EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Compilation of SANCO C6 TB/ci D(2008)/360028
Responses from Competent Authorities:
Questionnaire on the transposition and implementation of the European Blood and Blood Components regulatory framework

In preparation of the third meeting of competent authorities on blood and blood components which the Commission convenes in order to exchange experiences in the transposition of the Directives into their national law, competent authorities were invited to complete a questionnaire covering the transposition and implementation of the blood and blood components regulatory framework. This table presents responses regarding the situation from the Member States, EEA and candidate countries as of 25 January 2008.

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1. NAME OF COMPETENT AUTHORITY

AUSTRIA
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **Austrian Federal Ministry of Health, Family and Youth** **Address: Radetzkystrasse 2, 1030 Wien, Austria** **Executive Authority: Federal Office for Safety in Health Care, AGES PharmMed, Schnirchgasse 9, 1030 Wien, Austria**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Blood, medicines (veterinary and human), medical devices, tissues and cells for human application, haemovigilance, tissue vigilance, medical devices vigilance, import of blood components and blood products and plasma and plasma derivatives.
BELGIUM
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies): Federal Agency for Medicines and Health Products** **Address: Eurostation II, Place Victor Horta 40/40, 1060 Brussels, Belgium**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Medicines, medical devices, blood, tissues and cells for human application,
BULGARIA

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies): Bulgarian Drug Agency

National Competent Authority

Address: 1504 Sofia

26 Yanko Sakazov Blvd

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)
BDA is in charge of quality, efficacy and safety of medicinal products placed on Bulgarian pharmaceutical market, manufacturing authorization of medicines and GMP certification, authorization for wholesale distribution for medicinal products and clinical trials, market surveillance for medical devices, according to the Directives and blood donation system.

CROATIA

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

Ministry of Health and Social Care (MoHSC)

Croatian Institute of Transfusion Medicine (CITM)

Address: PETROVA 3. 10000 ZAGREB

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

CYPRUS

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

NAME: MEDICAL AND PUBLIC HEALTH SERVICES

STATUS: GOVERMENTAL DEPARTMENT OF THE MINISTRY OF HEALTH

Address: 10, MARCOU DRAKOU

PALOURIOTISSA 1449

NICOSIA - CYPRUS

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

Preventive medical care, development of primary medical care, promotion of community nursing care program, health nourishment services, sanitary services, occupational and environmental health, tissues and cells for human application, blood, etc.

CZECH REPUBLIC

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

1) Ministry of Health

2) State Institute for Drug Control

Address:

1) Palackého nám. 4, Praha 2, 128 01

2) Šrobárova 48, Praha 10, 100 41

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

blood and blood products,

medicines, medical devices, tissues and cells for human application
DENMARK
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **Danish Medicines Agency** **Under Ministry of the Interior and Health** **Address:** **Axel Heides Gade 1** **DK – 2300 København S**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) All scopes mentioned
ESTONIA
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies): Svetlana Orlova. MSc, specialist at department of biologicals at State Agency of Medicines** **Address: 1, Nooruse str. 50411, Tartu, Estonia**
Short description of the scope of competences of the competent authority

Blood and blood components for human application (transfusion)

FINLAND

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

National Agency for Medicines

Competent authority for the quality and safety requirements of human blood and blood components as defined in the Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC (transposed into national legislation by the Blood Service Act (197/2005), Decree (258/2006) and the Administrative Regulation 2/2006 given by the National Agency for Medicines).

Address:

P.O.Box 55 (Mannerheimintie 103b)

FI-00301 Helsinki, FINLAND

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

Responsibility of the National Agency for Medicines (NAM) is to ensure the efficacy, safety and quality of medicinal products on the market in Finland. NAM supervises also the safety and quality of blood products and human tissues /cells intended for human applications and medical devices.

FRANCE

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps))

Address:

143/147 Boulevard Anatole France F-93285 SAINT DENIS Cedex
Short description of the scope of competences of the competent authority The Afssaps is in charge of the evaluation, the inspection, the control, the vigilance of all health products intended for human application (e.g. medicinal products, medical devices and medical devices for in vitro diagnosis, blood and blood components, tissues and cells, organs, cosmetic products … etc) and the authorisation of the establishments.
FYRoM
Designated competent authority(ies) (Art. 4.1 directive) **Name and status of the competent authority(ies):**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) blood; transfusion medicine
GERMANY
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **1. 40 competent Land authorities ("Länderbehörden")** **2. Paul-Ehrlich-Institute (Higher Federal Authority)** **Address: ad 2.: Paul-Ehrlich-Straße 51-59, 63225 Langen**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) The Paul-Ehrlich-Institute is competent for sera, vaccines, blood preparations, bone marrow preparations, tissue preparations, allergens, gene transfer medicinal products, somatic cell therapy products, xenogenic cell therapy products and blood components manufactured using genetic engineering.

GREECE
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies): Hellenic National Blood Center (E.KE.A)** **Address: 7 Olympic Winner Christos Mantikas, Acharnes, GR-13671, Greece**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Organization, management and control of national blood transfusion system
HUNGARY
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** National Institute of Pharmacy Executive Office
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Medicines, blood, tissue and cells for human application
ICELAND
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **Ministry of Health and Social Security** **Address:**

Vegmúla 3, IS 150 Reykjavík, Iceland

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

The Ministry of Health and Social Security is the governing body in the field of health and health institutions

IRELAND

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

Irish Medicines Board

Address:

Kevin O' Malley House,

Irish Medicines Board,

Earlsfort Centre,

Earlsfort Terrace,

Dublin 2,

Ireland.

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

The Irish Medicines Board is competent authority for:

- Licensing of medicinal products for human use
- Licensing of veterinary products

- Licensing of wholesalers of human medicines
- Licensing of manufacturers of human and veterinary medicines
- Pharmacovigilance & Drugs safety monitoring
- Clinical Trial Licensing
- Inspection of wholesale and manufacturing sites
- Regulation of Medical Devices
- Blood
- Tissue & Cells Directive

ITALY

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

MINISTRY OF HEALTH

ITALIAN NATIONAL BLOOD CENTRE (CENTRO NAZIONALE SANGUE - CNS)

REGIONAL AUTHORITIES

Address: Centro nazionale Sangue – Istituto Superiore di Sanità (Italian National Institute of Health), Via Giano della Bella, 27 - 00162 Roma

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …): Coordination and technical and scientific control of all transfusion medicine issues ruled by national laws and European provisions, including plasma products, plasma pharmaceutical industries, coordination of the Italian Cord Blood Network (ITCBN).

LATVIA

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

Health statistics and medical Technologies state agency is the competent authority in Latvia

Address:

12/ 22 Duntes str. Riga, Latvia

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

Due to the national legislation in the process of supervision of the Blood Service takes part Health statistics and medical technologies state agency, which is under the supervision of the Ministry of Health .The agency also ensures :

-assesses Hospital blood banks, blood establishments, Blood Donor center, procurement organisations of tissues and cells, tissue and cell establishments, responsible for human applications due to the Rules of the Cabinet of Ministers of the Republic of Latvia.

-after the conformity assessment , agency determines- what kind of actions and with kind of conditions can perform Hospital blood banks, blood establishments, Blood Donor center, procurement organisations of tissues and cells, tissue and cell establishments, responsible for human applications

-confirms the technologies for the blood and bloods components preparations and use

-supervises the medical devices

-organizes the procedure of the vision in connection with the serious adverse event and serious adverse reactions connected with donors or recipients

LIECHTENSTEIN

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

Amt für Gesundheit

Address: Äulestrasse 51, 9490 Vaduz, Liechtenstein
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Medicinal products, medical devices, blood, tissues and cells for human application, insurance, public health affairs
LITHUANIA
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** Ministry of Health State Service of Accreditation for Health Care Activities under the Ministry of Health State Medical Audit Inspectorate under the Ministry of Health……. **Address: 33 Vilniaus str., Vilnius, Lithuania**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) **The competent authorities are responsible for implementing of the blood directives.**
MALTA
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** Director General Public Health Regulation **Address:** Ministry of Health, The Elderly & Community Care. "Palazzo Castellania" 15, Merchant Street,

Valletta VLT 2000
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Director General Public Health Regulation as the Superintendent of Public Health represents the Malta Competent Authority for medicinal products, and the safety and quality of blood and blood components.
THE NETHERLANDS
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):Minister of Health, Welfare and Sport** **Address: P.O. Box 20350** **2500 EJ Den Haag** **The Netherlands**
Short description of the scope of competences of the competent authority blood, medicines, medical devices, tissues and cells for human application, organs
NORWAY
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **Directorate for Health and Social Affairs (CA)** **Address:** **PO Box 7000 St Olavs plass**

N-0130 Oslo, Norway
Short description of the scope of competences of the competent authority Competent authority for medical devices, blood and tissues and cells for human application. Medicines/medicinal products (and future ATPs) regulated at the Norwegian Medicines Agency
POLAND
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies): Minister of Health** **Address: 15 Miodowa str. Warsaw**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) The Minister of Health is responsible for all issues of the health service system in Poland.
PORTUGAL
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **Autoridade para os Serviços de Sangue e Transplantação** **Address: Av. João Crisóstomo, 9 – 1º 1049-062 Lisboa Portugal**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) **Control and inspection of blood and transplant services activities.**
ROMANIA

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies): MINISTRY OF PUBLIC HEALTH

Address: str. Cristian POPISTEANU nr. 1-3, Bucharest - Romania

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

SLOVAK REPUBLIC

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):
STATE INSTITUTE FOR DRUG CONTROL,

Address: Kvetná 11, 825 08 Bratislava, Slovak Republic

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

SIDC is competent authority for inspections of blood, medicines, medical devices.

Ministry of Health in Slovak Republic inspect tissues and cells for human application.

SLOVENIA

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES OF THE REPUBLIC OF SLOVENIA (JAZMP)

Address: 1000 LJUBLJANA, SLOVENIA

PTUJSKA ULICA 21

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) JAZMP is competent authority for medicines for human in veterinary use, medical devices, blood and tissues/cells
SPAIN
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies** Ministry of Health and Consumer Affairs. (Directorate General of Public Health). Autonomous Communities: Health Departments **Address:** Dirección general de Salud Pública .Ministerio de Sanidad y Consumo. Paseo del Prado 18-20. Madrid 28071
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) BLOOD, Unidad de Hemoterapia del Ministerio de Sanidad y Consumo. Secretaria del órgano científico dependiente del Ministerio- Comité Científico para la Seguridad Transfusional (CCST) y de la Comisión Nacional de Hemoterapia (CNH), órgano de coordinación de las 17 Comunidades Autónomas.
SWEDEN
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** **The National Board of Health and Welfare** **Address: Socialstyrelsen, 106 30 Stockholm Sweden**
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) The National Board of Health and Welfare is the Swedish national authority responsible for regulation and surveillance of safety and quality of blood, tissues and cells for human application.

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

Medical Products Agency

Address: P.O Box 26, SE-751 03 Uppsala, Sweden

Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …)

The Medical Products Agency (MPA) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medicinal products. MPA is also responsible for medical device and cells and tissues for human application. The MPA is responsible for blood or plasma for use in the manufacture of medicinal products.

SWITZERLAND

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

1) Swissmedic, Swiss Agency for Therapeutic Products
2)Federal Office of Public Health
Address:
1)Hallerstrasse 7, CH-3000 Bern 9
2)Seilerstrasse 8, CH-3011 Bern

Short description of the scope of competences of the competent authority:

Swissmedic, the Swiss Agency for Therapeutic Products is the central Swiss supervisory authority for therapeutic products. It is a public service organization of the federal government. Swissmedic is linked to the Federal Department of Home Affairs (FDHA). Swissmedic's administrates the Swiss Law on Therapeutic Products (LTP). Therapeutic products is the term we use to describe human and veterinary medicines together with medical devices. To protect the health of humans and animals, Swissmedic strives to ensure that medicines and medical devices in Switzerland are effective and safe. Our core competence includes

- 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 Swiss inspection system
- monitoring medicines and medical devices already on the market
- controlling the traffic of narcotics
- laboratory testing of medicine quality
- drafting directives

The Federal Office of Public Health (FOPH) is part of the Federal Department of Home Affairs. As the national authority in health matters, the FOPH represents Switzerland in international organisations and in dealings with other countries. Within Switzerland it is responsible - together with the cantons - for public health and the development of national health policy. This includes the management and development of the social healthcare and accident insurance system. The FOPH specifies which services are paid for by compulsory health insurance and supervises the social healthcare and accident insurance funds.
The FOPH is drafting the laws on consumer protection e.g. the Swiss Law on Therapeutic Products (LTP) or Swiss law on food stuffs and utility articles and supervises the implementation.
The FOPH is responsible for monitoring transmissible diseases and for radiological protection in Switzerland and issues the necessary regulations.
The FOPH is responsible for national programmes designed to reduce substance dependence (tobacco, alcohol, illegal drugs) and promote healthy lifestyles (nutrition and exercise, health and the environment) and for the national HIV/AIDS programme.
It is also responsible for issuing the regulations governing the basic and advanced training of doctors, dentists, pharmacists and veterinary surgeons and awards the corresponding Swiss degrees.
Finally, the FOPH is also responsible for legislation on biological safety, research on humans (including stem cell research) and transplantation medicine, and for supervising these fields.
The FOPH employs around 500 people. It has an annual budget of CHF 224 million and administers CHF 2.3 billion reserved for premium reductions in the compulsory health insurance system.

TURKEY

DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive)

Name and status of the competent authority(ies):

Ministry of Health (MoH)

Address:

Mithatpaşa Cad. No:3 Sıhhiye/ ANKARA/ TURKEY
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) Blood, medicines, medical devices, tissue and cells for human application, preventive services (infectious diseases), maternal and reproductive health are within the scope of competences of MoH)
UNITED KINGDOM
DESIGNATED COMPETENT AUTHORITY(IES) (Art. 4.1 directive) **Name and status of the competent authority(ies):** Medicines and Healthcare products Regulatory Agency (MHRA) **Address:** Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Short description of the scope of competences of the competent authority (e.g. blood, medicines, medical devices, tissues and cells for human application, …) MHRA is the UK competent authority for medicinal products, medical devices and the safety and quality of blood and blood components.

2. TRANSPOSITION

AUSTRIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x No ☐
2- Has Directive 2004/33/EC been transposed into national law?	Yes x No ☐
3- Has Directive 2005/61/EC been transposed into national law?	Yes x No ☐
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No ☐
BELGIUM	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes X No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes X No □
BULGARIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes ☑

	No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes ☑ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes ☑ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes ☑ No □
CROATIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x□ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes x□ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes x□ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes x□ No □
CYPRUS	
1- Has Directive 2002/98/EC been transposed into national law?	Yes √□ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes √ □ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes √ □ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes √□ No □

CZECH REPUBLIC	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x No □
2- Has Directive 2004/33/EC been transposed into national law? *some parts are still as non-biding recommendation (see encloser)	Yes □* No □
If NO, when is transposition expected? (dd/mm/yyyy) law (1.1.2008) and MoH degree (1.4.2008)	
3- Has Directive 2005/61/EC been transposed into national law? *almost completely (see encloser)	Yes □* No □
If NO, when is transposition expected? (dd/mm/yyyy) law (1.1.2008) and MoH degree (1.4.2008) Additional comments:	
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No □
DENMARK	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes x No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes x No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No □

ESTONIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes × No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes × No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes × No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes × No □
FINLAND	
1- Has Directive 2002/98/EC been transposed into national law?	Yes ☒ No
2- Has Directive 2004/33/EC been transposed into national law?	Yes ☒ No
3- Has Directive 2005/61/EC been transposed into national law?	Yes ☒ No
4- Has Directive 2005/62/EC been transposed into national law?	Yes ☒ No
FRANCE	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X
2- Has Directive 2004/33/EC been transposed into national law?	Yes X

However, the update of the National guidelines concerning the eligibility criteria for blood and blood components donors is under publication in the French Official Journal	
3- Has Directive 2005/61/EC been transposed into national law?	Yes X
4- Has Directive 2005/62/EC been transposed into national law?	Yes X
FYRoM	
1- Has Directive 2002/98/EC been transposed into national law?	**Yes** □ No □
2- Has Directive 2004/33/EC been transposed into national law?	**Yes** □ No □
3- Has Directive 2005/61/EC been transposed into national law?	**Yes** □ No □
4- Has Directive 2005/62/EC been transposed into national law?	**Yes** □ No □
GERMANY	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes X No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes X No □
GREECE	

1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes X No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes X No □
HUNGARY	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes x No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes x No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No □
ICELAND	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes □ No X
If NO, when is transposition expected? Not known yet.	

Additional comments: The Directives have not yet been translated into Icelandic due to heavy backlog at our translation center, but the translation has been started	
4- Has Directive 2005/62/EC been transposed into national law?	Yes □ No X
If NO, when is transposition expected? Not known yet. Additional comments: The Directives have not yet been translated into Icelandic due to heavy backlog at our translation center, but the translation has been started	
IRELAND	
1- Has Directive 2002/98/EC been transposed into national law?	Yes √ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes √ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes √ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes √ No □
ITALY	
1- Has Directive 2002/98/EC been transposed into national law? Decree of 19 August 2005, n. 191 (2007 update forthcoming, within January 2008)	Yes **X** No □
2- Has Directive 2004/33/EC been transposed into national law? Decree of the Minister of Health of 3 March 2005	Yes **X** No □
3- Has Directive 2005/61/EC been transposed into national law? Decree of 9 November 2007, n. 207	Yes **X** No □
4- Has Directive 2005/62/EC been transposed into national law? Decree of 9 November 2007, n. 208	Yes **X** No □

LATVIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes × No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes × No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes × No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes × No □
LIECHTENSTEIN	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x□ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X □ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes x □ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes x □ No □
LITHUANIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes □x No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes □x No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes □x

	No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes □x No □
MALTA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes X No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes X No □
THE NETHERLANDS	
1- Has Directive 2002/98/EC been transposed into national law?	Yes □ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes □ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes □ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes □ No □
NORWAY	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x No □

2- Has Directive 2004/33/EC been transposed into national law?	Yes x No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes x No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No □
POLAND	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments: The ISBT 128 code will be implemented in 2008.	
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes X No □
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments: The Directive has not been completely transposed into national law. The not-transposed part of it presents a part of national guideline for blood transfusion service in Poland.	
4- Has Directive 2005/62/EC been transposed into national law?	Yes X No □
PORTUGAL	
1- Has Directive 2002/98/EC been transposed into national law?	Yes x No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes x

	No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes x No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No □
ROMANIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes ☒ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes ☒ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes ☒ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes ☒ No □
SLOVAK REPUBLIC	
1- Has Directive 2002/98/EC been transposed into national law?	Yes ☒ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes ☒ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes ☒ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes ☒ No □

SLOVENIA	
1- Has Directive 2002/98/EC been transposed into national law?	Yes ■ No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes ■ No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes ■ No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes ■ No □
SPAIN	
1- Has Directive 2002/98/EC been transposed into national law? RD. 1088/2005	Yes **x** No □
2- Has Directive 2004/33/EC been transposed into national law? RD 1088/2005	Yes **x** No □
3- Has Directive 2005/61/EC been transposed into national law? SCO /322/2007	Yes **x** No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes **x** No □
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments: Se ha sido publicado el 1 de noviembre 2007 el Real Decreto 1343/2007 por el que se establecen normas y especificaciones relativas al sistema de calidad de los centros y servicios de transfusión.	
SWEDEN	

1- Has Directive 2002/98/EC been transposed into national law?	Yes x No ☐
2- Has Directive 2004/33/EC been transposed into national law?	Yes x No ☐
3- Has Directive 2005/61/EC been transposed into national law?	Yes ☐ No x
If NO, when is transposition expected? (dd/mm/yyyy) Directive 2005/61/EC will be transposed into national law 1/1- 2008	
4- Has Directive 2005/62/EC been transposed into national law?	Yes x No ☐
SWITZERLAND	
1- Has Directive 2002/98/EC been transposed into national law?	Yes □ No x
If NO, when is transposition expected? (dd/mm/yyyy) Switzerland is not a Member State of the European Union. But the regulations in Switzerland are comparable to the Directive 2002/98/EC.	
2- Has Directive 2004/33/EC been transposed into national law?	Yes □ No x
If NO, when is transposition expected? (dd/mm/yyyy) Switzerland is not a Member State of the European Union. But the regulations in Switzerland are comparable to the Directive 2004/33/EC.	
3- Has Directive 2005/61/EC been transposed into national law?	Yes □ No x
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments:	

Switzerland is not a Member State of the European Union. But the regulations in Switzerland are comparable to the Directive 2005/61/EC.	
4- Has Directive 2005/62/EC been transposed into national law?	Yes □ No x
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments: Switzerland is not a Member State of the European Union. But the regulations in Switzerland are comparable to the Directive 2005/62/EC.	
TURKEY	
1- Has Directive 2002/98/EC been transposed into national law?	Yes □ No √
If NO, when is transposition expected? (dd/mm/yyyy)	
2- Has Directive 2004/33/EC been transposed into national law?	Yes □ No √
If NO, when is transposition expected? (dd/mm/yyyy)	
3- Has Directive 2005/61/EC been transposed into national law?	Yes □ No √
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments:	
4- Has Directive 2005/62/EC been transposed into national law?	Yes □ No √
If NO, when is transposition expected? (dd/mm/yyyy) Additional comments:	

UNITED KINGDOM	
1- Has Directive 2002/98/EC been transposed into national law?	Yes X No □
2- Has Directive 2004/33/EC been transposed into national law?	Yes X No □
3- Has Directive 2005/61/EC been transposed into national law?	Yes X No □
4- Has Directive 2005/62/EC been transposed into national law?	Yes X No □

3. ACCREDITATION

Member States shall ensure that activities (…) are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose – Art. 5 Directive 2002/98/EC

AUSTRIA	
5- How many blood establishments are there in your Member State? 17 Blood Establishments & 14 Plasmapheresis Centres	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes x No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 17 Blood establishments & 14 Plasmapheresis Centres	
BELGIUM	
5- How many blood establishments are there in your Member State? 6	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes X No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 6	
BULGARIA	
5- How many blood establishments are there in your Member State? 28	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes ☑ No ☐

7- How many blood establishments have received designation, authorisation, accreditation or license? 23	
CROATIA	
5- How many blood establishments are there in your Member State? 21	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No x□
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? Till the end 2009.	
7- How many blood establishments have received designation, authorisation, accreditation or license? 1	
CYPRUS	
5- How many blood establishments are there in your Member State? 1	
6- Have all blood establishments been designated, <u>authorised,</u> accredited or licensed by the competent authority(ies)?	Yes √□ No □
7- How many blood establishments have received designation, <u>authorisation</u>, accreditation or license? 1	
CZECH REPUBLIC	
5- How many blood establishments are there in your Member State? 83 blood establishments (but only 54 process blood into components, the others only collect blood and / or collect autologous blood)	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes x

	No □
7- How many blood establishments have received designation, authorisation, accreditation or license? all 83 of them	
DENMARK	
5- How many blood establishments are there in your Member State? 15	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes x No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 15	
ESTONIA	
5- How many blood establishments are there in your Member State? Four (4)	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)? ***** State Agency of Medicines has answered in respect of authorisation and license	Yes × No □
7- How many blood establishments have received designation, authorisation, accreditation or license? All four Blood establishments	
FINLAND	
5- How many blood establishments are there in your Member State? 1 blood establishment with 17 sites. Every site is inspected every second year.	

6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes ☒ No
7- How many blood establishments have received designation, authorisation, accreditation or license? One blood establishment (17 sites and their activities are defined in the licence of the Blood Establishment).	
FRANCE	
5- How many blood establishments are there in your Member State? 219 blood establishments	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes X
7- How many blood establishments have received designation, authorisation, accreditation or license? 219 blood establishments	
FYRoM	
5- How many blood establishments are there in your Member State? One National establishment	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ **No** □
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? The law has recently been adapted in a year	
7- How many blood establishments have received designation, authorisation, accreditation or license? None of them	
GERMANY	

5- How many blood establishments are there in your Member State? 163	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes X No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 163	
GREECE	
5- How many blood establishments are there in your Member State? 95	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes X No □
7- How many blood establishments have received designation, authorisation, accreditation or license? All of them, but not from the present competent authority (E.KE.A)	
HUNGARY	
5- How many blood establishments are there in your Member State? 6 regional blood centres + 17 blood banks belong to the Hungarian National Blood Transfusion Service (HNBTS)	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes x No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 6 regional blood centres of the HNBTS	
ICELAND	
5- How many blood establishments are there in your Member State? One	

6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No X
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? Inspection is scheduled for 9-10 October 2007. The inspection will be carried out with the assistance of Danish inspectors and looked upon as training for the Icelandic inspectors	
7- How many blood establishments have received designation, authorisation, accreditation or license? None	
IRELAND	
5- How many blood establishments are there in your Member State? 5 blood establishments	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No √
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? The process will be complete by the end of December 2007	
7- How many blood establishments have received designation, authorisation, accreditation or license? 3 blood establishments has been authorised to date 1 blood establishment authorisation is being progressed 1 blood establishment needs one further inspection in Q4 of 2007	
ITALY	
5- How many blood establishments are there in your Member State? In Italy, there is no distinction between "Blood Establishments" and "Hospital Blood Banks". Blood Transfusion Services (BTSs) are, by law, only public, hospital based services. BTSs are 326 (2005 survey), mostly organized in Transfusion Medicine Departments. Each regional health authority must have a regional blood coordinating Centre (21 regional Centres are in place).	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes **X** No □

- All BTSs are authorised complying with pre-existing national provisions - In some Regions BTSs are temporarily accredited complying with pre-existing national provisions - New authorisation and accreditation system to be realized applying 21st Oct 2005 national Blood Law and national Decrees transposing European Directives	
7- How many blood establishments have received designation, authorisation, accreditation or license? See answer to question n. 6	
LATVIA	
5- How many blood establishments are there in your Member State? 11	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes 11 No □
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? The conformity of assessment of the blood establishments of the State was done due the rules of the Cabinet of Ministers of the Republic of Latvia Nr.77, , Rules about the Compulsory requirements for the treatment institutions and their structural units''(requirements is similar with directive) and the handled certificates will be in force for other blood establishments till year 2009.	
7- How many blood establishments have received designation, authorisation, accreditation or license? 11	
LIECHTENSTEIN	
5- How many blood establishments are there in your Member State? 2	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes x□ No □
7- How many blood establishments have received designation, authorisation, accreditation or license?	

2	
LITHUANIA	
5- How many blood establishments are there in your Member State? 4	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □x No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 4	
MALTA	
5- How many blood establishments are there in your Member State? 1	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No X
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? The Health Division has just undergone an internal reorganisation with the setting up of three Director Generals (DG), namely DG Strategy and Sustainability, DG Health Care Service, and DG Public Health Regulations. Within the Public Health Regulations Division a Director Of Health Care Services Standards has been appointed who will have the explicit remit of safeguarding the health and well-being of the public and promoting patient safety through the enforcement of public health regulations. Regulating the use of human blood, and blood components in terms of the relevant legislation and the implementation of the requirements of the Directive is a responsibility of the utmost priority. In cooperation with the Malta Medicines Authority, as the nominated delegate of the responsible authority, by the end of June 2008 foreign experts from Ireland are expected to have come over to train local inspectors and license the Blood Establishment in Malta.	
7- How many blood establishments have received designation, authorisation, accreditation or license? None.	
THE NETHERLANDS	
5- How many blood establishments are there in your Member State?	

1 (1 legal entity but 4 'production centers')	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 1 (but all 4 individual production centers as well)	
NORWAY	
5- How many blood establishments are there in your Member State? 36	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes x No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 36	
POLAND	
5- How many blood establishments are there in your Member State? 23	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No X
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? The one remaining blood establishment will be granted accreditation in few weeks. The other one has to close or to improve the standard of its donation sites.	
7- How many blood establishments have received designation, authorisation, accreditation or license? : 21	
PORTUGAL	
5- How many blood establishments are there in your Member State?	

3	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes □ No x
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? We are starting to begin our activity and we think that until the end of next year we will be all blood establishments licensed.	
7- How many blood establishments have received designation, authorisation, accreditation or license? **All of them were authorised by the former authority.**	
ROMANIA	
5- How many blood establishments are there in your Member State? 42	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority (ies)	Yes □ No ☒
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? No norms for inspection have been implemented	
7- How many blood establishments have received designation, authorisation, accreditation or license? See point 6	
SLOVAK REPUBLIC	
5- How many blood establishments are there in your Member State? 50	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes ☒ No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 50	

SLOVENIA	
5- How many blood establishments are there in your Member State? The blood establishments in R.of Slovenia are in reorganisation phase at the moment to become compliant with the new Law on blood supply. They are in compliance with the previous legislative rules.	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes No
The blood establishments in R.of Slovenia are in reorganisation phase at the moment to become compliant with the new Law on blood supply. They are in compliance with the previous legislative rules. The new Law was issued 1 year ago; rules on detailed procedures for authorisation are about to be issued. Approval process according to the new Law on blood supply will be finished by the end of QI/2008	
7- How many blood establishments have received designation, authorisation, accreditation or license? They have authorisation according previous legislation (Official gazette of RS, No. 52/2000, 2/2004).	
SPAIN	
5- How many blood establishments are there in your Member State? 24	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes **x** No □
7- How many blood establishments have received designation, authorisation, accreditation or license? 24	
SWEDEN	
5- How many blood establishments are there in your Member State? The 32 Transfusions centres (organizations) include 82 blood establishments.	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes X No □

7- How many blood establishments have received designation, authorisation, accreditation or license?	
SWITZERLAND	
5- How many blood establishments are there in your State? 77	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes **X** No □
7- How many blood establishments have received designation, authorisation, accreditation or license?	
TURKEY	
5- How many blood establishments are there in your Member State? 368 blood establishments + Turkish Red Crescent Blood Establishment	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes √ No □
If NO, when will this approval process be completed? What is (are) the reason(s) for the delay in the approval process? 368	
7- How many blood establishments have received designation, authorisation, accreditation or license? 368	
UNITED KINGDOM	
5- How many blood establishments are there in your Member State? 13	
6- Have all blood establishments been designated, authorised, accredited or licensed by the competent authority(ies)?	Yes X No □

7- How many blood establishments have received designation, authorisation, accreditation or license?
13

4. HOSPITAL BLOOD BANKS

AUSTRIA	
8- How many Hospital Blood Banks are in activity? approx. 150	
9- 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 X No ☐
If YES, please describe The text of the Directive 2002/98/EC is implemented in the legislation of the regional provinces competent for supervising the hospitals.	

BELGIUM	
8- How many Hospital Blood Banks are in activity? 112	
9- 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 X No □
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	
8- How many Hospital Blood Banks are in activity? 56	
9- 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 ☐ No ☑

CROATIA
8- How many Hospital Blood Banks are in activity? 13

9- 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 □ No x□
CYPRUS	
8- How many Hospital Blood Banks are in activity? 6	
9- 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 □ No √ □
CZECH REPUBLIC	
8- How many Hospital Blood Banks are in activity? 47 blood banks (plus 54 blood banks are merged with blood establishments)	
9- 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 x No □
If YES, please describe inspections, responsible person, quality system, documentation and record keeping, transport and storage, traceability and notification of adverse events and reactions	
DENMARK	
8- How many Hospital Blood Banks are in activity? 63	
9- 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 x No □
If YES, please describe: Implemented where relevant into national law	
ESTONIA	

8- How many Hospital Blood Banks are in activity? There are twenty five (25) Hospital Blood Banks in Estonia	
9- 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 □ No ×
FINLAND	
8- How many Hospital Blood Banks are in activity? 54	
9- 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 No ☒
The Articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 are covered by the Articles 4, 6, 7, 8, 9, 10, 15 and 16 of the Blood Service Act (197/2005). So, the requirements of the Directives concerning especially hospital blood banks are transposed in the national legislation.	
FRANCE	
8- How many Hospital Blood Banks are in activity? 705 Hospital Blood Banks are in activity	
9- 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 X
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.	
FYRoM	
8- How many Hospital Blood Banks are in activity? There is no hospital blood banks	
9- 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 □ **No** □

GERMANY	
8- How many Hospital Blood Banks are in activity?	
9- 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 □ No X
GREECE	
8- How many Hospital Blood Banks are in activity? 95 same as blood establishments (not different structures in Greece)	
9- 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 □ No X
HUNGARY	
8- How many Hospital Blood Banks are in activity? 25	
9- 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 x No □
If YES, please describe Specific contracts with the HNBTS are regulated these points that are controlled by the Health officers and HNBTS.	
ICELAND	
8- How many Hospital Blood Banks are in activity? None	
9- 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 □ No X
IRELAND	
8- How many Hospital Blood Banks are in activity? There are 53 blood banks	

9- 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 √ No □
If YES, please describe All blood banks have to ISO 15189 (Medical laboratories -- Particular requirements for quality and competence) accredited by November 2008	
ITALY	
8- How many Hospital Blood Banks are in activity? See answer to question n. 5	
9- 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) Not applicable	Yes □ No □
LATVIA	
8- How many Hospital Blood Banks are in activity? 49	
9- 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 × No □
If YES, please describe Personnel is qualified for the tasks they perform and provided with training, each blood establishment establishes and maintains a quality system, maintain documentation on procedures, guidelines and reporting forms , blood and blood components traced from donor to recipient and vice versa, notified of serious adverse events and reactions accordance with the procedure, storage, transport and distribution of blood components comply with the requirements, the procedures are in place to resolve data discrepancies.	
LIECHTENSTEIN	
8- How many Hospital Blood Banks are in activity? We have only one hospital blood depot.	
9- 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 x □ No □
If YES, please describe	

Our national provisions are according to the Swiss provisions laid down in the Heilmittelgesetz, SR 812.21, and Arneimittelbewilligungsverordnung, SR812.212.1, which are also valid for FL, **(www.swissmedic.ch).**	
LITHUANIA	
8- How many Hospital Blood Banks are in activity? 115	
9- 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 □ No x□
MALTA	
8- How many Hospital Blood Banks are in activity? 4	
9- 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 □ No x□
THE NETHERLANDS	
8- How many Hospital Blood Banks are in activity?	
9- 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 □ No □
If YES, please describe	
NORWAY	
8- How many Hospital Blood Banks are in activity? 36	
9- 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 x No □
If YES, please describe; General laws regulation the health care sector, including hospitals in general, laws on patients rights, laws glowering medical records etc	

POLAND	
8- How many Hospital Blood Banks are in activity? : 748	
9- 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 X No □
If YES, please describe: The organisation of treatment with blood components, pretransfusion testing, reporting of adverse events in hospitals is covered by the disposition of the Minister of Health from 2005.	
PORTUGAL	
8- How many Hospital Blood Banks are in activity? » 80	
9- 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 x No □
If YES, please describe We have legislation that includes pre transfusion testing and records, a more extensive screening for transmissible diseases and traceability.	
ROMANIA	
8- How many Hospital Blood Banks are in activity? About 300	
9- 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 ☒ No □
If YES, please describe Ord. 1224/2006 – Norms regarding the activity of hospital blood banks.	
SLOVAK REPUBLIC	
8- How many Hospital Blood Banks are in activity?	
9- 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	Yes □

of Directive 2002/98/EC)	No ☒
SLOVENIA	
8- How many Hospital Blood Banks are in activity? The number of blood banks is approx. 10 at the moment, but they are also under reorganisation to become compliant with the new requirements.	
9- 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 ☒ No
Hospital blood banks are ruled by legislation on health activities (Health Activities Act - (OJ. RS.No 09/92, 26/92, 13/93, 45/94, 37/95 in 08/96)	
SPAIN	
8- How many Hospital Blood Banks are in activity? Existen 250 **Servicios de transfusión**, pertenecientes a Hospitales públicos, en los que se realiza el **95%** de las transfusiones de país. En los Hospitales en España **no se elaboran componentes sanguíneos.**	
9- 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 x No □
If YES, please describe 1. Implantación de **Sistemas de Calidad** en todos los Servicios de Transfusión (Art.32 del RD 1088/2005), y 2. Implantación de **Comités de Transfusión** (Art. 40 del RD 1088/2005)	
SWEDEN	
8- How many Hospital Blood Banks are in activity? 82	
9- 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 □ No x
SWITZERLAND	

8- 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)	
9- 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 X No □
If YES, please describe PIC/S Guide for Blood Establishments (PE 005-2) and Cantonal regulations	
TURKEY	
8- How many Hospital Blood Banks are in activity?	
9- 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 √ No □
If YES, please describe There was a Law and a By- Law published in 1983. New Law has recently come into force in May 2007	
UNITED KINGDOM	
8- How many Hospital Blood Banks are in activity? 380	
9- 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 X No □
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 Directive(s). When necessary, the competent authority will carry out inspections to assess the compliance status of hospital blood banks	

5. INSPECTIONS

Member States shall ensure that the competent authority organises inspections and appropriate control measures in blood establishments to ensure that the requirements of this Directive are complied with – Art. 8.1 Directive 2002/98/EC.

AUSTRIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x No ☐
If YES, please describe 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.	
11- Have inspections of blood establishments already been conducted?	Yes x No ☐
If YES, how many?	
Regular inspections 2007	7 Blood Banks 14 Plasma Centres
Inspection following serious adverse events or reactions, or suspicion thereof	2 Blood Banks
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) AGES PharmMed Institute for Inspections, Medical Devices and Haemovigilance is in charge of conducting inspections on behalf of the Bundesamt für Sicherheit im Gesundheitswesen (Federal Office in Safety of Health Care).	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes x No ☐
If YES, please describe AGES PharmMed Institute for Inspections, Medical Devices and Haemovigilance is performing the inspections. The Bundesamt für Sicherheit im Gesundheitswesen is granting the authorization.	

14- Is a system in place for inspecting Hospital Blood Banks (HBB)?	Yes X No □
If YES, please describe The local medical officers are inspecting the HBB according to a checklist issued by the Federal Ministry of Health, Family and Youth.	
BELGIUM	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes X No □
If YES, please describe Organised by the Inspection department of the Federal Agency for Medicines and Health Products	
11- Have inspections of blood establishments already been conducted?	Yes X No □
If YES, how many?	
Regular inspections	2 in 2007, all will be inspected before the end of 2007
Inspection following serious adverse events or reactions, or suspicion thereof	0
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Members of the staff, designated by the King, of the Federal Agency for Medicines and Health Products or of the FPS Public Health, Food chain Safety and Environment.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes X No □
If YES, please describe The Minister of Health is granting the accreditation.	
14- Is a system in place for inspecting Hospital blood banks?	Yes X No □
If YES, please describe	

Organised by the Regional Ministries of Public Health.	
BULGARIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes ☑ No □
If YES, please describe: According to Bulgarian legislation BDA shall organize and carry out inspections in blood establishments and hospital blood banks on a regular basis. The interval between two inspections shall not exceed one year. BDA draws out a plan for inspections every year. The plan must be published on the BDA's website by the end of November each year. The inspections are regular or in case of serious adverse event or reaction.	
11- Have inspections of blood establishments already been conducted?	Yes ☑ No □
If YES, how many? **5**	
Regular inspections	**5**
Inspection following serious adverse events or reactions, or suspicion thereof	**0**
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors appointed by the executive director of BDA	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes ☑ No □
If YES, please describe Ministry of Health	
14- Is a system in place for inspecting Hospital blood banks?	Yes ☑ No □
If YES, please describe The System is one and the same like Blood establishments.	
CROATIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x□ No □

If YES, please describe is responsible for organising inspections and contr. measures	
11- Have inspections of blood establishments already been conducted?	Yes x□ No □
If YES, how many? 1	
Regular inspections	yes
Inspection following serious adverse events or reactions, or suspicion thereof	yes
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) pharmaceutical insp.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No x□
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No x□
CYPRUS	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No √□
11- Have inspections of blood establishments already been conducted?	Yes □ No √□
If YES, how many?	
Regular inspections	**NONE**
Inspection following serious adverse events or reactions, or suspicion thereof	**NONE**
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC)	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes √ □ No □
If YES, please describe	

It has been decided that it will be the governmental Pharmaceutical Services	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No √□
CZECH REPUBLIC	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x No □
If YES, please describe Inspections at opening and at regular intervals (2 years) are done in any blood establishment by State Institute for Drug Control	
11- Have inspections of blood establishments already been conducted?	Yes x No □
If YES, how many? Blood establishments are inspected every other year, in 2006 total 50 inspections	
Regular inspections	50
Inspection following serious adverse events or reactions, or suspicion thereof	0
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors from State Institute for Drug Control	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No X
14- Is a system in place for inspecting Hospital blood banks?	Yes X No □
If YES, please describe As for blood establishments but with limited scope, total 16 inspections in 2006	
DENMARK	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x No □
If YES, please describe	

Frequent inspections performed - Every second year	
11- Have inspections of blood establishments already been conducted?	Yes x No □
If YES, how many? **63**	
Regular inspections	**All**
Inspection following serious adverse events or reactions, or suspicion thereof	**None**
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors employed in the Danish Medicines Agency	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No X
14- Is a system in place for inspecting Hospital blood banks?	Yes x No □
If YES, please describe Frequent inspections performed	
ESTONIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes × No □
All individual collection centres should be inspected by the competent authority every two years.	
11- Have inspections of blood establishments already been conducted?	Yes × No □
Regular inspections	
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) National authority (i.e. State Agency of Medicines) specialists – Inspection department specialist and specialist from department of biologicals.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes ×

	No □
For laboratory or quality accreditation blood establishments may use services of respective institutions/companies.	
14- Is a system in place for inspecting Hospital blood banks?	Yes × No □
All individual blood banks should be inspected by the competent authority every two years. Inspections are performed in further steps: inspection master plan, information provided by the Hospital blood bank (i.e. quality manual, organogram, list of SOPs, list of equipment etc.), inspection agenda, inspection of Hospital blood bank official written inspection report, response from inspected Hospital blood bank and re-inspection.	
FINLAND	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes ☒ No
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 (every second year).	
11- Have inspections of blood establishments already been conducted?	Yes ☒ No
If YES, how many? Totally 73 inspections since the year 1996.	
Regular inspections After the transposition of the Directives normal inspection interval is 2 years. So every permanent site of the blood establishment and every mobile team will be inspected every second year.	
Inspection following serious adverse events or reactions, or suspicion thereof According to the Blood Service Act (197/2005) the competent authority, National Agency for Medicines, has mandate to inspect blood establishment for these reasons. Until now there has been no need for this type of inspections. Procedures to handle SARs and SAEs are inspected as a part of normal inspections.	
12- What types of officials carry out inspections? (Article 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.	

13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes No ☒
14- Is a system in place for inspecting Hospital blood banks?	Yes No ☒
If YES, please describe National Agency for Medicines does not inspect hospital blood banks. According to the national legislation hospital blood banks are part of the hospital organisations and they are supervised by another Competent Authority.	
FRANCE	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes X
- The system in place for organising inspections was set up in France since 1994 and is based on regularly performed inspections. - 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.	
11- Have inspections of blood establishments already been conducted	Yes X
On 2006, 79 inspections concerning 101 blood activities	
77 Regular inspections	
2 Inspections following serious adverse events or reactions, or suspicion thereof	
12- What types of officials carry out inspections? Inspectors of the Afssaps	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	No X
By the same authority but by two different services.	
14- Is a system in place for inspecting Hospital blood banks?	Yes X
The organisation of the inspections system of Hospital blood banks was updated by the decree published at the French Official Journal on September 9, 2007. The inspections of these establishments are carried out at the regional level by the regional inspectorate.	
FYRoM	

10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ **No** □
11- Have inspections of blood establishments already been conducted?	Yes □ **No** □
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC)	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ **No** □
14- Is a system in place for inspecting Hospital blood banks?	Yes □ **No** □
GERMANY	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes X No □
If YES, please describe Section 64 sub-section 3 of the German Medicinal Products Act rules, that blood establishments inter alia have to be inspected before granting an authorisation. Furthermore they have to be inspected every two years.	
11- Have inspections of blood establishments already been conducted?	Yes X No □
If YES, how many? In all blood establishments before granting an authorisation and from then on every two years.	
Regular inspections	2-year-terms
Inspection following serious adverse events or reactions, or suspicion thereof	Yes
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors from the competent Land authorities carry out this activity as their main profession together with assessors from the higher federal authority (Paul-Ehrlich-Institute).	

13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No X
14- Is a system in place for inspecting Hospital blood banks?	Yes X No □
If YES, please describe The same as mentioned above for blood establishments.	
GREECE	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes X No
If YES, please describe: E.KE.A has not yet performed any inspections since its establishment	
11- Have inspections of blood establishments already been conducted?	Yes X No □
If YES, how many? 95	
Regular inspections yes, by previous competent authorities	
Inspection following serious adverse events or reactions, or suspicion thereof occasionally	
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Same as above	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No X
14- Is a system in place for inspecting Hospital blood banks?	Yes X No □
If YES, please describe: E.KE.A has not yet performed any inspections since its establishment	
HUNGARY	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x

	No □
If YES, please describe Inspectors of the National Institute of Pharmacy control the HNBTS every 2 years.	
11- Have inspections of blood establishments already been conducted?	Yes x No □
If YES, how many? 3 times	
Regular inspections	yes
Inspection following serious adverse events or reactions, or suspicion thereof	
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) According to directive Art 8.3.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No x
14- Is a system in place for inspecting Hospital blood banks?	Yes x No □
If YES, please describe Executive Office of Chief Medical Officer and the Headquarters of the HNBTS	
ICELAND	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No X
11- Have inspections of blood establishments already been conducted?	Yes □ No X
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors from the Icelandic Medicines Control Agency as well as representatives from the Chief Medical Officers office.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes X No □
If YES, please describe	

The Ministry of Health and Social Security issues licence based on the outcome of the inspection, see answer to question 12.	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No X
IRELAND	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes √ No □
If YES, please describe Blood establishments have been inspected at least two times prior to being authorised Once authorised we will inspect a new blood establishments after 12 months to observe how the quality system is operating Blood establishments will be inspected once every two years The inspections are organised by a planning manager who uses an Excel spreadsheet to manager the inspections	
11- Have inspections of blood establishments already been conducted?	Yes √ No □
If YES, how many? a) The main supplier of allogeneic blood in Ireland has been inspected since 1996. The site is inspected every 6 months at both of its fixed sites (4 times per year) b) Our 4 other blood establishments have been inspected at least 2 times since they applied for authorisation	
Regular inspections All the above inspections of (a) above have been carried out as regular inspections. For (b) above they have been inspected as part of the authorisation process	
Inspection following serious adverse events or reactions, or suspicion thereof None to date	
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) As per PICs document for training of inspectors	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No √
14- Is a system in place for inspecting Hospital blood banks?	Yes √ No □

If YES, please describe Hospital blood banks submit a yearly report and declaration in relation to compliance with legislation. If there are non compliances or concerns the IMB inspect the site All blood banks have to ISO 15189 (Medical laboratories -- Particular requirements for quality and competence) accredited by November 2008	
ITALY	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes **X** No □
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. The inspection system will be updated together with realization of the new authorisation/accreditation system, applying 21st Oct 2005 national Blood Law and national Decrees transposing European Directives. Legislative work for new authorisation/accreditation system will begin February 2008 and is expected to be completed by June 2008.	
11- Have inspections of blood establishments already been conducted? Inspections were performed based on pre-existing provisions.	Yes □ No **X**
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) To be determined when realizing the above new inspection system (regional inspection teams shall be integrated by National Blood Centre's auditors). Special training will be supplied care of the National Blood Centre.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes **X** No □
If YES, please describe Authorisation/accreditation is granted by regional health authorities through special inspection teams designated by means of regional provisions; objectivity and homogeneity shall be guaranteed by national auditors participating in regional inspection teams.	
14- Is a system in place for inspecting Hospital blood banks? See answer to question n. 5	Yes □ No □

LATVIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes × No □
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, Standards of quality for the collection, testing, processing, storage and distribution of human blood and blood components '' The collection of the blood and blood components for the check and analysis is planned in the end of year 2007	
11- Have inspections of blood establishments already been conducted?	Yes □ No ×
12- What types of officials carry out inspections? (Article 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	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No ×
14- Is a system in place for inspecting Hospital blood banks?	Yes × No □
If YES, please describe CA is ready realized Hospital blood banks inspection that provide for the Rule of the Cabinet of Ministers, Standards of quality for the collection, testing, processing, storage and distribution of human blood and blood components '' The conformity of assessment system in place for **inspecting** Hospital blood banks.	
LIECHTENSTEIN	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x □ No □
If YES, please describe, see answer 12	

11- Have inspections of blood establishments already been conducted?	Yes x □ No □
If YES, how many? Our blood establishments are inspected since 1999 on a regular basis of 2 years.	
Regular inspections	yes
Inspection following serious adverse events or reactions, or suspicion thereof	Up to now not necessary
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspections of blood establishments in FL are delegated to inspectors of Swissmedic by contract	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes x □ No □
If YES, please describe Inspections: See answer 12 The Competent Authority for licensing is the Amt für Gesundheit (before 1 July 2007 it was the Kontrollstelle für Arzneimittel)	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No □
If YES, please describe	

LITHUANIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □x No □
If YES, please describe According to the order of the Minister of Health, inspections and control measures of blood establishments shall be organised on a regular basis. The interval between two control measures shall not exceed two years**.**	
11- Have inspections of blood establishments already been conducted?	Yes □x No □
If YES, how many? 4	
Regular inspections YES	
Inspection following serious adverse events or reactions, or suspicion thereof	

12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Specialists from the Ministry of Health, State Service of Accreditation for Health Care Activities, State Medical Audit Inspectorate	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □partly x No □
If YES, please describe 2 authorities **(**Ministry of Health and Medical Audit Inspectorate) are different	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No □ x
MALTA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No x
If YES, please describe N/A	
11- Have inspections of blood establishments already been conducted?	Yes □ No x
12- What types of officials carry out inspections? According to Article 8.3 Directive 2002/98/EC.	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No X
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No x
THE NETHERLANDS	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No □

If YES, please describe	
11- Have inspections of blood establishments already been conducted?	Yes □ No □
If YES, how many? 1(= 4)	
Regular inspections	1(=4)
Inspection following serious adverse events or reactions, or suspicion thereof	--
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No □
If YES, please describe Minister is competent authority, but in practise: granting is Ministry of Health and inspecting is Inspectorate	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No □
If YES, please describe	
NORWAY	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x No □
If YES, please describe; Through the Medicines Agency and the Norwegian Board of Health Supervision	
11- Have inspections of blood establishments already been conducted?	Yes x No □

If YES, how many? A running program	
Regular inspections	Every second year
Inspection following serious adverse events or reactions, or suspicion thereof	Yes
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Persons with pharmaceutical background and officials (different backgrounds) from the Board of Health Supervision	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes x No □
If YES, please describe Directorate for Health and Social Affairs is the accreditation body.	
14- Is a system in place for inspecting Hospital blood banks?	Yes x No □
If YES, please describe; In Norway we only have hospital blood bank – for information of inspections please see question 10 to 12	
POLAND	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes X No □
If YES, please describe: Institute of Haematology and Blood Transfusion inspects blood establishments concerning collection, preparation, testing, storage, transportation and release of blood components. The Main Pharmaceutical Inspectorate inspects blood establishments as a producers of plasma for fractionation (according to the Pharmaceutical law) and issues GMP-certificates.	
11- Have inspections of blood establishments already been conducted?	Yes X No □
If YES, how many? Every 2 years	
Regular inspections	YES
Inspection following serious adverse events or reactions, or suspicion thereof	YES
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC): Institute of Haematology and Blood Transfusion and The Main Pharmaceutical Inspectorate (conc. plasma for fractionation). Both bodies are working on behalf of the Minister of Health	

13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes X No □
If YES, please describe: The Minister of Health grants the accreditation and Institute of Haematology and Blood Transfusion in Warsaw inspects the blood establishments and prepares a report for the Minister of Health.	
14- Is a system in place for inspecting Hospital blood banks?	Yes X No □
If YES, please describe: Hospital blood banks are inspected by the Regional Centres for Transfusion Medicine (which are legally independent from hospitals).	
PORTUGAL	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No x
11- Have inspections of blood establishments already been conducted?	Yes □ No x
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC)	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No x
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No x
ROMANIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No ☒
11- Have inspections of blood establishments already been conducted?	Yes □ No ☒
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC)	

13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes ☒ No □
If YES, please describe The accreditation authority is the Ministry of Public Health. The inspection authority is the State Sanitary Inspection	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No ☒
SLOVAK REPUBLIC	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes ☒ No □
If YES, please describe	
11- Have inspections of blood establishments already been conducted?	Yes ☒ No □
If YES, how many? Every two year	
Regular inspections 10 inspections in year 2007	
Inspection following serious adverse events or reactions, or suspicion thereof	No
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Inspectors of SIDC, Slovak Republic	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes ☒ No □
If YES, please describe Accreditation: Ministry of Health, Slovak Republic Inspections: STATE INSTITUTE FOR DRUG CONTROL	
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No ☒

SLOVENIA	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes ■ No □
If YES, please describe §7 Blood Supply Act (Official gazette of RS, No. 104/2006, 9. October 2006)	
11- Have inspections of blood establishments already been conducted?	Yes □ No □
If YES, how many? Only 1 pre-verification inspection was conducted according to the new Law on blood supply. (others were conducted according to the previous legislation)	
Regular inspections	
Inspection following serious adverse events or reactions, or suspicion thereof	
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Pharmaceutical supervisors/inspectors from competent authority (JAZMP), with the same competencies as described in Medicinal Product Act (Official gazette of RS, No. 31/2006)	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes ■ No □
If YES, please describe Pharmaceutical supervisors/inspectors from competent authority (JAZMP) are competent to perform inspections and conduct authorisation procedures – authorisation is issued by JAZMP Accreditation is issued by accreditation body.	
14- Is a system in place for inspecting Hospital blood banks?	Yes ■ No
If YES, please describe Hospital blood banks are ruled by legislation on health activities and also inspected by MoH Administrative inspection and supervised by Chamber of Medicines,	
SPAIN	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x

	No □
If YES, please describe : Existen dos tipos: 1.Por las **Comunidades Autónomas** (**Autoridades Sanitarias Regionales**), que tienen la competencia en conceder las autorizaciones/licencias. La inspección se realiza por el **inspector** de la Consejeria de Salud, siempre acompañado de un experto en medicina transfusional. Los estándares utilizados son los criterios recogidos en el RD 1088/2005 2.Inspecciones derivadas de los Sistemas de Acreditación realizada por el **CAT** (Comité de Acreditación en Transfusión). Auditorias externas realizadas por las **Sociedades Científicas.**	
11- Have inspections of blood establishments already been conducted?	Yes **x** No □
If YES, how many? **24**	
Regular inspections	**SI**
Inspection following serious adverse events or reactions, or suspicion thereof	**NINGUNA**
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) 1.Por las **Comunidades Autónomas** (**Autoridades Sanitarias Regionales**), que tienen la competencia en conceder las autorizaciones/licencias. La inspección se realiza por el **inspector** de la Consejeria de Salud (funcionario), siempre acompañado de un experto en medicina transfusional. Los estándares utilizados son los criterios recogidos en el RD 1088/2005 2.Inspecciones derivadas de los Sistemas de Acreditación realizada por el **CAT** (Comité de Acreditación en Transfusión). Auditorías externas realizadas por las **Sociedades Científicas.** Los inspectores son expertos de Medicina Transfusional, y los estándares son propios del CAT (basados en la legislación vigente)	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No **x**
14- Is a system in place for inspecting Hospital blood banks?	Yes **X** No □
If YES, please describe 158 Servicios de Transfusión han sido inspeccionados en los últimos años por las autoridades regionales y por el CAT, que supone en relación al volumen transfusional total del país, que el 80% ha sido inspeccionado de alguna manera. De forma progresiva las autoridades regionales están implantando sistemas de inspección, de manera que en la actualidad, el 30% de la inspecciones ha sido realizadas por ellas, y el 70% restante por las Sociedades Científicas.	
SWEDEN	

10- Is a system in place for organising inspections and control measures of blood establishments?	Yes x No ☐
If YES, please describe NBHW: An instrument is developed, we have a plan for inspections according to the law MPA: MPA has been inspecting blood establishments every second year since 1994. Establishment that been inspected is those who supply components for manufacturing of medicinal products.	
11- Have inspections of blood establishments already been conducted?	Yes x No ☐
If YES, how many? MPA: see question 10	
Regular inspections	NBHW: 2
Inspection following serious adverse events or reactions, or suspicion thereof	NBHW: 1 MPA: 0
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) NBHW: Officials from The National Board of Health and Welfare MPA: Pharmaceutical inspectors at the MPA	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes ☐ No x
14- Is a system in place for inspecting Hospital blood banks?	Yes x No ☐
If YES, please describe The same system as we described in number 10	
SWITZERLAND	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes **X**

	No □
If YES, please describe The Department Inspectorates of Swissmedic conducts these inspections and has a quality management system and accreditation according to ISO 17020 for their activities.	
11- Have inspections of blood establishments already been conducted?	Yes **X** No □
If YES, how many?	
Regular inspections Approximately 40 per year since 1996	Since 1996
Inspection following serious adverse events or reactions, or suspicion thereof (has not been considered necessary)	1
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) Employees of Swissmedic with the ISO 17020-QM-contolled qualification as Inspectors	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No **X**
14- Is a system in place for inspecting Hospital blood banks?	Yes **X** No □
If YES, please describe Cantonal authorities (see also under 8)	
TURKEY	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes □ No √
11- Have inspections of blood establishments already been conducted?	Yes □ No □
If YES, how many? ---	
Regular inspections	
Inspection following serious adverse events or reactions, or suspicion thereof	---

12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) ---	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No √
14- Is a system in place for inspecting Hospital blood banks?	Yes □ No √
UNITED KINGDOM	
10- Is a system in place for organising inspections and control measures of blood establishments?	Yes X No □
If YES, please describe. The collection, processing and storage sites of blood banks are subject to a regular inspection programme by the MHRA every 2 years, with more frequent inspections when considered necessary.	
11- Have inspections of blood establishments already been conducted?	Yes X No □
If YES, how many? 5 pre-approval inspections of new BEs prior to 8th Nov 2005	
Regular inspections (Since 8th Nov 2005)	18
Inspection following serious adverse events or reactions, or suspicion thereof	None of BEs
12- What types of officials carry out inspections? (Article 8.3 Directive 2002/98/EC) GMP Inspectors employed by the MHRA	
13- Is the authority/service granting the accreditation different than the authority/service inspecting the blood establishment?	Yes □ No X
If YES, please describe	
14- Is a system in place for inspecting Hospital blood banks?	Yes X No □
If YES, please describe See answer to question 9	

6. DONOR'S ELIGIBILITY CRITERIA

AUSTRIA	
15- 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.2.1 Directive 2004/33/EC)	Yes X No ☐
If YES, please describe (including dates of adoption/review(s) and rational) 1999 by the Blutsicherheitsgesetz (Blood safety Act) and the Blutspenderverordnung (Blood donor ordinance) Rational: This 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	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
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	
15- 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.2.1 Directive 2004/33/EC)	Yes ☑ No ☐
If YES, please describe (including dates of adoption/review(s) and rational)	
CROATIA	
15- 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.2.1 Directive 2004/33/EC)	Yes x□ No □

If YES, please describe (including dates of adoption/review(s) and rational) August 2007.	
CYPRUS	
15- 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.2.1 Directive 2004/33/EC)	Yes √□ No □
If YES, please describe (including dates of adoption/review(s) and rational) With questions to the donor such as: ‘’your sexual life is steady with the same partner?’’ Date of adoption: 2006, when Directive 2004/33/EC was transposed into our national law.	
CZECH REPUBLIC	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
If YES, please describe (including dates of adoption/review(s) and rational) Decree of MoH No. 411/2004 Col. (valid since July 13, 2004)	
DENMARK	
15- Are there national guidelines for the assessment of riskful sexual behaviour? ("Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - Annex III.2.1 Directive 2004/33/EC)	Yes x No □
If YES, please describe (including dates of adoption/review(s) and rational) Executive Order No. 24 of Jan 19 on safety related to the donation of blood.	
ESTONIA	
15- 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.2.1 Directive 2004/33/EC)	Yes × No □

Regulation of the minister of Social Affairs was adopted on 29. April 2005 and took effect on 15th May 2005.	
FINLAND	
15- 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.2.1 Directive 2004/33/EC)	Yes □ No □
If YES, please describe (including dates of adoption/review(s) and rational) There are no national guidelines; only the Directive requirements have been transposed into national legislation. The licenced blood establishment (Finnish Red Cross Blood Service) has detailed guidance how to assess the risk sexual behaviour. That guidance is based on the Directives and Council of Europe Guide to the preparation, use and quality assurance of blood components.	
FRANCE	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
France has a blood selection donor process. This process are excluding man/man sexual partners because an assessment of a high risk. The Health Minister is going to firm a regulation based on a rigorous work of a group which had brought together all experts of agencies. This group is going to proposed new rules.	
FYRoM	
15- 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.2.1 Directive 2004/33/EC)	**Yes** □ No □
If YES, please describe (including dates of adoption/review(s) and rational)	
GERMANY	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
If YES, please describe (including dates of adoption/review(s) and rational) Point 2.2.1, last bullet point of the "Haemotherapy-Directives" of Bundesärztekammer and Paul-Ehrlich-Institute (published in the Bundesanzeiger of 5 November 2005) says that persons, whose sexual behaviour or life-circumstances put them at a clearly higher risk of acquiring severe infectious diseases that can be transmitted	

by blood (e.g. HBV, HCV or HIV) than the average population, are permanently excluded from blood donation.	
GREECE	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
If YES, please describe (including dates of adoption/review(s) and rational) Presidential decree 138/2005	
HUNGARY	
15- 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.2.1 Directive 2004/33/EC)	Yes x No □
If YES, please describe (including dates of adoption/review(s) and rational)	
ICELAND	
15- 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.2.1 Directive 2004/33/EC)	Yes □ No X
IRELAND	
15- 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.2.1 Directive 2004/33/EC)	Yes √ No □
If YES, please describe (including dates of adoption/review(s) and rational) There is no National legislation in relation to assessment of at risk sexual behaviours. However, our allogenic blood establishment has its own guidance and deferral criteria in place for assessment of at risk sexual behaviours.	
ITALY	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □

If YES, please describe (including dates of adoption/review(s) and rational):

The Decree of the Minister of Health of 3 March 2005 transposed the above provision as follows: "persons with sexual behaviours implying high risk of transmission of infectious diseases or affected by HIV and/or hepatitis infection shall not donate blood". General orientation is that physicians in charge of blood donor selection are responsible for assessing at risk behaviours case by case. Blood donor selection and eligibility is by law on charge of a physician, who must be transfusion medicine specialist or, at least, suitably trained.

LATVIA

15- 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.2.1 Directive 2004/33/EC)	Yes × No □

If YES, please describe (including dates of adoption/review(s) and rational)

, , Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood" - this requirement included 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 ''(in force since 27th of December , 2005)

LIECHTENSTEIN

15- 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.2.1 Directive 2004/33/EC)	Yes □ No □

If YES, please describe (including dates of adoption/review(s) and rational)

FL does not have national guidelines. The blood is collected by the Austrian Red Cross in FL, executed by an Austrian blood bank.

LITHUANIA

15- 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.2.1 Directive 2004/33/EC)	Yes x□ No □

If YES, please describe (including dates of adoption/review(s) and rational)

The donor's questionnaire is approved by the order of the Minister of Health on 4 February, 2005.

MALTA

15- 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.2.1 Directive 2004/33/EC)	Yes x No □

If YES, please describe (including dates of adoption/review(s) and rational) As per Council of Europe recommendations since 1984. Regular review yearly or as issues arise.	
THE NETHERLANDS	
15- 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.2.1 Directive 2004/33/EC)	Yes □ No □
If YES, please describe (including dates of adoption/review(s) and rational) Richtlijn donorkeuring	
NORWAY	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
If YES, please describe (including dates of adoption/review(s) and rational) A national guideline is published by the Directorate for Health and Social Affairs and followed by all blood banks. The latest one is of November 2006.	
POLAND	
15- 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.2.1 Directive 2004/33/EC)	Yes X No □
If YES, please describe (including dates of adoption/review(s) and rational): adopted in 18.04.2005.	
PORTUGAL	
15- 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.2.1 Directive 2004/33/EC)	Yes x No □
If YES, please describe (including dates of adoption/review(s) and rational) We do not accept as donor MSM, prostitutes and person with multiple partners.	
ROMANIA	

15- 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.2.1 Directive 2004/33/EC)	Yes ☒ No □
If YES, please describe (including dates of adoption/review(s) and rational) Ord. 1193/2007 – Information provided to donors, information received from donors and donors acceptability criteria	
SLOVAK REPUBLIC	
15- 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.2.1 Directive 2004/33/EC)	Yes ☒ No □
If YES, please describe (including dates of adoption/review(s) and rational) Decree Ministry of Health Nr. 333/2005 - Annex 2	
SLOVENIA	
15- 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.2.1 Directive 2004/33/EC)	Yes ■ No □
If YES, please describe (including dates of adoption/review(s) and rational) Laid down in rules on criteria for blood donors and in rules on necessary testing of every blood bag [Pravilnik o strokovno medicinskih pogojih za odvzem krvi (Official gazette of RS, No. 9/2007); Pravilnik o obveznem testiranju krvi in komponent krvi (Official gazette of RS, No. 9/2007); 2. February 2007]	
SPAIN	
15- 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.2.1 Directive 2004/33/EC)	Yes **x** No □
If YES, please describe (including dates of adoption/review(s) and rational) En España se dispone de una Guía nacional donde se recogen de forma pormenorizada los comportamientos de riesgo asociados a la infección VIH, sin provocar en el donante un efecto de discriminación u ofensa**.** (Fuente: "Guía para la promoción de la donación de sangre. Criterios básicos para la selección de donante de sangre y componentes sanguíneos".Ministerio de Sanidad y Consumo. última edición 2006).	
SWEDEN	
15- Are there national guidelines for the assessment of at risk sexual behaviours? *("Persons whose sexual behaviour puts them at*	Yes **X**

high risk of acquiring severe infectious diseases that can be transmitted by blood" **- Annex III.2.1 Directive 2004/33/EC)**	No □
If YES, please describe (including dates of adoption/review(s) and rational) According to the directive issued in December 2006	
SWITZERLAND	
15- 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.2.1 Directive 2004/33/EC)	Yes **X** No □
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 Recommendations of the Council of Europe (Guide to the preparation, use and quality assurance of blood components).	
TURKEY	
15- 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.2.1 Directive 2004/33/EC)	Yes √ No □
If YES, please describe (including dates of adoption/review(s) and rational) There is a questionnaire for blood donors and on explanation sheet for the questionnaire.	
UNITED KINGDOM	
15- 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.2.1 Directive 2004/33/EC)	Yes x No □
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 ('The Red Book') state the UK position that a man who has ever had oral or anal sex with another man, even if a condom or other protective was used must never donate.	

7. SERIOUS ADVERSE EVENTS AND REACTIONS

AUSTRIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No ☐
If YES, 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 for Poisening) 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. The reports are collected at the ÖBIG/GÖG, in the future 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.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes X** **No** ☐
Please describe The two vigilance systems are implemented in the same agency. Plasma derivatives have to be linked with the plasma sourcing in case of recalls or reporting of a seroconverted plasma or blood donor or vice versa.	
18- Is there a link with a national vigilance system for medical devices?	Yes X No ☐
Please describe It is in the same agency and the same institute. Infectious marker testing and blood component collection by aphaeresis machines need a thorough connection with haemovigilance for donor and recipient safety.	
BELGIUM	

16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
YES, 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.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes X** **No** □
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.	
18- Is there a link with a national vigilance system for medical devices?	Yes X No □
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.	
BULGARIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes ☑ No □
If YES, please give a short description of the system	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** ☑
18- Is there a link with a national vigilance system for medical devices?	Yes □

	No ☑
CROATIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x□ No □
If YES, please give a short description of the system Voluntary system since 1998	
17- Is there a link with the national/European pharmacovigilance system?	**Yes x□** **No** □
Please describe The report is send to Croatian agency for medicines and to EHN	
18- Is there a link with a national vigilance system for medical devices?	Yes x□ No □
Please describe MOH, Agency for medicines, medical devices is informed and MOH does withdrawal of MD	
CYPRUS	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes □ No √ □
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** √□
18- Is there a link with a national vigilance system for medical devices?	Yes □ No √□
CZECH REPUBLIC	

16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x No □
If YES, please give a short description of the system reporting of any serious "blood product related" adverse events and reactions in donor and recipient to State Institute for Drug Control	
17- Is there a link with the national/European pharmacovigilance system?	Yes X No □
Please describe organised by the same institution, e.g. State Institute for Drug Control	
18- Is there a link with a national vigilance system for medical devices?	Yes x No □
Please describe organised by the same institution, e.g. State Institute for Drug Control	
DENMARK	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x No □
If YES, please give a short description of the system Executive Order No. 1016 of Oct 9 on reporting and monitoring of serious adverse events and reactions related to the usage of human blood products.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No x**
18- Is there a link with a national vigilance system for medical devices?	Yes □ No x

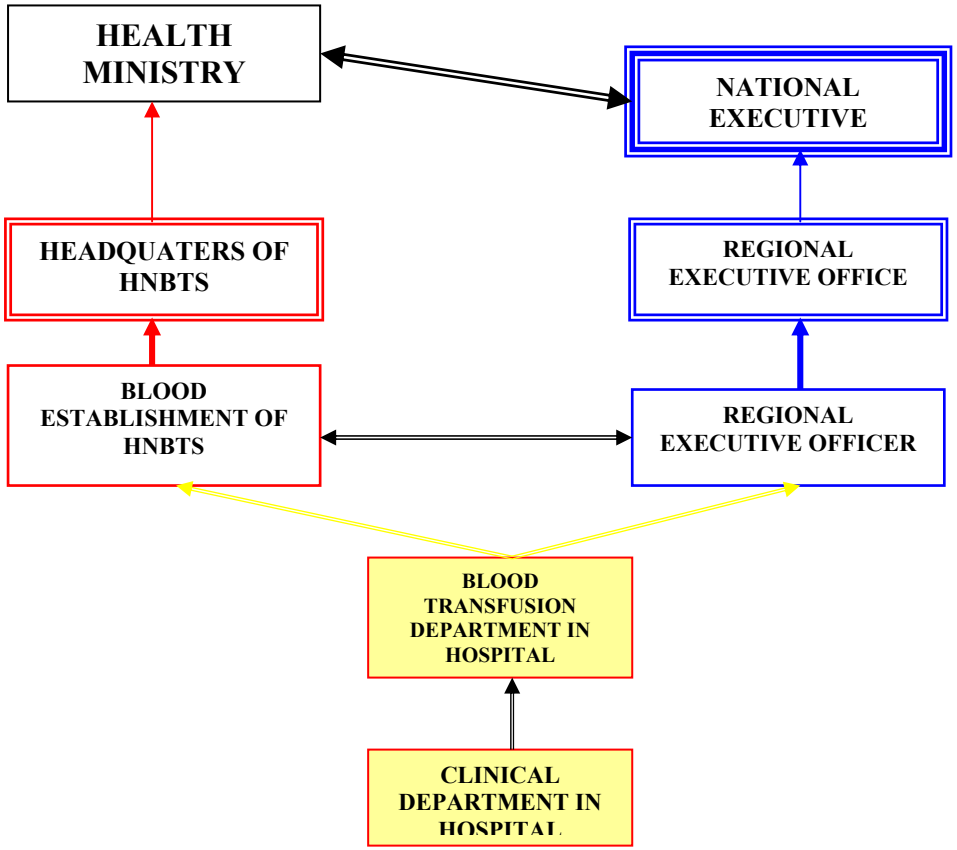
Please describe Manual intern circulation	
ESTONIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes × No □
Blood bank (reporting establishment) informs appropriate Blood establishment of serious adverse event. Blood establishment must report to the State Agency of Medicines about serious adverse event (ADR), initialisation of flashback procedure, recall of suspicious blood and blood components and inappropriate management of blood and blood components. State Agency of medicines compiles on the basis of the blood establishment reports the annual report for the minister of Social Affairs. *Recall procedure of the blood and blood components is regulated by the regulation of the minister of Social Affairs.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** × **No** □
There is equal system for all medicinal products in Estonia. Health care professionals report local ADR cases to the State Agency of Medicines, which transmits cases to EMEA Eudravigilance database and to marketing authorisation holder.	
18- Is there a link with a national vigilance system for medical devices?	Yes × No □
Healthcare service provider informs manufacturer or authorised representative and State Agency of Medicines about incidents of medical device that caused or could have caused serious adverse reaction in patient. Manufacturer or authorised representative informs immediately State Agency of Medicines about incidents of medical device. Medical device distributor must inform manufacturer about incidence of medical device. State Agency of Medicines must be informed of the investigation results on subject what have caused incidence. If such incidence has caused serious adverse reaction in patient, healthcare service provider must also be informed of investigation results.	

FINLAND	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes ☒ No
If YES, 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).	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** □
Please describe Responsibility of the National Agency for Medicines (NAM) is to ensure the efficacy, safety and quality of medicinal products on sale in Finland. The authority responsible for pharmacovigilance and haemovigilance is the same and co-operation between these two systems is active.	
18- Is there a link with a national vigilance system for medical devices?	Yes □ No □
Please describe NAM oversees also the safety and quality of medical devices and co-operation between these systems is also active.	
FRANCE	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X
The French system of haemovigilance was set up since : - January 1994 to collect, supervise and evaluate all the adverse reactions occurring at the patients, - May 2007 to collect, supervise and evaluate the serious adverse reactions occurring at the blood and blood components donors, - May 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.	

17- Is there a link with the national/European pharmacovigilance system?	Yes X
There is a link between the haemovigilance system and the other vigilance systems (pharmacovigilance, biovigilance, vigilance systems for medical devices and for medical devices of in vitro diagnosis, etc…), but only at the national level.	
18- Is there a link with a national vigilance system for medical devices?	Yes X
There is a link between the haemovigilance and the medical devices vigilance system at the national level and in co-operation with the European Haemovigilance Network (EHN)	
FYRoM	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	**Yes** □ No □
If YES, please give a short description of the system Hospital transfusion committee are planed to be orm	
17- Is there a link with the national/European pharmacovigilance system?	Yes □ **No** □
18- Is there a link with a national vigilance system for medical devices?	Yes □ **No** □
GERMANY	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
If YES, please give a short description of the system Section 63c of the German Medicinal Products Act obligates the holder of a marketing authorisation for blood preparations to maintain documentation about all serious adverse events and reactions and to notify them to the competent Higher Federal Authority. At least once a year, he has to present an updated report to the	

competent Higher Federal Authority. Regarding autologous and directed blood products the reports are presented to the competent Land authorities.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes X** **No** □
Please describe Haemovigilance is a part of the national pharmacovigilance system.	
18- Is there a link with a national vigilance system for medical devices?	Yes □ No X
Please describe There exists an information system between the responsibles for MD vigilance and blood components between the higher competent authorities. Moreover, the responsibility for haemovigilance and IVD vigilance is administrated by the same personnel in a department in one of the higher federal authorities (Paul-Ehrlich-Institute).	
GREECE	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
If YES, please give a short description of the system E.KE.A reports directly to the Ministry of Health and/or Hellenic National Coordinating Haemovigilance system	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No X**
Please describe	
18- Is there a link with a national vigilance system for medical devices?	Yes □ No X

Please describe	
HUNGARY	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x No □
If YES, please give a short description of the system Process of the dispatch	



17- Is there a link with the national/European pharmacovigilance system?	**Yes x** **No** □
Please describe	
18- Is there a link with a national vigilance system for medical devices?	Yes x

	No □
Please describe	
ICELAND	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
If YES, please give a short description of the system So far only within Iceland to the blood establishment.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No X**
Please describe **It is planned to link adverse events and reactions reporting to the national pharmacovigilance system. At the moment they are reported to the European Haemovigilance.**	
18- Is there a link with a national vigilance system for medical devices?	Yes □ No X
IRELAND	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes √ No □
If YES, please give a short description of the system The blood establishment and blood banks report to the National Haemovigilance office who subsequently investigate and report to the competent authority at regular meetings	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** √

18- Is there a link with a national vigilance system for medical devices?	Yes □ No √
ITALY	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes **X** No □
If YES, please give a short description of the system System in place appears rather cumbersome and not fully compliant with Commission Directive 2005/61/CE. Thus, it has been renewed by the national Decree transposing Commission Directive 2005/61/EC (Decree of 9 November 2007, n. 207), and it will be integrated in the new national blood information system (SISTRA), instituted by the Decree of the Minister of Health of 21 December 2007.	
17- Is there a link with the national/European pharmacovigilance system? A link with the national pharmacovigilance system is envisaged, as vigilance on plasma derived products is included in the latter	**Yes X** **No** □
18- Is there a link with a national vigilance system for medical devices? A link can be envisaged if deemed necessary	Yes □ No **X**
LATVIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes × No □
If YES, please give a short description of the system The system for reporting of serious adverse events and serious adverse 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 the cause and the ensuing outcome.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □

	No ×
18- Is there a link with a national vigilance system for medical devices?	Yes × No □
Please describe Have a procedure of unite supervision system in Latvia.	
LIECHTENSTEIN	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x □ No □
If YES, please give a short description of the system Our blood establishments have to report both to the Swiss authority Swissmedic and have also to report to the Austrian blood bank which is collecting the blood in FL.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** x □ **No** □
Please describe: via Austria	
18- Is there a link with a national vigilance system for medical devices?	Yes x □ No □
Please describe The national vigilance system for medical devices is via the Swissmedic Vigilance System.	
LITHUANIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes □x No □

If YES, please give a short description of the system According to the order of the Minister 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.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** **x**□
Please describe	
18- Is there a link with a national vigilance system for medical devices?	Yes □ No x□

MALTA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x No □
If YES, please give a short description of the system There is an internal procedure of documenting and reporting adverse events. Serious adverse events are notified to the delegate of the responsible authority.	
17- Is there a link with the national/European pharmacovigilance system?	Yes x No □
Please describe Currently, the contact point for haemovigilance, where serious adverse events and serious adverse reactions are reported to by blood banks and other establishments, is the Malta Medicines Authority. The reports received are then acknowledged and forwarded to the Licensing Authority responsible for haemovigilance. The Medicines Authority is also responsible for pharmacovigilance of medicinal products and for populating eudravigilance. Therefore, a formal link exists with the national/EU pharmacovigilance system.	
18- Is there a link with a national vigilance system for medical devices?	Yes □ No x

THE NETHERLANDS	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes □ No □
If YES, please give a short description of the system. The hospitals and the Blood Establishment are obliged to report the serious adverse events and serious adverse reactions to the competent authority and on a voluntarily basis to an independent foundation called TRIP (Transfusion Reactions in Patients). TRIP is responsible for haemovigilance. The Blood Establishment 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.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** □
18- Is there a link with a national vigilance system for medical devices?	**Yes** □ **No** □
Please describe there is a link with the human tissues and cells vigilance system; both are performed by TRIP (see www.tripnet.nl)	
NORWAY	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x No □
If YES, please give a short description of the system A national system for vigilance and surveillance of blood/blood products is established according to directive 2005/61/EF, and is put into the Norwegian blood regulation of 4 February 2008 no. 80 as last changed 1 January 2008.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes x** **No** □

Please describe Only on colleague basis. This will need to be further developed.	
18- Is the link with a national vigilance system for medical devices?	Yes x No □
Please describe Only on colleague basis. This will need to be further developed	
POLAND	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
If YES, 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 (IHBT).	
17- Is there a link with the national/European pharmacovigilance system?	**Yes X** **No** □
Please describe: IHBT reports Polish data to the European haemovigilance system. According to Polish law (Pharmaceutical law act) every user of medical products is obliged to report to the responsible bodies all suspicions of incompliance of medical product with its specification and all events in which medical product may be involved.	
18- Is the link with a national vigilance system for medical devices?	Yes X No □
Please describe: According to Polish law every user of medical devices is obliged to report to the responsible body all data of medical devices used that might be involved in adverse reaction or adverse event.	
PORTUGAL	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes x No x

If YES, please give a short description of the system Yes there is a system in place in all the hospitals but it is not centralized yet. Now with the start of our activity we are creating a national system.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No x**
18- Is there a link with a national vigilance system for medical devices?	Yes □ No x
Please describe There is not a link in a formal way but our medicine agency that has in charge the vigilance for medical devices, usually inform us.	
ROMANIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes □ No ☒
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** □
Please describe	
18- Is there a link with a national vigilance system for medical devices?	Yes ☒ No □
Please describe EQAS for TTI and immunohaematology	
SLOVAK REPUBLIC	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes ☒ No □

If YES, please give a short description of the system Decree Ministry of Health Nr. 487/2006	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** ☒ **No** □
Please describe	
18- Is there a link with a national vigilance system for medical devices?	Yes ☒ No □
Please describe	
SLOVENIA	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes ■ No □
If YES, please give a short description of the system Laid down in rules governing haemovigilance [Pravilnik o hemovigilanci (Official gazette of RS, No. 9/2007)]	
17- Is there a link with the national/European pharmacovigilance system? We have possibility to see the information, but there is no direct IT link or connection.	**Yes** □ **No**
Please describe JAZMP is responsible for haemovigilance, pharmacovigilance and materiovigilance	
18- Is there a link with a national vigilance system for medical devices? We have possibility to see the information, but there is no direct IT link or connection.	Yes □ No

Please describe JAZMP is responsible for haemovigilance, pharmacovigilance and materiovigilance	
SPAIN	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes **x** No □
If YES, please give a short description of the system Se ha constituido una **Unidad de Hemovigilancia**, dependiente de la DG de Salud Pública, que cuenta con una responsable, experta en Sistemas de Control de Alertas y Sistemas de Información. Las **17 regiones** han constituido **Sistemas de Hemovigilancia**. En cada una de las regiones existe un coordinador de Hemovigilancia, responsable de recoger y enviar con posterioridad los datos al Ministerio de Sanidad, quien tras su análisis edita el informe nacional.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No x**
18- Is there a link with a national vigilance system for medical devices?	Yes □ No x
SWEDEN	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
If YES, please give a short description of the system NBHW: The National Board of Health and Welfare register and judge the submitted reports MPA: Blood establishment have to inform the MPA as well as the manufacturer in writing.	
17- Is there a link with the national/European pharmacovigilance system? MPA: Only in that we can export cases from our national system via E2B to the EV.	Yes □ No X (NBHW)
18- Is there a link with a national vigilance system for medical devices?	Yes X (MPA) No x (NBHW)

Please describe NBHW: Ad hoc contacts between The National Board of Health and MPA MPA: All devices put on the market as medical devices must be covered by a vigilance system according to the requirements given in the applicable directive.	
SWITZERLAND	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes **X** No □
If YES, please give a short description of the system Every Health care Establishment (Hospitals, nursing homes etc.) that applies blood components is legally (Ordinance on medicines) obliged to denominate a Haemovigilance-Representative who complies with the mandatory reporting of adverse events.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes X** **No** □
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	
18- Is there a link with a national vigilance system for medical devices?	Yes **X** No □
Please describe The Division Medical Devices (Sector Market Surveillance of Swissmedic) is responsible for the Materiovigilance	
TURKEY	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes □ No √
17- Is there a link with the national/European pharmacovigilance system?	**Yes** □ **No** √

18- Is there a link with a national vigilance system for medical devices?	Yes □ No √
UNITED KINGDOM	
16- Is there a system in place for the reporting of serious adverse events and serious adverse reactions?	Yes X No □
If YES, please give a short description of the system "SABRE" is an online system, accessible through the MHRA's (UK Competent Authority) 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 set out in the Directive. Reporters may attach supporting documents and images to their online report. The Competent Authority's database that is connected to this system facilitates production of the annual summary reports required from reporters as well as the annual summary report to the Commission.	
17- Is there a link with the national/European pharmacovigilance system?	**Yes X** **No** □
Please describe The UK system for reporting SAEs and SARs is operated by the MHRA, the same Competent Authority as operates the pharmacovigilance system.	
18- Is there a link with a national vigilance system for medical devices?	Yes X No □
Please describe The UK system for reporting SAEs and SARs is operated by the MHRA, the same Competent Authority as operates the medical device vigilance system.	

8. TESTING REQUIREMENTS

AUSTRIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV1/2/O, HBsAg, HCV,	Serological tests
Neopterin	Serological tests
HCV	NAT
Voluntary: HIV, HBV, ParvoB19, HAV, HBc-Ak, CMV	NAT or serological, respectively
20- Are inactivators of pathogens used?	Yes □ No X
BELGIUM	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV1	Serological (anti-HIV1+2); NAT (HIV1NAT)
HIV2	Serological (anti-HIV1+2)
Hepatitis B	Serological (HbsAg, and for new donors also anti-HBc)
Hepatitis C	Serological (anti-HCV); NAT (HCVNAT)
Syphilis	Serological (TPHA, USR)
20- Are inactivators of pathogens used?	Yes X

	No □
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 has been authorised recently. Pathogen inactivation of platelet concentrates is not mandatory. The psoralene method was used in 2006 for the treatment of a small percentage of the platelet concentrates.	
BULGARIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Anti-HIV 1 and HIV 2 antibodies and antigen	Serological (ELISA)
HBsAg	Serological (ELISA)
Anti-HCV antibodies	Serological (ELISA)
Lues	Serological (ELISA)
20- Are inactivators of pathogens used?	Yes □ No ☑
CROATIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBV	HbsAg serological
HCV	HCV Ag / Ab serological
HIV	HIV Ag /Ab serological
SIFILIS	TP EIA serological

20- Are inactivators of pathogens used?	Yes □ No x □
CYPRUS	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Hepatitis B (HBs-Ag)	**Serological (enzyme immunoassay)**
HIV1 and HIV2 (p24)	**Serological (enzyme immunoassay)**
HCV	**Serological (enzyme immunoassay)**
Syphilis	**Serological (haemaglutination: TPHA)**
20- Are inactivators of pathogens used?	Yes □ No √□
CZECH REPUBLIC	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV	serology, HIV ½ antibody + HIV p24 antigen
HBV	serology, HBV surface antigen
HCV	serology, HCV antibody or HCV antibody + antigen
syphilis	serology, total antibody
20- Are inactivators of pathogens used?	Yes □* No X
If YES, please describe the processes used and the blood components concerned	

* comment: plasma is kept in 6 month quarantine	
DENMARK	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBsAG	Serological
Anti-HCV	Serological
Anti HIV 1/2	Serological
Anti HTLV I/II	Serological
20- Are inactivators of pathogens used?	Yes □ No x
ESTONIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Blood groups in ABO, Rh(D) and K systems	immunohematologically
Erythrocytic antibodies (D, C, E, c, e, K, k, Fya, Fyb, Jka, Lea, Leb, P1, M, N, S, s)	immunohematologically
Anti-HIV-1/HIV-2, Anti-HCV, HBsAg	serologically
HIV-Ag or HIV-NAT, HCV-Ag or HCV-NAT	two establishments perform serological tests, and two have implemented NAT
Treponema pallidium pathogen	Specifically or non-specifically
20- Are inactivators of pathogens used?	Yes □ No ×

FINLAND	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)? **Obligatory:**	
HBsAg	ABO Group
anti-HCV	Rh D Group
anti-HIV 1, 2	
The Finnish Red Cross Blood Service is testing also HIV Ab/Ag, HIV NAT, HCV NAT, Parvo B19 and Syphilis. HTLV is tested from the first donation and after that every 3. year.	The Finnish Red Cross Blood Service is testing twice also C, c, E, e and K antigens and some other clinically important antibodies of the first time donors.
20- Are inactivators of pathogens used?	Yes No ☒
FRANCE	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Laboratory blood screening tests for infectious agents	
Detection of HIV 1	Serological antibody test and NAT
Detection of HIV 2	Serological antibody test
Detection of HCV	Serological antibody test and NAT
Detection of HBV	Serological antigen test (HBsAg) and serological core antibody test (HBcAb)
Detection of HTLV I/II	Serological antibody test
Detection of Syphilis	Serological antibody test
Detection of Malaria, if necessary (individuals who have lived a malarial area or	Serological test

with history of undiagnosed febrile illness, visitors to endemic area …)	
Laboratory blood grouping tests	
Determination of the ABO group	Serological test
Determination of the Rh D group	Serological test
Detection of the anti-A and anti-B antibodies immunes	Serological test
Detection of the clinically significant irregular red cells antibodies	Serological test
Other laboratory tests for blood donors eligibility	
Dosage of haemoglobin	Photometric test
Dosage of protein (for plasma for fractionation donors)	Photometric test
Platelets counting (for platelets donors)	Photometric test
Additional laboratory tests	
The tests listed above are the minimum laboratory tests required by the French regulation for blood and blood components donation. Other tests can be added according to the : - Specific therapeutic indications (detection of anti-CMV antibodies, determination of the extended red cells phenotypes, determination of the extended platelets phenotypes, etc…) - Particular epidemiologic situations (WNV, VHB NAT, Chagas disease, Chikungunya virus, etc…).	
20- Are inactivators of pathogens used?	Yes X
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 treatment of red cells) : - Amotosalen with exposure to the UVA light, used for the treatment of platelets (platelets aphaeresisleukocytee-depleted and platelets recovered pooled leukocyte-depleted), - Solvent-detergent, used only for the viral inactivation of plasma (plasma fresh-frozen leukocyte-depleted), - Methylen blue with exposure to the visible light, used only for the viral inactivation of plasma (plasma fresh-frozen leukocyte-depleted), - Amotosalen with exposure to the UVA light, used for the treatment of plasma (plasma fresh-frozen leukocyte-depleted). Riboflavin with exposure to the UV light, used for the treatment of platelets (platelets apheresis leukocyte-depleted and platelets recovered pooled leukocyte-depleted), currently used only in clinical trials.	

FYRoM	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV 1+2 , HIV Ag	ENZYGNOST HIV INTEGRAL
HBsAg	HBsAg ENZYGNOST HBsAg 5-0
ANTI –HCV	ANTI-HCV ORTHO HCV 3.0 ELISA
SYPHILIS	
20- Are inactivators of pathogens used?	Yes □ **No** □

GERMANY	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
HIV-1/2	serological test for antibodies or combined antigen/antibody test
HIV-1	NAT
HCV	Serological test for antibodies and NAT
HBV	Serological test for HBsAg and for Anti-HBc-antibodies
T.pallidum	Serological test for T.pallidum antibodies

20- Are inactivators of pathogens used?	Yes X No □
If YES, please describe the processes used and the blood components concerned Methylenblue/light treatment of plasma, amotosalen/light treatment of platelets, solvent/detergent treatment of pooled plasma.	
GREECE	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV 1, 2	Serological 100%
Hep B & C	NAT for HIV 1, 2; hep B & C; 60%
HTLV I/II	
syphilis	
20- Are inactivators of pathogens used?	Yes X No □
If YES, please describe the processes used and the blood components concerned Methylen blue in few hospitals without centralized control	
HUNGARY	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Anti-HIV1/2	serological
Anti-HCV	serological
Anti-HBc for each first donor's sample	

HBsAg	serological
syphilis	serological
20- Are inactivators of pathogens used?	Yes □ No x
ICELAND	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
HIV (ag/ab)	Serological
Hepatitis B (ag)	Serological
HCV (ab)	Serological
ABO and D confirmation typing	Serological
20- Are inactivators of pathogens used?	Yes □ No X
IRELAND	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
For Allogeneic Blood	
HIV 1 & 2	NAT and Serology
Hepatitis B surface Antigen	Serology
Hepatitis B Core	Serology
Hepatitis C	NAT and Serology

Syphilis testing	Serology
CMV (immunocompromised patients paediatric patients)	Serology
	Serological requirements dictated by Blood Directive. However, our blood establishment responsible for 100% of Ireland's allogeneic blood performs NAT testing as listed above.
For Autologous Blood	
HIV 1 & 2	Serology
Hepatitis B surface Antigen	Serology
Hepatitis B Core	Serology
Hepatitis C	Serology
20- Are inactivators of pathogens used?	Yes √ No □
If YES, please describe the processes used and the blood components concerned Our major supplier of allogeneic blood is assessing Mirasol as an inactivator for plasma	
ITALY	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBsAg, Anti-HIV1-2, Anti-HCV, Syphilis	**Serological (mandatory)**
HCV RNA	**NAT (mandatory)**
HIV1 RNA, HBV DNA	**NAT (Recommended by the Minister of Health since April 2006. Decree for mandatory application approved by the Minister of Health, expected to be published within February 2008)**
AB0 Rh Typing / IAT	**Serological (mandatory)**
20- Are inactivators of pathogens used?	Yes **X**

Not routinely	No □
If YES, please describe the processes used and the blood components concerned Plasma: a) methylene blue (in house); b) S/D (pharmaceutical): commercially available treated plasma (Octaplas®) and contract manufacturing treatment of national plasma (Plasmasafe®). Platelets: a) psoralen-UV (in house); b) riboflavin-UV (in house)	
LATVIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBs Ag	Pathogenic agent of syphilis
Anti-HCV	
Anti- HIV 1/2	
20- Are inactivators of pathogens used?	Yes □ No ×
LIECHTENSTEIN	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)? See art. 18 of the Arzneimittelbewilligungsverordnung SR 812.212.1	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)

Arzneimittelbewilligungsverordnung

Art. 18 Testpflicht

1 Von jeder entnommenen Blutspende muss eine Probe unvermischt auf HIV 1 und 2, das Hepatitis-B-Virus (HBV), das Hepatitis-C-Virus (HCV) sowie auf Treponema pallidum getestet werden.

2 Von jeder entnommenen Fremdblutspende, die zur Transfusion oder zur Herstellung labiler Blutprodukte verwendet wird, muss zusätzlich eine Probe vermischt oder unvermischt auf das HI-Virus (HIV-1) und das Hepatitis-C-Virus (HCV) getestet werden. Der Test muss mittels einer geeigneten Nukleinsäuren-Amplifikationstechnik erfolgen, die nach dem Stand von Wissenschaft und Technik validiert ist.11

3 Bei den Tests muss Folgendes bestimmt werden:

a. Antikörper gegen HIV 1 und 2 (Anti-HIV 1+2-Antikörper);

b. Oberflächenantigen des Hepatitis-B-Virus (HBsAg);

c. Antikörper gegen das Hepatitis-C-Virus (Anti-HCV-Antikörper);

d. Antikörper gegen Treponema pallidum;

e. Alanin-Aminotransferase (ALAT).

4 Bei jeder entnommenen Blutspende müssen die Blutgruppe AB0 und der Rhesusfaktor D bestimmt werden.

5 Bei Plasma, das für die Fraktionierung verwendet werden soll, muss von jeder entnommenen Blutspende eine Probe unvermischt auf HIV 1 und 2, HBV und HCV getestet werden. Es müssen dafür Tests nach Absatz 3 Buchstaben a–c durchgeführt werden. Absatz 4 gilt nicht für Plasma, das für die Fraktionierung verwendet werden soll.

6 Bevor Blut oder Erythrozytenpräparate transfundiert werden, muss ihre Kompatibilität mit der Empfängerin oder dem Empfänger mit geeigneten Methoden überprüft werden.	
20- Are inactivators of pathogens used?	Yes □ No □
If YES, please describe the processes used and the blood components concerned	

LITHUANIA

19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
anti-HIV 1+2	HIV NAT and serological
HBsAg	HBV NAT and serological
anti-HCV	HCV NAT and serological
Syphilis	serological
20- Are inactivators of pathogens used?	Yes □ No x□

MALTA

19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)

Anti HIV 1 + 2	Serological
Hepatitis B including HBsAg, anti HCV, Anti HBc	Serological
Hepatitis C	Serological
Treponema pallidum	VDRL
CMV	Serological
HIV HBsAg HCV Anti HBc VDRL ALT	EIA serological
20- Are inactivators of pathogens used?	Yes □ No x
THE NETHERLANDS	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Treponema pallidum	TPPA
Hepatitis B and C	B: serological. C: serological and NAT
HIV 1/2	Serological and NAT
HTLV I/II	Serological antibodies
PARVO and CMV	On request
20- Are inactivators of pathogens used?	Yes □ No □
If YES, please describe the processes used and the blood components concerned For plasma: quarantine method	

For platelets: large multi-centre clinical trial with pathogen inactivation.		
NORWAY		
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?		
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)	
According to the directives	According to the directives	
20- Are inactivators of pathogens used?		Yes x No □
If YES, please describe the processes used and the blood components concerned Only in one hospital blood banks		
POLAND		
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?		
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)	
HIV1/2	Serological and NAT	
HCV	Serological and NAT	
HBV	Serological and NAT	
Lues	Serological	
20- Are inactivators of pathogens used?		Yes □ No X
PORTUGAL		
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)? Yes		

Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Hbs-Ag, anti Hbc	serological
Anti - HCV	serological
Anti HIV 1/2	serological
Anti HTLV ½, syphilis and ALT	serological
20- Are inactivators of pathogens used? **In Portugal about 60 -70 % of FFP used are SD Plasma. For platelets and red cells we are not used inactivation.**	Yes x No x
ROMANIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Ag-Ac HIV 1.2.0	Serological ELISA
Ag HBs	Serological ELISA
Ac anti HCV	Serological ELISA
Ac anti HTLV I/II	Serological ELISA
20- Are inactivators of pathogens used?	Yes □ No ☒
SLOVAK REPUBLIC	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Hepatitis B (Hbs-Ag)	
Hepatitis C (Anti HCV)	

HIV 1/2 (Anti HIV 1/2)	
Syphilis	
20- Are inactivators of pathogens used?	Yes □ No □
If YES, please describe the processes used and the blood components concerned	
SLOVENIA	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)? Pravilnik o obveznem testiranju krvi in komponent krvi (Official gazette of RS, No. 9/2007); 2. February 2007	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBsAg; HBV DNA	Serological
anti-HIV1/2/0 in p24Ag; HIV RNA	NAT
anti-HCV; HCV RNA	
anti-Treponema pallidum	
20- Are inactivators of pathogens used?	Yes □ No ■
SPAIN	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV I/II	Serological and NAT (100%)
HVC	Serological and NAT (100%)

AgHBs	Serological (100%) and NAT (70%)
Lues	Serological (100%)
20- Are inactivators of pathogens used?	Yes x No □
If YES, please describe the processes used and the blood components concerned Plasma (PFC): : 64% de los Centros utilizan Azul de Metileno (Methylene Blue), 34% Cuarentenado(Quarantined) Plaquetas: 3 Centros en rutina, 4 Centros en proceso de validación	
SWEDEN	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBsAg, anti-HCV, anti-HIV 1+2. For new donors also anti-HBc, anti-HTLV1/11 and syphilis	
20- Are inactivators of pathogens used?	Yes x No □
If YES, please describe the processes used and the blood components concerned Just a few use psoralene for platelets and plasma	
SWITZERLAND	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HIV 1 & 2	Serological (Ag/Ab) and NAT
HCV	Serological (Ab) and NAT

HBV	Serological (Ab)
Treponema pallidum	Serological (Ab)
20- Are inactivators of pathogens used?	Yes □ No **X**
TURKEY	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)?	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
Anti- HIV ½	(ELISA) Serological
HBs Ag	(ELISA) Serological
Anti- HCV	(ELISA) Serological
Syphilis	(VDRL, RPR, TPHA) Serological
20- Are inactivators of pathogens used?	Yes □ No √
UNITED KINGDOM	
19- What are the minimum laboratory tests required for blood and blood components donation in your country (these might be more stringent than the tests required by the Directive)? In addition to blood group serology requirements, blood and blood components must be found negative for the following mandatory microbiological tests: HBsAG, anti-HIV 1&2, HCV NAT, anti HTLV I/II and syphilis antibodies. Normally the presence or absence of these markers is determined by testing donor serum. However, plasma is usually the preferred analyte for HCV NAT, anti-HTLV and syphilis antibody testing.	
Agent (e.g. HIV 1, Hepatitis B, C, …)	Type of test (e.g. serological, NAT, …)
HBsAG, anti-HIV 1&2, anti HTLV I/II and syphilis antibodies	Serological
HCV	NAT
HIV	NAT (At some centres, as part of duplex HIV/HCV NAT test)

20- Are inactivators of pathogens used?	Yes X No □
If YES, please describe the processes used and the blood components concerned Methylen blue treated fresh frozen plasma obtained from outside the EU.	

9. IMPORT AND EXPORT OF BLOOD AND BLOOD COMPONENTS

AUSTRIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No ☐
If YES, please describe The customs require an import certificate from the Federal Agency for Safety in Health Care.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes ☐ No X
BELGIUM	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No ☐
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 fulfill 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 fulfill the required conditions.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes ☐ No X
BULGARIA	

21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes ☑ No □
If YES, please describe: Low on Blood, Blood donation and blood transfusion has articles for the requirements for importation of blood and blood components in case of disasters and accidents only. The imported blood and blood components shall be collected, tested, storied, and prepared in accordance with the Blood Directives requirements.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □ No ☑
CROATIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x□ No □
If YES, please describe No import, only exceptional, MOH has to give permission	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x□ No □
If YES, please describe No export, only exceptional, MOH has to give permission	
CYPRUS	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes √□ No □
If YES, please describe **Implementing Article 7 of Directive 2005/61/EC**	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes √□ No □
If YES, please describe **Implementing Article 7 of Directive 2005/61/EC**	
CZECH REPUBLIC	

21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No □
If YES, please describe Any import should be announced to and licensed by Ministry of Health	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x No □
If YES, please describe Any export should be announced to and licensed by Ministry of Health	
DENMARK	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x No □
If YES, please describe Only blood drawn in public Danish Blood Banks according to the Danish act on blood supply	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x No □
If YES, please describe Authorisation from Blood Donor Organisations and Danish Medicines Agency	
ESTONIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes × No □
According to national legislation blood and blood components are medicines, which importation requires special licence from National Authority (State Agency of Medicines). Special license may claim organisations that are listed in the national law. There is no fractionation plant in Estonia.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes ×

	No □
According to national legislation blood and blood components are medicines, which exportation requires special licence from National Authority (State Agency of Medicines). Special license may claim organisations that are listed in the national law. National Blood Centres are not collecting plasma for fractionation, as the amount of recovered plasma we could give for fractionation is just 10 tons and we have not found a company, who is interested in so small amount of plasma.	
FINLAND	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes ☒ No
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 and blood components from third countries to Finland only if they have a 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).	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes No ☒
FRANCE	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X
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.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes X
The export of blood and blood components (for transfusion or fractionation to EU Member States and third countries) is carried out by the French Blood Establishment (EFS) which into formless the Afssaps in the form of declaration.	
FYRoM	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or	Yes □

fractionation from EU Member States or third countries?	**No** □
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □ **No** □
GERMANY	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No □
If YES, please describe For the importation of blood and blood components from third countries the importer needs an authorisation of the competent authority as well as a certificate about the compliance with GMP-Standards (Sections 72 and 72a of the German Medicinal Products Act).	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes X No □
If YES, please describe Manufacturing authorisation and contact to the competent authority of the third country in case of absence of a marketing authorisation are prescribed.	
GREECE	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No □
If YES, please describe According to European Directive 2002/98/EC and Presidential decree 138/2005	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes X No □
If YES, please describe According to European Directive 2002/98/EC and Presidential decree 138/2005	
HUNGARY	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or	Yes x

fractionation from EU Member States or third countries?	No □
If YES, please describe 3/2005/HM decree	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x No □
If YES, please describe decree	
ICELAND	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No □
If YES, please describe **Internal rules of the blood establishment**	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes X No □
If YES, please describe **Internal rules of the blood establishment**	
IRELAND	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes □ No √
If YES, please describe The onus is placed on the importing blood establishment to demonstrate that EU requirements are meet for transfusion. No fractionation occurs in Ireland at the moment	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □ No √
If YES, please describe No fractionation occurs in Ireland nor is Irish plasma supplied for fractionation	
ITALY	

21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes **X** No □
If YES, please describe Import blood and blood components for transfusion must fulfil requirements established for national products. Import plasma for fractionation must fulfil European Pharmacopea's requirements.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes **X** No □
If YES, please describe Export blood and blood components for transfusion: same rules as in answer to question 21 concerning blood and blood components for transfusion. Plasma for fractionation: at the moment plasma for fractionation produced at national level is not exported as it is contract manufactured into plasma derived products by a nationally established pharmaceutical company. Implementation of 21 October 2005 Law will allow plasma for contract manufacturing to be exported, though only to selected European countries, where plasma derivative companies are in place. Exportation to third countries (e.g. USA) will not be allowed.	
LATVIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes □ No ×
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □ No ×
LIECHTENSTEIN	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x □ No □
If YES, please describe Requirement: Licensing by Swissmedic	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x □

	No □
If YES, please describe Requirement: Licensing by Swissmedic	
LITHUANIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x□ No □
If YES, please describe Approved by the Ministry of Health, never used in practice	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x No □
If YES, please describe Ministry of Health is entitled to give the authorisation for plasma fractionation to the EU Member States	
MALTA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x No □
If YES, please describe; The medicines authority and the Blood Products advisory committee regulate all importation of blood products.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □ No x
THE NETHERLANDS	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes □ No □
See enclosed the articles of the Blood Supply Act **CHAPTER IV. IMPORT AND EXPORT** Section 15	

1. It is forbidden to import blood products and intermediate products from a third country without a licence from the Minister.
2. The Minister shall grant a licence only if this would, in his opinion, be in the interests of fulfilling in a medically effective manner the need for blood products or special circumstance warrants this.
3. If the interest referred to in subsection 2 necessitates this or if a special circumstance warrants this, The Minister may attach rules to the licence or issue the licence subject to limitations. The licence may be cancelled; section 3, subsection 4, shall apply *mutatis mutandis*.
4. The prohibition referred to in subsection 1 shall not apply to:
(a) a person who, when crossing the border, is in possession of a quantity of a blood product which is clearly intended for his own use;
(b) an institution of scientific research in so far as the blood product or intermediate product to be imported is intended for scientific research;
(c) a product that is intended to be handed over as a sample upon application for registration under the Medicines Act.

Section 16

1. It is forbidden to export blood products and intermediate products to a third country without a licence from the Minister.
2. The Minister shall grant a licence only if this would not, in his opinion, be contrary to the interests of fulfilling in a medically efficient manner the need for blood products.
3. The Minister may, attach rules to a licence or issue a licence subject to limitations. A licence may be cancelled; section 3, subsection 4, shall apply *mutatis mutandis*
.4. The prohibition referred to in subsection 1 shall not apply to:
(a) a person who, when crossing the border, is in possession of a quantity of a blood product which is clearly intended for his own use;
(b) the Red Cross Society, in so far as the export takes place in the course of assistance provided in accordance with the constitution of that society.

Section 17

1. It is forbidden, without a licence from the Minister, to export blood products as referred to in section 12, subsection 1, and intermediate products to a State 1 that is a member of the European Union or a party to the Treaty establishing the European Economic Area.
2. The Minister shall grant a licence only if this would not, in his opinion, be contrary to the interests of fulfilling in a medically efficient manner the need for blood products.
3. The Minister may attach rules to a licence or issue a licence subject to limitations. A licence may he cancelled; section 3, subsection 4, shall apply *mutatis mutandis*.
4. The prohibition referred to in subsection 1 shall not apply to:
(a) a person who, when crossing the border, is in possession of a quantity of a blood product which is clearly intended for his own use;
(b) the Red Cross Society, in so far as the export takes place in the course of assistance provided in accordance with the constitution of that society;
(c) the Blood Supply Organisation;
(d) as regards intermediate products, the persons designated pursuant to section 13, subsection 1 (d), including legal entities.

22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □

	No □
See the articles of the Blood Supply Act (above)	
NORWAY	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x No □
If YES, please describe Yes within the medicinal products regulations.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x No □
If YES, please describe	
POLAND	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes □ No X
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes X No □
If YES, please describe: Each exportation of blood components is regulated and strictly controlled by the Minister of Health.	
PORTUGAL	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x No □
If YES, please describe Only those previewed in the EU directives, however Portugal does not import blood components.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or	Yes x

fractionation to EU Member States or third countries?	No ☐
If YES, please describe Fractionated abroad according national and international laws.	
ROMANIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes ☒ No ☐
If YES, please describe Law 282/2005, Art. 2	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes ☒ No ☐
If YES, please describe See point 21	
SLOVAK REPUBLIC	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes ☒ No ☐
If YES, please describe	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes ☒ No ☐
If YES, please describe	
SLOVENIA	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes ☐ No ■

If YES, please describe §14(3) Blood Supply Act (Official gazette of RS, No. 104/2006, 9. October 2006) The blood from third country should have the same traceability as regulated in RS.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes ■ No □
If YES, please describe §28 Blood Supply Act (Official gazette of RS, No. 104/2006, 9. October 2006) The health minister can approve the exportation of blood in the case of humanitative help of RS to other countries.	
SPAIN	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x No □
If YES, please describe Es obligatoria la presentación de unos protocolos que deben ser cumplimentados por la empresa importadora. Estos deben ser autorizados por la AEM (Agencia Española del Medicamento), previo informe favorable de la DG de Salud Pública. Legislado en la Ley del Medicamento, y RD 1088/2005. En España **no se importan** componentes sanguíneos para transfusión. Sólo para fraccionamiento	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes x No □
If YES, please describe Ídem anterior. Es obligatoria la presentación de unos protocolos que deben ser cumplimentados por la empresa exportadora. Estos deben ser autorizados por la AEM (Agencia Española del Medicamento), previo informe favorable de la DG de Salud Pública. Legislado en la Ley del Medicamento, y RD 1088/2005.	
SWEDEN	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes x No □
If YES, please describe NBHW: According to the directive MPA: There are rules in place for import from a third country which means that the blood and blood components must fulfil the rules in the blood directives. We also have a rule that says that the blood establishment in the third country must be inspected and approved by an authority in the EU. The blood establishment in the third country should not report adverse advents and reactions to the MPA but to the buyer of the blood components/blood establishment in Sweden who then reports to the	

MPA.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes X No □
If YES, please describe NBHW: According to the directive MPA: In case the blood and blood components are imported from a third country and than distributed in a EU member State we have rules for export (see answer to question 21).	
SWITZERLAND	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes **X** No □
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.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes **X** No □
If YES, please describe An Establishment license for Exportation is required. The license is issued by Swissmedic, Sector Licensing.	
TURKEY	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes √ No □
If YES, please describe MoH is the responsible authority	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes √ No □
If YES, please describe MoH is the responsible authority	

UNITED KINGDOM	
21- Are there rules in place for the authorisation and control of importations of blood and blood components for transfusion or fractionation from EU Member States or third countries?	Yes X No □
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 undertaken by a manufacturer or a legal entity contracted to act on behalf of the manufacturer. The blood and blood components must have been prepared in accordance with the requirements of the Annex to Directive 2005/62/EC and meet the standards of Annex V to Directive 2004/33/EC.	
22- Are there rules in place for the authorisation and control of exportation of blood and blood components for transfusion or fractionation to EU Member States or third countries?	Yes □ No X

10. SANCTIONS

AUSTRIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes ☐ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x No ☐
If YES, have penalties already been imposed?	Yes ☐ No x
BELGIUM	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No X
BULGARIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No ☑
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes ☑ No □
If YES, have penalties already been imposed?	Yes □ No ☑
CROATIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent	Yes □

authorities? (Art. 5.5 Directive 2002/98/EC)	No x□
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x□ No □
If YES, have penalties already been imposed?	Yes □ No x□
CYPRUS	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No √ □
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes √ □ No □
If YES, have penalties already been imposed?	Yes □ No √□
CZECH REPUBLIC	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □* No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x No □
If YES, have penalties already been imposed?	Yes □ No x
DENMARK	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No x

ESTONIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC) * - State Agency of Medicines has answered in respect of authorisation and license.	Yes □ No ×
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC) * According to National legislation after the inspection process, a prescription is composed by the NA (i.e. State Agency of Medicines). In case of non-performance of the prescription NA is able to define a penalty. Penalty rates are also defined in the National legislation.	Yes × No □
Have penalties already been imposed?	Yes □ No ×
FINLAND	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes No ☒
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC) The article 21 of the Blood Service Act (197/2005) prescribes the penalties.	Yes ☒ No
If YES, have penalties already been imposed?	Yes No ☒
FRANCE	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? One temporary suspension of authorisation was given concerning blood collection activity	Yes X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down?	No X

FYRoM	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ **No** □
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ **No** □
GERMANY	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes X No □
If YES, what were the reasons for the revocation(s) or suspension(s)? Failure in donor selection and testing, untrustworthiness of responsible person.	
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC) ?	Yes X (Section 96 of the German Medicinal Products Act) No □
If YES, have penalties already been imposed?	Yes X No □
If YES, what were the reasons for imposing the penalties? Failure in donor testing.	
GREECE	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No X

HUNGARY	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x No □
If YES, have penalties already been imposed?	Yes x No □
If YES, what were the reasons for imposing the penalties?	
ICELAND	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No X
IRELAND	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No √
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes √ No □
If YES, have penalties already been imposed?	Yes □ No √
ITALY	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent	Yes □

authorities? (Art. 5.5 Directive 2002/98/EC) **Not yet applicable**	No **X**
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No **X**
If YES, have penalties already been imposed?	Yes □ No **X**
LATVIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No ×
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No ×
LIECHTENSTEIN	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x □
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No x □
LITHUANIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x□
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x □ No □
If YES, have penalties already been imposed?	Yes □ No x □

MALTA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x No □
If YES, have penalties already been imposed?	Yes □ No x
THE NETHERLANDS	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No □
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC) Yes and no: those penalties were already laid down in the Blood Supply Act of 4 December 1997.	Yes □ No □
If YES, have penalties already been imposed? See above	Yes □ No □
NORWAY	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x No □
If YES, have penalties already been imposed?	Yes □ No x
POLAND	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent	Yes □

authorities? (Art. 5.5 Directive 2002/98/EC)	No X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes X No □
If YES, have penalties already been imposed?	Yes □ No X
PORTUGAL	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes x No □
If YES, have penalties already been imposed? Not yet.	Yes □ No □
If YES, what were the reasons for imposing the penalties? There are three levels of penalties, in all the areas inspected.	
ROMANIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No ☒
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes ☒ No □
If YES, have penalties already been imposed? Law 282/2005, chapter 8	Yes ☒ No □
If YES, what were the reasons for imposing the penalties? Transposition of the Directive 98/2002 EC, art. 27	

SLOVAK REPUBLIC	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No ☒
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes ☒ No □
If YES, have penalties already been imposed?	Yes □ No ☒
SLOVENIA	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No ■
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC) §39 Blood Supply Act (Official gazette of RS, No. 104/2006, 9. October 2006)	Yes ■ No □
If YES, have penalties already been imposed?	Yes □ No ■
SPAIN	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No x
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC) Las incluidas en el artículo 46 del RD 1088/2005 de 16 de septiembre	Yes x No □
If YES, have penalties already been imposed?	Yes □ No x

SWEDEN	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No X
SWITZERLAND	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No **X**
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes **X** No □
If YES, have penalties already been imposed?	Yes □ No **X**
TURKEY	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No √
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes □ No √
UNITED KINGDOM	
23- Have accreditations, designations, authorisations or licenses already been revoked or suspended by the competent authorities? (Art. 5.5 Directive 2002/98/EC)	Yes □ No X
24- Have penalties for infringements of the national provisions adopted pursuant to the Directive been laid down? (Art. 27 Directive 2002/98/EC)	Yes X No □

If YES, have penalties already been imposed?	Yes □ No X