suspicion of a transfusion transmitted SAR to the PEI and to the blood establishment (German Transfusion Act Art. 16 para. 2).
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes

7.2.1 If yes, Please describe	PEI is the competent authority for haemovigilance as well as tissue vigilance
7.3 Is there a link with the national/European pharmacovigilance system?	
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	•Haemovigilance (as described in 2005/61/EC) is part of the German Pharmacovigilance system. There is, however, no link to the European pharmacovigilance system.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	The Robert Koch-Institut, another independent higher federal higher authority, is responsible for vigilance for communicable diseases and other threats to health and collects data on donor epidemiology. The data are annually published in a cumulated form. There is cooperation with PEI in cases of threats and risks.
GREECE	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	It is planned in the context of SKAE - HCDCP activities for the implementation of a biovigilance system.
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	SKAE of HCDCP notifies to EOF adverse events which may affect quality and safety of blood components due to a deviation in materials and equipment.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes

7.5.1 If yes, Please describe	SKAE is cooperating with HCDCP offices for HIV, Hepatitis, malaria, epidemiological surveillance for communicable diseases and other infectious threats.
HUNGARY	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	EACH OF SERIOUS ADVERSE EVENTS IS COLLECTED IN THE BLOOD ESTABLISHMENT, THE TRANSFUSION EXPERTS HAVE TO FOLLOW UP THE TREATMENT OF THE PATIENT. EVERY YEAR THE HUNGARIAN NATIONAL BLOOD TRANSFUSION SERVICE COLLECT THE REPORTS IN THE WHOLE COUNTRY, THEN ANALYZING, AND SENDING TO THE HEALTH MINISTRY AND THE NATIONAL HEALTH OFFICE AND THE SANCO, EU COUNCIL AS WELL.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	NOW IT IS REORGANIZED BY THE HEALTH MINISTRY AND THE INSTITUTE FOR HEALTH CARE QUALITY IMPROVEMENT AND HOSPITAL ENGINEERING.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	HUNGARIAN NATIONAL BLOOD TRANSFUSION SERVICE (HNBTS) SENDS THE DATA TO THE NATIONAL INSTITUTE OF PHARMACY.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	HNBTS COLLABORATE WITH THE NATIONAL CENTRE OF EPIDEMIOLOGY, e.g. ON A RAPID ALARM SYSTEM
IRELAND	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	The National Haemovigilance Office is responsible for collecting and collating serious adverse events and reactions. The NHO provide this information on a monthly and quarterly basis to the Irish Medicines Board as Competent Authority.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
ICELAND	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	
7.5.1 If yes, Please describe	

ITALY	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	The national haemovigilance system has been created fully complying with the Directive 2005/61/EC; it is being implemented within the national blood information system instituted by the national blood law of 21st Oct 2005.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	A link is envisaged for vigilance on plasma products.
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
LIECHTENSTEIN	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	There is a legal obligation for every blood establishment to nominate a Haemovigilance responsible person who is responsible for the mandatory reporting of adverse events.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	Yes

7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	
LITHUANIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	According to the order of the Ministry of Health, blood establishments and hospitals have to notify to the competent authority serious adverse events and serious adverse reactions related to the collection, testing, processing, storage and distribution of blood and blood components
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
LATVIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	The system for reporting of serious events and serious reactions in place. Blood establishments have recalling procedures in place to notify Hospital Blood Banks about blood components, which may influence the quality and safety. Have procedures in place to communicate Hospital Blood Banks to the Competent Authority without delay all relevant available information about serious adverse events and serious adverse reactions. Have procedures in place to the Competent Authority to analyse and ensure outcome.

7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	Have a procedure of unite supervision system in Latvia.
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	Have a procedure of unite supervision system in Latvia.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
LUXEMBOURG	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	the establishment has to notify a serious event or serious reaction to the competent authority
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
MALTA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	Any adverse reaction is reported to a Haemovigilance Unit within the Department for Health Care Services Standards within the Ministry for Social Policy and a root cause analysis is carried out.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	Vigilance on tissues and cells is done by the same Unit as Haemovigilance.
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	The Haemovigilance Unit is linked directly to the rapid alert system for Medical Devices.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	The above mentioned haemovigilance Unit has direct links with the Communicable Disease Unit within the Department for Health Promotion and Disease Prevention, within the same Public Health Regulation Division.
THE NETHERLANDS	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Hospitals and the Blood Establishment are obliged to report serious adverse events and serious adverse reactions to the competent authority (CA) and on a voluntarily basis to an independent foundation "TRIP" (Transfusion reactions in patients). TRIP is responsible for haemovigilance. The CA cooperates cordially with this organisation and has above that its own database mainly to trace quickly donor-related products. TRIP participates in the European Haemovigilance Network.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	

7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
NORWAY	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	The system is operated by the Norwegian Knowledge Centre for the Health Services which is organised under the Norwegian Directorate of Health
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
POLAND	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	All serious adverse events and serious adverse reactions have to be reported to the Institute of Haematology and Blood Transfusion in Warsaw.

7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	All blood establishments authorised by the Main Pharmaceutical Inspector underlay pharmaceutical law and have to report all serious adverse events and reactions to the pharmaceutical inspector.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	All adverse reactions and all adverse events have to be reported to the registry body for medical materials and medical devices if there is a proof or suspicion that their malfunction or incompliance with the specification may be attributable with the event.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	All cases of diagnosed hepatitis B, C, AIDS, Syphilis and all positive laboratory tests for HIV and Syphilis have to be reported to the local body responsible for the communicable diseases.
PORTUGAL	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	The system is a national on-line registry. This registry includes all transfusions reactions. Next month the registry will include a "near miss". The national registry of blood donors reactions will be available
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No

7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
ROMANIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Minister's of Health Order 1228/2006 sets up regulation on haemovigilance, traceability and reporting of adverse reactions/events. The structure is drawn up and responsibilities for each level of the network (local, county, regional and national) listed. In practice, the system is not yet functional.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	It is not asked by the current legislation, but in practice every event is controlled by the Sanitary State Inspection.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	NO information or requirement on this topic has been introduced in the above mentioned order. In practice, all the information are requested or transmitted to the competent structures from the ministry's directorate (Public Health Authority, Pharmaceutical Directorate, Sanitary State Inspection).
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	NO information or requirement on this topic has been introduced in the above mentioned order. In practice, all the information are requested or transmitted to the competent structures from the ministry's directorate (Public Health Authority, Pharmaceutical Directorate, Sanitary State Inspection).
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes

7.5.1 If yes, Please describe	No information or requirement on this topic has been introduced in the above mentioned order. If it is the case, according to other regulation, MOH – Public Health Authority will sent relevant information to the National Institute of Transfusion Haematology; the Institute will disseminate the information to the BEs. In parallel, County Public Health Authorities receive the information from the national office and distribute it to the medical institutions interested, BEs included.
SLOVAKIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Transfusion stations have obligation in our national legislation reporting of serious adverse events and serious adverse reactions to State Institute for Drug control.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
SLOVENIA	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	All data are submitted to Blood Transfusion Centre of Slovenia by blood transfusion establishments on data collecting sheets. All SAE/SAR are notified to CA. If it is necessary, CA takes preventive or other necessary measures. The national legislation on haemovigilance is described in: Pravilnik o hemovigilanci (Official gazette of RS, No. 9/07).
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
SPAIN	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	A Haemovigilance Unit depending on the Public Health Directorate (Ministry of Health and Consumer Affairs) was set up in 2007 year. All the 17 regions have set their own haemovigilance systems up. There is one coordinator in every region responsible of the picking up of the adverse events and reactions reported by the blood establishments and hospital blood banks. The data are sent to the Unit of Haemovigilance which publish a national report and send the annual report to the Commission
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No

7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	The “Coordinating centre for health alerts and emergencies” (CCAES), reports to the Haemovigilance Unit all relevant information about blood they receive.
SWEDEN	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Person responsible for the blood establishment have an obligation to report every serious adverse events and serious adverse reaction to the board on a special form, according to the directive.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	Pharmacovigilance is performed according to VOLUME 9A of The Rules Governing Medicinal Products in the European Union.
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	According to VOLUME 9A of The Rules Governing Medicinal Products in the European Union.
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	The unit for Communicable Disease Prevention and Control within the board is responsible for these issues.
SWITZERLAND	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	Every Blood Establishment and Hospital Blood bank, and every Health care Establishment (Hospitals, nursing homes etc.) that collects/manufactures and/or applies blood components is legally (Ordinance on medicines) obliged to denominate a Haemovigilance-Representative who complies with the mandatory reporting of adverse events.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	The national vigilance system for human tissues and cells is about to be established and will be run by the same authority (Swissmedic) as the Haemovigilance system, although probably by a different division because it will be linked to the Advanced Therapy medicinal products (which are derived from tissues and cells). So far, there is no legal requirement for a vigilance system just for tissues and cells. The vigilance system for organs is a separate system and data is collected by the FOPH.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	The Vigilance Unit (in the Division Safety of Medicines, Sector Market Surveillance of Swissmedic) is responsible for the Pharmaco-, Haemo- and Veterinary-Vigilance and relevant data and information are shared systematically
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	The Division Medical Devices (Sector Market Surveillance of Swissmedic) is responsible for the Materiovigilance and relevant information is exchanged between the two divisions
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes

7.5.1 If yes, Please describe	The FOPH has given a mandate to a laboratory of the blood transfusion service of the Swiss red cross to act as a reference laboratory for infectious disease markers. This laboratory performs confirmatory testing for all blood donations collected in Switzerland. The reference laboratory reports data on numbers of donations and test results systematically to the FOPH. This information and other information on communicable diseases and other threats to health related to blood are regularly exchanged between the Swiss Federal Office for Public Health and Swissmedic.
TURKEY	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes
7.1.1 Please give a short description of the system	Committees of hospital transfusion reports to Ministry of Health regularly.
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	No
7.2.1 If yes, Please describe	
7.3 Is there a link with the national/European pharmacovigilance system?	No
7.3.1 If yes, Please describe	
7.4 Is there a link with a national vigilance system for medical devices?	No
7.4.1 If yes, Please describe	
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	No
7.5.1 If yes, Please describe	
UNITED KINGDOM	
7.1 Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes

7.1.1 Please give a short description of the system	"SABRE" is an online system, accessible through the MHRA website. Reporters are provided with a confidential online workspace from which they can draft, save, edit and submit notifications and confirmations of SAEs and SARs. The online report form meets all the data requirements of the Directive. Reporters may attach supporting documents and images to their online report. The MHRA database associated with this system facilitates production of annual summary reports from reporters as well as the annual summary report to the Commission
7.2 Is there a link with a national vigilance system for human tissues, cells and organs?	Yes
7.2.1 If yes, Please describe	When necessary, the MHRA will liaise with with the UK competent authorities (HTA/HFEA) that operate the system.
7.3 Is there a link with the national/European pharmacovigilance system?	Yes
7.3.1 If yes, Please describe	The MHRA is also the UK competent authority for medicinal products
7.4 Is there a link with a national vigilance system for medical devices?	Yes
7.4.1 If yes, Please describe	The MHRA is also the UK competent authority for medical devices
7.5 Is there a link with a national vigilance system for communicable diseases and other threats to health?	Yes
7.5.1 If yes, Please describe	When necessary, the MHRA will liaise with the UK Health Protection Agency (HPA)

8. TESTING REQUIREMENTS

AUSTRIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	no
HBs ag	yes
NAT HBV	no
Anti HCV	yes
NAT HCV	yes
Anti HIV-1/2	yes
Ag HIV	no
NAT HIV 1	yes
Treponema Pallidum	yes
HTLV	no
8.2 Are any other laboratory tests required?	yes
8.2.1 If yes, Please specify	non specific immunactivating marker (e.g. neopterin)
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Pathogen inactivation of fresh frozen plasma is mandatory. But also quarantine plasma may be produced. SD treated FFP is on the market as a medicinal product with a marketing authorisation. Pathogen inactivation of platelet concentrates is not mandatory.

BELGIUM	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	

Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	anti-HBc for new donors and on indication
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Pathogen inactivation of fresh frozen plasma is mandatory. Methylene blue method is used by blood establishments and SD treated FFP is on the market as a medicinal product. The psoralene method and riboflavin method can also be used. Pathogen inactivation of platelet concentrates is not mandatory. The psoralene method was used in 2008 for the treatment of +/- 15 % of the platelet concentrates.
BULGARIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	No

Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
CROATIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	
HBs ag	Yes
NAT HBV	
Anti HCV	Yes
NAT HCV	
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	
Treponema Pallidum	Yes
HTLV	
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	HCV Ag
8.3 Please provide any other comment on the testing requirements.	confirmatory testing of HCV,HBV,HIV in CITM
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
CYPRUS	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No

HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	CMV for immunosupressed patients
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
CZECH REPUBLIC	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	

8.3 Please provide any other comment on the testing requirements.	Other testing than infectious disease markers are not mentioned in this section
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	No, but plasma for clinical use is kept in quarantine until the donor is retested after 6 month gap
DENMARK	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	No
HTLV	Yes (Only for first time donors and donors, who travelled in endemic areas)
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	None
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
FINLAND	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	Yes

Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	Yes
Treponema Pallidum	No
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	According to the epidemiological situation extra testing may be required.
8.3 Please provide any other comment on the testing requirements.	Also NAT B19, NAT HAV and cardiolipine antibodies are tested systematically.
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
FRANCE	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	Yes

8.2.1 If yes, Please specify	NAT HBV* In some French areas with particular epidemiologic situations (French overseas departments) Detection of Malaria infectious markers If necessary (individuals who have lived a malarial area or with history of undiagnosed febrile illness, visitors to endemic area …)
8.3 Please provide any other comment on the testing requirements.	Additional laboratory tests. 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 and/or the particular epidemiologic situations
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Several systems of treatment for inactivation of pathogen agents in blood and blood components are used in France (2 for the treatment of platelets including one used only in clinical trials, 3 for the treatment of plasma, none for the treatment of red cells): -Amotosalen with exposure to the UVA light, used for the treatment of platelets (platelets apheresis leucocyte-depleted and platelets recovered pooled leucocyte-depleted), -Solvent-detergent, used only for the viral inactivation of plasma (fresh-frozen plasma, leucocyte-depleted, collected by apheresis), -Methylen blue with exposure to the visible light, used only for the viral inactivation of plasma (fresh-frozen plasma, leucocyte-depleted, collected by apheresis), -Amotosalen with exposure to the UVA light, used for the treatment of plasma (fresh-frozen plasma, leucocyte-depleted, collected by apheresis). Riboflavin with exposure to the UV light, used for the treatment of platelets (platelets apheresis leucocyte-depleted and platelets recovered pooled leucocyte-depleted), currently used only in clinical trials.
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No

NAT HIV 1	
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
GERMANY	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Amotosalen/light treatment of pooled platelets and platelets from apheresisethylen Blue/light treatment of plasmaSD inactivation of pooled plasma
GREECE	

8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	Yes
Treponema Pallidum	No
HTLV	Yes
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	Anti-HBC and Treponema Pallidum testing is performed when required. For the screening of infectious markers the national guidelines are based on the "Guide to the preparation, use and quality assurance of blood components" 14th Edition EDQM, Council of Europe 2008.
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Pathogen inactivation is performed for the 9-11% of fresh frozen plasma by a Methylene Blue (MB) system in single donations.
HUNGARY	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes

Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	PCR TECHNIQUES ARE USED IN THE CONFIRMATORY PROCESS, BECOUSE THE HNBTS CAN NOT AFFORED USING THIS METHOD FOR SCREENING OF THE DIFFERENT AGENTS.
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
IRELAND	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	No
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	

8.3 Please provide any other comment on the testing requirements.	Anti-HBs ag, Anti-HCV and Anti HIV 1/2 are the minimum tests as required by our National Legislation. Our largest blood establishment, the main supplier of allogeneic blood, also performs NAT Testing (HCV and HIV 1/2) on all blood components.
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
ICELAND	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	No
HTLV	No
8.2 Are any other laboratory tests required?	
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	If need arises samples are sent to Denmark for NAT HBV; Ag HIV; NAT HIV 1 or HTLV testing
8.4 Are pathogen reduction/inactivation techniques used?	
8.4.1 If yes, Please describe the processes used and the blood components concerned	
ITALY	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	

Anti HBc	No
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Pathogen reduction/inactivation techniques are not mandatory. Plasma: a) methylene blue (in house/industrial); b) S/D (pharmaceutical): commercially available (Octoplas) and contract manufacturing treatment of national plasma (Plasmasafe) Platelets: a) psoralen-UV (in house); b) riboflavin-UV (in house).
LIECHTENSTEIN	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes

Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	ALT
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
LITHUANIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
LATVIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	

Anti HBc	No
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
LUXEMBOURG	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	Yes
Treponema Pallidum	
HTLV	Yes
8.2 Are any other laboratory tests required?	Yes

8.2.1 If yes, Please specify	VDRL
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
MALTA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	Tests are required for:- Haemoglobin - Liver function tests- Anti-CMV / Parvovirus (on request).
8.3 Please provide any other comment on the testing requirements.	Testing is carried out in accordance with the Council of Europe Guidelines.
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
THE NETHERLANDS	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes

NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	Parvo B19 for selected donations and bacterial culture for all platelets.
8.3 Please provide any other comment on the testing requirements.	First time donors are tested the first visit to the blood bank before they are allowed to give blood for transfusion.
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Quarantine (donor retested) for plasma for transfusion and there are inactivation techniques for plasma for fractionation.
NORWAY	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes, on first donation and if more than 6 months since last donation
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes, on first donation
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	

8.3 Please provide any other comment on the testing requirements.	Anti HBc and Treponema Pallidum only for new donors/ before first donation
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Done at a few establishments for platelets
POLAND	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	ALT
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Quarantine. Pathogen inactivation techniques are not required. They are under validation in some blood establishments.
PORTUGAL	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes

NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	Additional tests are required for specific clinical situations (ex blood donors coming from endemic paludism regions)
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
ROMANIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	ALT; HIV testing is performed using AG/Antibody anti HIV combined kits.
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No

8.4.1 If yes, Please describe the processes used and the blood components concerned	
SLOVAKIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	Yes
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	/
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
SLOVENIA	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes

Ag HIV	Yes
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	NAT, anti HIV1/2/0 and p24Ag, HIV RNA , HCV RNA , HBV DNA are obligatory.
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	No
8.4.1 If yes, Please describe the processes used and the blood components concerned	
SPAIN	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	Yes
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	T.CRUZI
8.3 Please provide any other comment on the testing requirements.	
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Plasma (PFC): Plasma quarantined for transfusion 34%. Virus inactivated plasma for transfusion (Methylene Blue) 66%.
SWEDEN	

8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	Yes
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	Haemoglobin
8.3 Please provide any other comment on the testing requirements.	Anti HBc, Treponema Pallidum and HTLV is only required for first time donors.
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	A few establishments use psoralene for platelets and plasma.
SWITZERLAND	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	Yes

Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	ALAT (Alanine Amino Transferase)
8.3 Please provide any other comment on the testing requirements.	HIV-Ag Detection is performed for approx. 90 % of the blood donations in Switzerland on a voluntary basis because most screening laboratories use a HIV Ag/Ab-Combination-Assay. NAT HBV is performed on approx. 70% of the blood donations in Switzerland on a voluntary basis.
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Pathogen reduction/inactivation techniques need to be licensed by Swissmedic. Currently, there is one technique licensed (The "Theraflex"-System for Plasma), but it is not in use in blood establishments in Switzerland on a regular basis. Furthermore, SD-treated plasma is licensed as a medicinal product and is distributed in Switzerland.
TURKEY	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	No
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	No
8.2 Are any other laboratory tests required?	No
8.2.1 If yes, Please specify	
8.3 Please provide any other comment on the testing requirements.	

8.4 Are pathogen reduction/inactivation techniques used?	
8.4.1 If yes, Please describe the processes used and the blood components concerned	
UNITED KINGDOM	
8.1 Please specify the laboratory tests required in your country as minimum requirements.	
Anti HBc	No
HBs ag	Yes
NAT HBV	No
Anti HCV	Yes
NAT HCV	Yes
Anti HIV-1/2	Yes
Ag HIV	No
NAT HIV 1	No
Treponema Pallidum	Yes
HTLV	Yes
8.2 Are any other laboratory tests required?	Yes
8.2.1 If yes, Please specify	Not for mandatory donor screening. Certain additional tests may be performed, depending on need, e.g. anti-CMV testing
8.3 Please provide any other comment on the testing requirements.	NAT for HIV1 & 2 is performed, but is not a national mandatory requirement
8.4 Are pathogen reduction/inactivation techniques used?	Yes
8.4.1 If yes, Please describe the processes used and the blood components concerned	Methylene blue and UV light treatment of fresh frozen plasma obtained from outside the EU e.g the USA

9. IMPORTS AND EXPORTS OF BLOOD AND BLOOD COMPONENTS

AUSTRIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	yes
9.1.1 If yes, Please describe	Arzneiwareneinfuhrgesetz (Medicines Import Act) says that the customs have to require an import certificate from the Federal Agency for Safety in Health Care. The importer has to prove that the blood or plasma did not get in contact with any infectious agents transmittable to humans or animals. This provision is enforced by AGES PharmMed on behalf of Federal Office for Safety in Health Care for human blood and plasma sources and by the Federal Ministry of Health for animal sourced blood and sera
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	yes
9.1.2.1 Please specify	The law does not require inspections in third countries. An ordinance requires a plasma master file for all blood derived products. Verification of equivalence is by evaluation of documents. Plasma sources for blood products holding a central marketing authorisation are inspected within the framework of the plasma master file.
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	no
9.1.3.1 If yes, Please provide this data by the country of origin	n.a.

9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	no
9.2.1 If yes, Please describe	n.a.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	no
9.2.2.1 If yes, Please provide this data by the destination	n.a.
BELGIUM	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Law of July 5, 1994 concerning blood and blood derivatives of human origin: - Importation of blood and blood derivatives: only with due regard for the conditions which are imposed by this law and by the implementation decrees promulgated by the King. - Importation of labile blood derivatives for distribution and use in Belgium is only permitted by establishments which meet the conditions laid down by the King and recognized by the Minister competent for public health. The imported labile blood derivatives must fulfil the in Belgium required conditions, e.g. collected from voluntary and unpaid donors. The recognized establishments importing labile blood derivatives are also responsible to make sure that the foreign establishment disposes of equivalent quality, traceability and notification systems. - Importation of stable blood derivatives (and subsequent storage, distribution and use): the legislation in the country, where the blood or plasma is collected for the production of medicines, imposes guarantees of quality and safety equivalent to the ones laid down in this law with regard to the collection. Furthermore the blood derivatives offer guarantees of quality and safety, especially with regard to their serostatus, equivalent to the ones laid down in this law. Blood derivatives used for the production of medicines that received a marketing authorization based on regulation EC 2309/93 of 22/07/1993 are considered to fulfil the required conditions. The Law on Blood, Blood donation and blood transfusion has articles for the requirements for importation of blood and blood components. The imported blood and blood components shall be collected, tested, stored, and prepared in accordance with the Blood Directives requirements (including traceability and notification systems).
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	

9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	The blood components must fulfil the Belgian requirements.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
BULGARIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Blood and blood components can be imported in the country in case of emergency, disasters and big industrial accidents.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	There has not been imported any unit blood component in Bulgaria. The provisions for import are strict.
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Bulgarian Law on Blood… does not permit any exportation of blood or blood components.

9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
CROATIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	According to our legislation import or export of blood components is not allowed (with possible exception in specific situation)
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements); International standards (JACIE/NETCORD/WMDA)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	There is no blood components imported in Croatia from third countries
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	
CYPRUS	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	As per Article 7 of Directive 2005/61/EC

9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	
9.2.2.1 If yes, Please provide this data by the destination	
CZECH REPUBLIC	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Importer must guarantee the same level of safety
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	No import in 2008

9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Any export to third country and / or delivery to other EU state should be licensed by MoH (acc. to law)
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	blood components: red cells 300 units Afghanistan, 300 units Georgia; plasma 300 units Afghanistan, 300 units Georgia
DENMARK	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Blood Directives apply
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	None is imported
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	EU directives should be followed. In addition for export of blood components for transfusion permission should be given by the donor association in each case if it is not for disaster relief or to a neighbouring country.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes

9.2.2.1 If yes, Please provide this data by the destination	None is exported
FINLAND	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	According to the Blood Service Act (197/2005) blood establishment may import blood or blood components from EU countries. Blood establishment may import blood or blood components from third countries to Finland only if they have licence, given by the National Agency for Medicines, for that imported batch. The imported batch shall comply with the quality, safety and traceability requirements of the Blood Service Act (and Directives).
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	Compliance with quality and safety requirements is assessed case by case.
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
FRANCE	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes

9.1.1 If yes, Please describe	The rules governing the authorisation and control of importations of blood and blood components (for transfusion or fractionation from EU Member States and third countries) were updated by the decree published at the French Official Journal on February 22, 2006.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	To date, the importations, of blood and blood components intended for transfusion, were realised from certain European countries. Only 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
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	No blood component imported in 2008
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	The export of blood and blood components (for transfusion or fractionation to EU Member States and third countries) is carried out by the French national blood establishment which into formless the Afssaps in the form of declaration.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes

9.2.2.1 If yes, Please provide this data by the destination	Non exhaustive data: 55 Red Blood Cells Concentrates and 6 Fresh Frozen Plasmas exported into 2008 to 13 countries (Algeria, Belgium, Canada, Congo, Egypt, Gabon, Germany, Hungary, Ireland, Mali, Nigeria, Senegal, Switzerland)It is difficult, at the date of this questionnaire, to provide exhaustive data on the number of blood components exported in 2008, year which has just finished. Also, the data of export are provided in a global number (the import countries are indicated).
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	under the new law for blood safety
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	International standards (JACIE/NETCORD/WMDA)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	100 units of RBC-SAG exported as aid for Albania
GERMANY	

9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	German Medicinal Products Act § 72
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	In case of blood products verifying the equivalent standards of quality and safety for importation of blood components from third countries has to be done by inspection on location (Medicinal Products Act § 72a)
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	Not for 2008 but for 2007: 0 blood components, 1,136,060 litres plasma for fractionation
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Manufacturing authorisation Cooperation with the third country in the case of no national marketing authorisation (Medicinal Products Act § 73a)
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	Not for 2008 but for 2007: 805 red blood cell concentrates; 7,868 FFP; 1,498,332 litres plasma for fractionation (destination not centralised registered)
GREECE	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes

9.1.1 If yes, Please describe	A small amount (approximately 25000-30000 units) of red cell concentrates is imported annually from "BTS Berne" on the grounds of a contract between the Swiss Blood Centre and the Hellenic Ministry of Health. Blood Transfusion Service Berne Swiss Red Cross Ltd is performing molecular testing with NAT(PCR) for HIV, HCV and HBV in the imported blood units as requested by the Greek Government (Ministry of Health).
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	26000 units of red cell concentrates imported from Switzerland
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
HUNGARY	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	A DECREE OF HEALTH MINISTRY RULES IT AND THE RESPONSIBLE PERSON IS THE DIRECTOR OF THE HUNGARIAN NATIONAL BLOOD TRANSFUSION SERVICE.

9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	WE HAVE NOT GOT IT.
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	THE EXPORT AND IMPORT OF THE BLOOD COMPONENTS ARE CONTROLLED BY THE DIRECTOR OF THE HNBTS AGREEMENT AND THE HEALTH MINISTER SUPERVISES IT.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
IRELAND	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	These requirements are in line with Directive 2002/98/EC.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	This is the responsibility of the Responsible Person at the Blood Establishment. Verification of equivalent standards is performed on each inspection by the Competent Authority.

9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
ICELAND	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	No
9.1.1 If yes, Please describe	
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	

ITALY	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Import of blood and blood components for transfusion must fulfil requirements established for national products. Import plasma for fractionation must fulfil European Pharmacopeia's requirements.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Export of blood and blood components for transfusion must fulfil requirements established for national products. At the moment plasma for fractionation produced at the national level cannot be exported; it is contract manufactured into plasma derived products by a nationally established pharmaceutical company (Kedrion Biopharmaceuticals).
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
LIECHTENSTEIN	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes

9.1.1 If yes, Please describe	
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	The Austrian Red Cross is collecting blood in Liechtenstein according to the Austrian and Liechtenstein legislation and exporting it to Austria. There are exports to Switzerland within the Customs Union treaty. There are no other exports from Liechtenstein.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
LITHUANIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Ministry of Health is entitled to give the authorisation for plasma fractionation to the EU Member State
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)

9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Ministry of Health is entitled to give the authorisation for the export to EU or third countries
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
LATVIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	No
9.1.1 If yes, Please describe	
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	International standards (JACIE/NETCORD/WMDA)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	

9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
LUXEMBOURG	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	by law (loi du 15 mars 1979 art.5)
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
MALTA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes

9.1.1 If yes, Please describe	Blood, blood products and blood components have to satisfy the requirements under the Human Blood and Transplants Act (Cap. 453) and the Blood (Quality and Safety) Regulations (LN272/06). http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_15/Chapt483.pdf http://www.doi.gov.mt/EN/legalnotices/2006/11/LN272.pdf
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	All importation of blood and blood components requires the authorisation of the Licensing Authority and such authorisation is only granted if the product to be imported satisfies EU Quality and Safety Standards.
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
THE NETHERLANDS	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	It is necessary to have a license for import of blood products and blood components from third countries.

9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	There were no blood components for transfusion imported.
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	For the export of all blood components to third countries it is necessary to have a permit from the Minister of Health. For export to EU-members states it is only necessary to have a permit for components for transfusion.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
NORWAY	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Regulation on blood and blood components have same requirements regarding traceability, reporting on adverse events & adverse reactions and quality systems for imported blood.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No

9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Same requirements as for blood used in Norway
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
POLAND	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Minister of Health approval is required for import of blood and blood components.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	0
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	Minister of Health approval is required for export of blood components.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	107 032.5 litres of plasma for fractionation (0 outside EU).
PORTUGAL	

9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	We receive no blood or blood components from EU member States or third countries.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	0
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	0
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	0
ROMANIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Art. 2, Law 282/2005: special authorisation granted by MoH is required.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	

9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	No blood components imported.
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	- Art. 2, Law 282/2005 Special authorisation granted by the MOH is required.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	No blood components exported.
SLOVAKIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	If The transfusion stations want import the blood or blood components for transfusion or fractionation from EU Member States need the authorisation from Ministry of Health.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes

9.2.1 If yes, Please describe	The relus for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries are presented in our national legislation.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
SLOVENIA	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	The blood from third countries must have the same traceability as requested in the national law in the Republic of Slovenia and must be of the same quality.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	NONE
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	It is described in the national low (Official gazette of RS, No. 104/06), exporting of blood is allowed by health minister just in case of humanitarian help to the third countries.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	Yes
9.2.2.1 If yes, Please provide this data by the destination	NONE

SPAIN	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	There is a protocol which must be filled by the import enterprise in. The protocol is reviewed and authorised by the Agencia Española de Medicamentos y Productos Sanitarios. Imports are carried out solely for plasma fractionation
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	There is a protocol which must be filled by the export enterprise in. The protocol is reviewed and authorised by the Agencia Española de Medicamentos y Productos Sanitarios, previous favourable report from the Directorate General for Public Health (Ley del Medicamento, and RD 1088/2005) Export are carried out solely for plasma fractionation
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
SWEDEN	

9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	According to the directive.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	The Medical Products Agency: Yes Significant amounts of plasma used as a source material for medicinal products is imported from USA. The exact number is proprietary.
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	See 9.1.2
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
SWITZERLAND	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	For importation of blood and blood components an establishment license as well as an authorisation for each individual importation of blood or blood components is required. Both licenses are issued by Swissmedic, Sector Licensing, and regular inspections take place.

9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other
9.1.2.1 Please specify	Importation of blood components for transfusion into Switzerland takes place only in very rare situations (e.g. because of a rare blood group) and verification takes place in assessing the request for importation. Importation of plasma for fractionation is linked to the plasma master file requirements and are verified on this basis.
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	Yes
9.1.3.1 If yes, Please provide this data by the country of origin	Data could be collected but is currently not available (see also answer to question 9.1.2).
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	An Establishment license for Exportation is required. The license is issued by Swissmedic, Sector Licensing, and regular inspections take place.
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
TURKEY	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	According to regulation enforced in 4 December 2008 under the 5624 number law which is known as Blood and Blood compenents this regulation has been made.

9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Equivalent standards (bilateral agreements)
9.1.2.1 Please specify	
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	No
9.2.1 If yes, Please describe	
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	
UNITED KINGDOM	
9.1 Are there rules in place for the authorisation and control of the import of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes
9.1.1 If yes, Please describe	Blood and blood components may only be imported into the UK by the holder of a blood establishment authorisation, unless the importation is by a manufacturer or a contractor on his behalf. The blood and blood components must be prepared in accordance with the requirements of the Directives.
9.1.2 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of blood components from third countries? Equivalent standards (bilateral agreements), International standards or other.	Other

9.1.2.1 Please specify	Risk based inspection of sites in third countries that supply the UK with blood components for transfusion. all legal entities are inspected, although not every site operated by the legal entity may be inspected.
9.1.3 Do you have data on the numbers of blood components imported from third countries (outside the EU) in 2008?	No
9.1.3.1 If yes, Please provide this data by the country of origin	
9.2 Are there rules in place for the authorisation and control of the export of blood and blood components for the transfusion or fractionation to EU member States or third countries?	Yes
9.2.1 If yes, Please describe	A blood establishment must be authorised for importation. Because of vCJD risks the UK is not an exporter of blood and blood components
9.2.2 Do you have data on the number of blood components exported from your Member State to third countries (outside EU) in 2008?	No
9.2.2.1 If yes, Please provide this data by the destination	

10. SANCTIONS

AUSTRIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	no
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	n.a.
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	yes
10.2.1 If yes, Have penalties already been imposed?	no
10.2.2 If yes, What were the reasons for imposing the penalties?	n.a.
BELGIUM	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
BULGARIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
CROATIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
CYPRUS	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
CZECH REPUBLIC	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
DENMARK	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
FINLAND	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
FRANCE	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	Yes
10.2.2 If yes, What were the reasons for imposing the penalties?	
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
GERMANY	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	Yes
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	Incorrect donor testing.
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
GREECE	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
HUNGARY	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
IRELAND	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
ICELAND	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
ITALY	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
LIECHTENSTEIN	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
LITHUANIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
LATVIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
LUXEMBOURG	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
MALTA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No

10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
THE NETHERLANDS	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	Yes
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	The main reason was postponed privacy facilities for the donor. There wasn't a suitable donor interview facility, interviews were carried out in the same room as blood collection without any sound barrier. Additional to this, there was also no suitable space to fill in the questionnaire which is the first important contribution to the quality and safety of blood.
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
NORWAY	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	

POLAND	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
PORTUGAL	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
ROMANIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	

SLOVAKIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	Yes
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	2 transfusion stations were revoked because these transfusion stations preparation the blood components without the authorisation. 1 transfusion station was suspension because it does not respect the Directive 2002/98/EC.
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
SLOVENIA	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
SPAIN	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No

10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
SWEDEN	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
SWITZERLAND	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	Yes
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	The blood establishments decided to stop their activities on a voluntary basis (e.g. autologous donations). Therefore, the establishment licenses were withdrawn by Swissmedic.
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	No
10.2.2 If yes, What were the reasons for imposing the penalties?	
TURKEY	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	

10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	No
10.2.1 If yes, Have penalties already been imposed?	
10.2.2 If yes, What were the reasons for imposing the penalties?	
UNITED KINGDOM	
10.1 Have authorisations been revoked or suspended by the competent authorities in 2008? (Art. 5.5 Directive 2002/98/EC)	No
10.1.1 If yes, What were the reasons for the revocation(s) or suspension(s)?	
10.2 Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes
10.2.1 If yes, Have penalties already been imposed?	Yes
10.2.2 If yes, What were the reasons for imposing the penalties?	Non-compliance by 2 hospital blood banks with the quality systems requirements of Directive 2005/62/EC

11. OTHERS

AUSTRIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	none
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Following Thomas Brégeon' email on October 6th 2008 notifying us of the WNV outbreak, a 28 day deferral period was imposed for donors who have visited Bologna and Ferrara regions in Italy and regions in Hungary.
BELGIUM	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Questions: Are platelet lysates, prepared and used for culturing cells, blood components?
11.2. 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

11.2.1 If yes, Please provide us with detailed information	General measure: candidate donors are deferred from donation for a period of 28 days after returning from a country outside the EU, with the exception of Albania, Algeria, Bosnia-Herzegovina, Iceland, Israel, Jordan, Croatia, Lebanon, Libya, Macedonia, Morocco, Montenegro, Norway, Palestine, Serbia, Syria, Tunisia, Turkey and Switzerland. Specific measure for WNV: visitors of endemic regions (Emilia Romagna in Italy, Hungary) have been deferred from donation for a period of 28 days after leaving the endemic region.
BULGARIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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
11.2.1 If yes, Please provide us with detailed information	The Competent Authority sent a notification letter to the all blood establishment in country for preventive measures. The National Blood Collection Center has temporary deferred all donors that had been in the concerned countries.
CROATIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	There is a lack of institutional capacity and financial resources necessary for the full implementation of Directives. Therefore Croatia has applied for I component IPA 2009 (blood, tissue and cells sector)
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Some additional questions related to risk zone of West Nile virus, are being added in donor selection questionnaire
CYPRUS	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Implementation difficulties: political and specific infrastructure support Request from Commission: the provision of on side expertise for implementation purposes
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Following Thomas Brégeon email on October 6th 2008 notifying us of the WNV outbreak, a 28 day deferral period was imposed for donors who have visited Bologna and Ferrara regions in Italy.
CZECH REPUBLIC	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Overregulation: according to Czech experience there is little rationale for setting all the quality requirements (volume, number of elements etc.) as a part of legally binding regulation. It would be better to set only the obligation of "proper information to users" (there was heavy discussion in the Czech Parliament which delayed a transposition of directive 2004/33/EC) Haemovigilance: separation of reporting SAE / SAR whether they are caused by the quality impairment of blood components or the cause lays in an individual patient is sometimes confusing. EU should give to individual states free hand in technical details of reports Unclear definitions: including a "prolongation of hospitalisation" into definition of severe adverse event / reaction makes lot of troubles in interpretation Some data asked for in EU reports are not available on the national level (number of transfused patients within individual hospitals is not possible to summarize etc.)
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Outbreak of WNV in different countries was announced through SUKL to blood establishments, donors at risk are excluded for 28 days

DENMARK	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	None
11.2. 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
11.2.1 If yes, Please provide us with detailed information	
FINLAND	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Temporary deferral criteria for fever limits and flu-like illness is a little bit unclear.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	
FRANCE	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	- The time is a little short to provide exhaustive data, in particular on the number of blood components exported or imported (data by the country of origin), concerned by the current year. In the future, thanks for addressing the questionnaire earlier to lay out a reasonable delay. - 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. - In 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.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	A deferral period of 28 days following return from areas where human cases of West Nile Virus are declared, were applied to: - blood donors returned from Portugal, Tunisia and Israel: from July to October 2004, -blood donors returned from the Italy's areas where cases were declared on the summer 2008: from October 7 to November 30, 2008. In addition, since 2003, blood donors were, systematically deferred for 28 days following return from North America or of Mexico. These deferral measures are set up, every year, from June 1st to November 30. Also, since 2003, French public health authorities set up an Alert managing unit to take the appropriate measures, following discussion and motivation through the evaluation by a network of internal and external experts. This Alert managing unit is registered in the guide of the procedures of the Health Directorate (Ministry of Health).
FORMER YUGOSLAV REPUBLIC OF MACEDONIA	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	change of the Minister of Health was a reason for delay of putting in place the adopted Blood legislative
11.2. 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
11.2.1 If yes, Please provide us with detailed information	
GERMANY	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Obligation by the PEI (first publication September 2003) concerning any blood component not treated for virus inactivation or not tested for WNV: donor deferral for 4 weeks after return journey from countries with acute high WNV epidemiology.
GREECE	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Due to geographical reasons and the decentralized scheme in the function of our Blood Transfusion Services it has become difficult to take away from the Hospital Blood Banks activities such as blood collection, blood testing (blood grouping and serological screening of blood for infectious markers) and blood processing. In the context of a gradual centralization plan of our blood transfusion services it is now generally accepted and foreseen in the new draft law "Regulations for the organizations of the Ministry of Health and Social Solidarity and other Provisions", chapter B " Regulations for the National Blood Centre (EKEA)" that the blood centres will be reduced to 9 from 14 and that blood testing and processing of blood will be performed by these 9 centres which currently have the responsibility of blood screening with NAT in single donations for HIV-RNA, HCV-RNA and HBV-DNA at national level. The responsibility for organizing surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions associated with all parts of the donation-transfusion chain has drawn specific attention to the discussions of the blood transfusion services and existing systems serving well the cause of haemovigilance have been placed under question as to their position towards the component authority of blood transfusion. The case of SKAE functioning since 1996 and consistently cooperating with the European Haemovigilance Network and ISBT is one example proving that professional work and cooperation with the authorities as well as with the laboratory and clinical aspects of transfusion medicine may gain general acceptance and provide considerable help for the development of a holistic haemovigilance system at a national level. This may be an issue to be elaborated by the Commission.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	In compliance with Directive 2004/33/EC we introduced on July 2004 the measure of temporary deferral from blood donation of any person 28 days after leaving an area with ongoing transmission of WNV namely USA and Canada. The blood transfusion committee has recently discussed the outbreaks of WNV in Italy, Hungary and Romania but no decision has been taken for the extension of the above measure to people after leaving these affected regions. In a recent multicenter study, which is under press, entitled "Searching for West Nile Virus (WNV) in Greece" for the presence of WNV RNA in 9590 blood samples from blood donors and 115 cerebrospinal fluid specimens derived from aseptic meningitis cases during the period June to October 2006 and 2007 showed that despite the presence of WNV in Balkan countries, WHV has not reached significant levels in Greece.
HUNGARY	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	HUNGARY HAD NOT GOT PROBLEM WITH THE TRANSPOSITION.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	YES, IN 2008 THE CO-OPERATION HAS BECOME STRONGER WITH THE NATIONAL CENTER OF EPIDEMIOLOGY AND THE HNBTS HAVE TAKEN MEASUREMENTS ACCORDING TO THE DIRECTIVES. THIS YEAR THE SERVICE WOULD LIKE TO IMPLEMENT PCR TECHNIQUE IN THE CONFIRMATORY LABORATORY ENABLING US TO SCREEN THE DONOR SAMPLES DURING THE CRITICAL SEASONS FOR EXPERIMENTAL PURPOSES.
IRELAND	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Lack of specific control measures to be implemented for Hospital Blood Banks posed some difficulties.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Donor Selection Criteria and Donor Deferrals have been implemented appropriately by each Blood Establishment.
ICELAND	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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

11.2.1 If yes, Please provide us with detailed information	
ITALY	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Difficulties: a) Harmonization of the transposition 2002/98/EC with the 21st Oct 2005 national blood law; b) national organizational model of BTSs not corresponding to the organizational models proposed by the Directive 2002/98/EC; c) due to the essentiality of safety requirements for blood and blood components established by the Directive 2002/98/EC problems were encountered revising national requirements of import plasma for fractionation and in harmonizing them with the provisions derived from the transposition of the Directive 2001/83/EC.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Following Summer 2008 WNV outbreak in the Emilia Romagna Region a specific national plan is being defined, which will be issued within April 2009. Seroprevalence studies on donors resident in the affected areas are ongoing. During the outbreak, WNV NAT was implemented on blood donations from donors resident in the interested areas; at the national level 28 day deferral of blood donors having been for at least one night in affected areas was introduced. Precautionary measures were discontinued beginning of Dec 2008. Regional and national multisciplinary cooperation revealed of paramount importance to manage the whole event and to preserve the blood stock's safety.
LIECHTENSTEIN	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	-

11.2. 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
11.2.1 If yes, Please provide us with detailed information	
LITHUANIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Inspection of blood establishments
11.2. 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
11.2.1 If yes, Please provide us with detailed information	temporary deferral of suspected person
LATVIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Difficulties in the implementation of the Directives- limited personnel and financial resources in hospitals. Specific issues need to be addressed by the Commission-training of inspectors, Guide for Auditing Blood establishments and Hospital Blood Banks
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Person will be the donor 28 days after returning from an endemic area - this requirement included in national guidelines.
LUXEMBOURG	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	

11.2. 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
11.2.1 If yes, Please provide us with detailed information	temporary deferral in certain cases
MALTA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	The major difficulty encountered by Malta is in finding and training adequate personnel to be able to implement all the requisites of the EU Directives.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	The precautionary measures adopted include those advised by the European Commission which include: - Deferral for 28 days of donors having been for one night in the affected areas (the 28 day period starting from the day after the donor has left the concerned area); and - Laboratory facilities for the testing for the West Nile Virus have been ensured.
THE NETHERLANDS	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	The pH upper limit for platelets during storage is not feasible.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Temporary deferral of donors returning from countries with ongoing transmission to humans.
NORWAY	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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
11.2.1 If yes, Please provide us with detailed information	deferral from donation 28 days after leaving region with outbreak
POLAND	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	No difficulties were encountered in the transposition of the Directives.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Temporary suspension of donors who have visited areas where WNV is being transmitted to humans and/or animals.
PORTUGAL	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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
11.2.1 If yes, Please provide us with detailed information	
ROMANIA	

11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	IN 2008, during West Nile cases registered in Romania, the MOH encountered problem in implementing the deferral period (28 days) according to Commission Directive 2004/33/EC. It is Romanian proposal to review the actual directive and complete with more specific information regarding these cases.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Temporary deferral for 28 days after leaving the area with identified ongoing human infection cases and additional questions during the medical interview/ questionnaire regarding the living/passage through this area. Potential donors living in the area with identified ongoing human infection cases are deferred along the whole period of risk, as it is recommended by the Public Health Authority.
SLOVAKIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	/
11.2. 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
11.2.1 If yes, Please provide us with detailed information	
SLOVENIA	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	

11.2. 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
11.2.1 If yes, Please provide us with detailed information	Precautionary measures for blood donation were taken and are as follows: The blood donors are asked about coming form or travelling to the risk areas in Italy (Emilia-Romagna, Bologna, Ferrara, Forli-Cesena, Parma, Piacenca, Ravenna, Reggio Emilia and Rimini) and Hungary. The donors which were in the risk areas are declined for one month.
SPAIN	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Blood Safety Scientific Committee (CCST): Donors exclusion for people who have been in interested areas. Information reported to responsible of all blood establishments through the eRoom system, and Information available in the Ministry' website: http://www.msc.es/profesionales/saludPublica/medicinaTransfusional
SWEDEN	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	The National Board of Health and Welfare: National implementations of the donors deferral rules based on sexual behaviour.
11.2. 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

11.2.1 If yes, Please provide us with detailed information	Responsible person at the establishments have been notified and control measures have been taken according to regulations (person may be accepted as blood donor earliest 28 days after leaving risk area).
SWITZERLAND	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	The regulations have already been in place before the EU directives. See also answer to question 2.
11.2. 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
11.2.1 If yes, Please provide us with detailed information	Blood donations are not accepted from persons who have – within the last four weeks before presentation at the donation site - stayed in an area where WNV-transmission is known to occur. A revision of the areas of concern and consequently, an adaptation of the rejection criteria is performed if necessary based on epidemiologic data.
TURKEY	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	
11.2. 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
11.2.1 If yes, Please provide us with detailed information	
UNITED KINGDOM	
11.1 What difficulties were encountered by the Member State in the transposition or implementation of the Directives? What specific issues need to be addressed by the Commission?	Completion and publication of the "Good Practice" guidance by the Commission and possible amendments to donor haemoglobin levels

11.2. 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
11.2.1 If yes, Please provide us with detailed information	28 day deferral for donors who have travelled to a WNV affected area