EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

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Summary Table of Responses from Member State representatives at meeting of Competent Authorities on a Draft Questionnaire

Directive 2002/98/EC on the quality and safety of blood and blood components requires Member States to designate the competent authority or authorities responsible for implementing its requirements (Article 4 para. 1). It also specifies that the Commission shall hold regular meetings with the competent authorities designated by the Member States to exchange information on the experience acquired in the implementation of the Directive (Article 25).

The Commission convened a first meeting of representatives of the competent authorities on 26 September 2005 in order to have an exchange on the experiences encountered in the transposition of the Directives into their national law. Participants to the meeting were invited to complete a questionnaire covering certain aspects of the Directive.

This table presents their responses regarding the situation in the Member States, EEA countries and accession countries as of 26 September 2005.

1. NAME OF COMPETENT AUTHORITY

Member State	Competent authority (Article 4)
BE - Belgique / België	Ministre de la Santé Publique
CZ - Česká Republika	Ministry of Health State Drug Control Institute
DK - Danmark	Ministry of the Interior and Health Danish Medicines Agency
DE - Deutschland	Jedes Bundesland hat eigene zuständige Behörden, die die Aufsicht über alle in dem jeweiligen Bundesland angesiedelten Blutspendeeinrichtungen haben (33 Inspektorate); zuständige Bundesoberbehörde: Paul-Ehrlich-Institut.
EE - Eesti	Ministry of Social Affairs State Agency of Medicines
EL - Elláda	Ministry of Health and Social Solidarity National Blood Centre
ES - España	Ministry of Health – at national level 18 Regional authorities
FR - France	Agence française de sécurité sanitaire des produits de santé (Afssaps)

Member State	Competent authority (Article 4)
IE - Ireland	Irish Medicines Board
IT - Italia	Ministry of Health. Instituto Superiore de Sanita. Autonomous Regions and Provinces, according to respective competences. Ministry of Defence (for military transfusion services)
CY - Kypros	Medical and Public Health Services of the Ministry of Health
LV - Latvija	State Pharmaceutical Inspection. Health Statistics and Medical Technologies State Agency
LT - Lietuva	Ministry of Health. State Medicines Control Agency under Ministry of Health. State Service of Accreditation for Health Care Activities under Ministry of Health. State Medical Audit Inspectorate under Ministry of Health.
LU - Luxembourg	Ministère de la Santé
HU - Magyarország	National institute of Pharmacy; Executive Office of Chief Medical Officer
MT - Malta	Superintendent of Public Health
NL - Nederland	Public Health Supervisory Service
AT - Österreich	Bundesministerium für Gesundheit und Frauen
PL - Polska	Ministry of Health - Office of Accreditation. Main pharmaceutical Inspectorate
PT - Portugal	Portuguese Blood Institute at present. In progress towards a national regulatory entity
SI - Slovenija	Agency for Medical Products & Medical Devices
SK - Slovensko	Ministry of Health
FI - Suomi/Finland	National Agency for Medicines
SE - Sverige	National Board of Health and Welfare ('Socialstyrelsen') Medical Products Agency ('Läkemedelsverket')
UK - United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA)

EEA/EFTA countries

Iceland	Ministry of Health & Social Security
Norway	Directorate of Health and Social Affairs

Accession countries

Romania	Ministry of Health
Bulgaria	Ministry of Health

2. TRANSPOSITION BY 8 FEBRUARY 2005

Member State	2002/98/EC	2004/33/EC	Comment
BE - Belgique / België	Yes	Yes	
CZ - Česká Republika	Yes	Not fully	New version of 'law on drugs' Now being discussed and expected to be accepted by end of 2005
DK - Danmark	partially	partially	
DE - Deutschland	Yes	Re >>>>	Die Umsetzung erfolgte durch die Richtlinien zur Hämotherapie der Bundesärztekammer und des Paul-Ehrlich-Instituts. Diese Richtlinien stellen den allgemein anerkannten Stand der medizinischen Wissenschaft und Technik in Deutschland dar und sind von allen Blutspendeeinrichtungen grundsätzlich zu beachten. Sie werden zur Zeit von dem Paul-Ehrlich-Institut im Bundesanzeiger amtlich bekannt gemacht.
EE - Eesti	Yes	Yes	
EL - Elláda	No	Yes	A new law for reorganisation of blood transfusion services is coming into force by end of October 2005
ES - España	No	No	Expected within two months
FR - France	partially	partially	Ces directives ont été transposé dans les grandes lignes. Certaines dispositions détaillées sont en cours de transposition
IE - Ireland	Yes	No	Expected 2006
IT - Italia	Yes	Yes	
CY - Kypros	Yes	No	In approx. two months
LV - Latvija	No	No	Expected * November 2005
LT - Lietuva	Yes	Yes	
LU - Luxembourg	No	No	La directive 2002/98/CE (et la directive 2004/33/CE) se trouve déjà partiellement transposée par la loi du 15 mars 1979 portant réglementation de la transfusion sanguine et par ses règlements d'exécution. Les dispositions de la directive Non encore couvertes par la législation nationale font l'objet d'un projet de règlement grand-ducal, actuellement en instance de consultation auprès des organismes concernés. Ce texte devrait être présenté au Conseil de gouvernement d'ici la fin du mois de Novembre. La publication du règlement, une fois définitivement adopté, devrait dès lors se situer au plus tard vers la mi-décembre
HU - Magyarország	Yes	Yes	
MT - Malta	Yes	No	Prior to November 2005
NL - Nederland	Yes	Yes	
AT - Österreich	Yes	Yes	
PL - Polska	Yes	Yes	

Member State	2002/98/EC	2004/33/EC	Comment
PT - Portugal	No	No	In two months - both Directives will be transposed into national law. (December)
SI - Slovenija	Yes	Yes	Transposition is in process of being adopted into national law by 31 December 2005
SK - Slovensko	Yes	Yes	
FI - Suomi/Finland	Yes	No	1 November 2005; Regulation given by National Agency for Medicines
SE - Sverige	No	No	1 July 2006
UK - United Kingdom	Yes	Yes	

EEA/EFTA countries

Iceland	Yes	No	Before end of year
Norway	Yes	Yes	

3. NUMBER OF BLOOD ESTABLISHMENTS

Member State	Number	Designated, authorised, accredited etc. (Article 5)
BE - Belgique / België	5	Yes
CZ - Česká Republika	71	Yes. All services that are running have received approval
DK - Danmark	29	Yes
DE - Deutschland	190 271 only for autologous blood donations	
EE - Eesti	4	
EL - Elláda	Number remains to be fixed by the end of October when new law comes into force.	No. By end of year
ES - España	Information not received	
FR - France	18 établissement de transfusion sanguine de l'EFS et le centre de transfusion des armées le tout correspondant à 220 sites	Oui. Les 220 sont agréés par l'Afssaps
IE - Ireland	4	No. By November 2005
IT - Italia	~300	Yes
CY - Kypros	None, one under construction	Approval process completed in 6 months
LV - Latvija	19 State Blood Centre & 18 blood preparation divisions in medical institutions.	All designated etc.
LT - Lietuva	4	Yes
LU - Luxembourg	1	Yes
HU - Magyarország	26 belong to Hungarian National Blood Transfusion service	Yes. 6 regional blood centres received approval
MT - Malta	1	None
NL - Nederland	1	Yes
AT - Österreich	20	19 of 20 received approval. Process to be completed by December 2005
PL - Polska	23	Yes. 21 of 23 received approval
PT - Portugal	3 + 26	Yes all
SI - Slovenija	2	No. To be completed in next 6 months
SK - Slovensko	51 (12 belong to National transfusion Service; 39 are hospital departments of Haematology)	Yes
FI - Suomi/Finland	1 establishment with 17 sites	No. By 1 November 2005
SE - Sverige	70 blood establishments, within which an additional 49 collection centres are organised	Yes according to national law including GMP
UK - United Kingdom	At least 4	No. Completed by 8 November 2005

EEA/EFTA countries

Iceland	1	As soon as transposition is

		finished
Norway	49	No

4. PROVISION OF INFORMATION AND TIME EXTENSION

Member State	Blood establishments submitted information required by Annex I of Directive 2002/98/EC to competent authority(ies) (Article 5)	National provisions extended from 8 February 2005 to 8 November 2005 (Article 7)
BE - Belgique / België	Not all	Yes
CZ - Česká Republika	Not a complete set	Yes- a new law is expected
DK - Danmark	Yes	Yes
DE - Deutschland	Yes	No
EE - Eesti	Yes	No response
EL - Elláda	No	No response
ES - España	Information not received	Information not received
FR - France	Yes	Yes
IE - Ireland	No	Yes
IT - Italia	No. Implementation of transposed Decree will enter into force in October.	No response
CY - Kypros	No	Yes
LV - Latvija	No	Yes
LT - Lietuva	50%	Yes
LU - Luxembourg	Yes	Yes
HU - Magyarország	Yes	Yes
MT - Malta	No response	Yes
NL - Nederland	Yes	No response
AT - Österreich	Yes	Yes
PL - Polska	Yes	Yes
PT - Portugal	No	No answer given
SI - Slovenija	No	Yes
SK - Slovensko	Yes	No
FI - Suomi/Finland	Yes	Yes
SE - Sverige	No	No (Not applicable due to delayed implementation)
UK - United Kingdom	No	Yes

EEA/EFTA countries

Iceland	Yes	Yes
Norway	Yes	Yes

5. INSPECTIONS CARRIED OUT BY (ARTICLE 8)

Member State	Comment
BE -Belgique / België	Les membres du SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnent, désignés par le Roi Les Membres du 'SPF….', par le Roi.. SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement' Members, appointed/nominated by the King.
CZ - Česká Republika	State Drug Control Institute
DK - Danmark	Blood establishment inspectors from Danish Medicines Agency
DE - Deutschland	Autorisierte GMP-Inspektoren der Länderbehörden in Verbindung mit Sachverständigen der zuständigen Bundesoberbehörde (Paul-Ehrlich-Institut)
EE - Eesti	State Agency of Medicines; Department of Biologicals & Inspectorate.
EL - Elláda	Personnel of the National Blood Center
ES - España	Information not received
FR - France	Inspecteurs assermentés, habilités de l'Afssaps
IE - Ireland	Blood and tissue inspectors
IT - Italia	The autonomous Regions and Provinces organise inspections
CY - Kypros	Not defined yet
LV - Latvija	Not yet conducted. State Pharmaceutical Inspection
LT - Lietuva	Inspectors
LU - Luxembourg	Medecin-inspecteur
HU - Magyarország	No response
MT - Malta	Foreign experts
NL - Nederland	Public Health Services
AT - Österreich	Speziell geschulte GMP-Inspektoren
PL - Polska	GMP inspectors from Main Pharmaceutical Inspectorate
PT - Portugal	Physicians – MD (transfusion medicine experts)
SI - Slovenija	Specialists in pharmacy, specialists in transfusion medicine of the Agency for Medical Products & Medical Devices of the Republic of Slovenia
SK - Slovensko	National Institute for Drug Control with collaboration of National Transfusion Service
FI - Suomi/Finland	Inspectorate of the National Agency for Medicines
SE - Sverige	Pharmaceutical inspectors at the MPA Inspectorate. The intention is that the two Competent authorities will coordinate inspections according to Directive 2002/98/EC
UK - United Kingdom	MHRA GMP Inspectors

EEA/EFTA countries

Iceland	Joint inspections by the Chief Medical Officer & Icelandic Medicines Control Agency
Norway	Norwegian Medicines Agency Norwegian Board of Health

6. PENALTIES (ARTICLE 27)

Member State	Comment
BE - Belgique / België	Les infractions aux dispositions légales sont punies d'une amende de 200 francs à 1.000.000 francs et d'un emprisonnement d'un mois à un an ou de l'une de ces peines seulement. The Infringements of the legal provisions are punished of a fine from 200 francs to 1MIO francs and of an imprisonment from 1 month to 1 year or of the one of these penalties/punishments/sentences only.
CZ - Česká Republika	From financial penalties to loss of authorisation but Not harmonised wit EU Directives yet. It should be done by the new law.
DK - Danmark	Fines
DE - schland	Die Sanktionen ergeben sich aus den §§ 95, 96 und 97 AMG. Es handelt sich sowohl um Straf- als auch Bußgeldvorschriften
EE - Eesti	Up to 50,000EEK; cancellation of license or temporarily stopped
EL - Elláda	None adopted
ES - España	Information not received
FR - France	- Suspension d'agrément d'établissements de transfusion sanguine - Suspension d'utilisation de produits sanguins - Sanctions pénales en cas de Non respect des dispositions applicables Ces sanctions existaient en droit national avant l'application de la directive
IE - Ireland	Revocation/ suspension/ withdrawal of license – 6 moths jail plus fine
IT - Italia	Administrative and criminal penalties
CY - Kypros	Practical implementation
LV - Latvija	Not adopted
LT - Lietuva	Competent authority may suspend or revoke license
LU - Luxembourg	Emprisonnement de huit jours à six mois et/ou amende de 251 Euros à 12500 Euros. Ces peines peuvent être portées au double du maximum lorsque le délit a été commis dans les deux ans qui suivent une condamnation définitive d'une infraction à la législation en matière de transfusion sanguine.
HU - Magyarország	Not adopted
MT - Malta	Fines or revoking license
NL - Nederland	Withdrawal of license
AT - Österreich	Geldstrafen bei Verwaltungsübertretungen und /oder Schließung des Betriebes. Fines and/or revocal of license
PL - Polska	Suspension or revocation of accreditation
PT - Portugal	In progress
SI - Slovenija	Financial penalties will be adopted by 31st December 2005: Financial penalties for establishments: 450 Eur – 125 000 Eur Financial penalties for responsible person: 40 Eur – 4000 Eur
SK - Slovensko	None adopted. Provisions already existed – annulment of authorisation for collection and/or processing
FI - Suomi/Finland	Withdrawal of the license; financial penalties
SE - Sverige	Intention is to adopt prison and fine
UK - United Kingdom	Fines and/or imprisonment

EEA/EFTA countries

Iceland	Varies depending on actual situation from daily fines to withdrawal of license and fines.
Norway	Not adopted

7. DIFFICULTIES ENCOUNTERED BY THE COMPETENT AUTHORITIES / MEMBER STATES IN TRANSPOSITION OF DIRECTIVES

Member State	Difficulties encountered
BE - Belgique / België	Surtout des problèmes d'ordre linguistique: incompatibilité des versions NL et FR sur certains points. Nécessité d'une bonne coopération entre juristes et experts médicaux. Especially problems of linguistic nature: incompatibility between NL and FR versions on certain points. Necessity of a good co-operation between lawyers and medical experts.
CZ - Česká Republika	- dead-lines for implementation EU Directives are sometimes too short (all 'obligations' should pass through the Parliament and legislation process is time consuming) - specific problems are in situation when EU Directive goes into deep details especially when a requirement it is Not in accordance with current science (as an example: Dir 2004/33/EC Annex V, part 2- quality control requirements for Granulocytes, apheresis etc.)
DK - Danmark	Denmark has been waiting for the last two technical directives relating to a quality system for blood establishments and Notification of serious adverse reactions etc.
DE - Deutschland	Dokumentationsmängel, Organisationsmängel, Mängel bei Räumen und Ausstattungen, jedoch keine schwerwiegenden oder kritischen Mängel
EE - Eesti	As the number of blood banks is small, the experience of inspectors is Not good as we wish it to be.
EL - Elláda	No comment
ES - España	Information not received
FR - France	Pas de difficultés majeures liées à l'absence de structure nationale, mais il était nécessaire d'adapter l'activité transfusionnelle à certaines dispositions des directives
IE - Ireland	Quality standards for blood banks Not specified
IT - Italia	No comment
CY - Kypros	No comment
LV - Latvija	Division of responsibilities among competent authorities
LT - Lietuva	Lack of Directive laying down standards relating to inspection and control measures for blood establishments
LU - Luxembourg	No comment
HU - Magyarország	No comment
MT - Malta	No local expertise available; training required / foreign experts to carry out inspections
NL - Nederland	Definition of blood establishment QP (h) qualification
AT - Österreich	Lack of privacy during donor interview Interpretation of remuneration Keine, weil Blut und Plasma bereits als Arzneimittel eingestuft war und daher GMP Regeln und das Arzneimittelgesetz eingehalten werden mussten. None because human blood and plasma have been defined as medicinal products since 1984 and the BE had to follow GMP guidelines and the medicines act already.
PL - Polska	No comment
PT - Portugal	The adoption of the recommended mode; with two different services: either blood service or hospital transfusion service
SI - Slovenija	Lack of human & financial resources
SK - Slovensko	No comment
FI - Suomi/Finland	Different transposition schedules of the Commission Directives

Member State	Difficulties encountered
SE - Sverige	The dual legislation for processing, storage and transport for transfusion and medicinal products respectively
UK - United Kingdom	Requirement to transpose in the absence of 2 of the 3 EC Technical Directives and 'good practice guidelines'.

EEA/EFTA countries

Iceland	No comment
Norway	No comment

8. SPECIFIC ISSUES TO BE ADDRESSED BY THE COMMISSION

Member State	Comment
BE - Belgique / België	No comment
CZ - Česká Republika	No comment
DK - Danmark	Denmark looks forward to having a common electronic data reporting system for the Notification referred to in Article 15.2 at member state level and EU level.
DE - Deutschland	No comment
EE - Eesti	Organisation of joint inspection teams
EL - Elláda	No comment
ES - España	Information not received
FR - France	Pas de problèmes particuliers identifiés par l'Afssaps. (Vraisemblablement un problème au niveau de la mise en place de l'hémoglobine pré don)
IE - Ireland	Training of inspectors Quality system for blood banks
IT - Italia	No comment
CY - Kypros	Extension of twinning light project
LV - Latvija	No comment
LT - Lietuva	Directive should be prepared laying down standards relating to inspection and control measures for blood establishments, hospital blood banks Workshop or conference on the issue mentioned above would be very useful.
LU - Luxembourg	No comment
HU – Magyarország	No comment
MT - Malta	Training guidelines
NL - Nederland	No comment
AT - Österreich	Traffic of blood components within Europe and to and from third countries Informations system der getätigten Inspektionen (Data base of licensed and inspected BE) Hämovigilianzsystem – rapid alert - EHN
PL - Polska	No comment
PT - Portugal	Not anything special. Only comprehensiveness withth ecountries in development
SI - Slovenija	Influencing political decision makers
SK - Slovensko	No comment
FI - Suomi/Finland	National language versions should be available in time.
SE - Sverige	Imports form third country: In these countries the blood establishments are obliged to comply with the national legislation, for instance they have No obligation to use CE marked test kits. To whom should the blood establishment in third country report serious adverse events?
UK - United Kingdom	Adoption and publication of remaining Technical Directives as soon as possible and rapid development of 'good practice guidelines'.

EEA/EFTA countries

Iceland	No comment
Norway	No comment