EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels, 16 November 2006

Table of responses from Member State's Competent Authorities on blood and blood components to a questionnaire on the transposition of the Blood Directive

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 second meeting of representatives of the competent authorities on 13 September 2006 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 on the transposition of the Blood Directives.

This table presents the responses received by the Commission regarding the situation in the Member States, EEA countries and accession countries as of 16 November 2006.

A questionnaire on the level of transposition was also sent in advance to the first meeting of the Competent Authorities in September 2005. Changes mentioned in the tables below refer to the 2005 version of the questionnaire.

1. NAME OF COMPETENT AUTHORITY

In ***Bold italic***: information dating from 2005.

Member State	Competent authority (Article 4)	Change since 2005
BE - Belgique / België	FPS Health, Food Chain Safety and Environment. Directorate General for Health Care facilities Organisations	Yes (Ministry of Health)
CZ - Česká Republika	Ministry of Health	Yes (Ministry of Health + State Drug Control Institute)
DK - Danmark	Ministry of the Interior and Health Danish Medicines Agency	
DE - Deutschland	On behalf of Ministry of Health: Paul-Ehrlich-Institut Federal authority: Rejierungsprädium Darmstadt	
EE - Eesti	State Agency of Medicines – Health care board	Yes (Ministry of Social Affairs in addition to SAM)
EL - Elláda	***Ministry of Health and Social Solidarity*** ***National Blood Center***	
ES - España	Ministerio de Sanidad y Consumo. Responsable Area de Hemoterapia. Dirección general de Salud Pública	Yes (Ministry of Health at national level; 18 Regional authorities)
FR - France	Ministry for health	Yes (Agence française de sécurité sanitaire des produits de santé (Afssaps))
IE - Ireland	Irish Medicines Board	
IT - Italia	Related to Articles 4 and 25: Ministero della Salute - Direzione Generale della Prevenzione Sanitaria. Related to Articles 5 and 8: Regional Government of each Italian Region.	
CY - Kypros	Medical and Public Health Services of the Ministry of Health	

Member State	Competent authority (Article 4)	Change since 2005
LV - Latvija	Latvian State Blood center	Yes (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	Hungarian Health Ministry, Hungarian National blood Transfusion Service	Yes (Drug Agency)
MT - Malta	Director General Health	Yes (Superintendent of Public Health)
NL - Nederland	***Public Health Supervisory Service***	
AT - Österreich	Bundesministerium für Gesundheit und Frauen (Executive: Federal Agency for Safety in Healthcare)	
PL - Polska	Ministry of Health - Office of Accreditation. Main pharmaceutical Inspectorate	
PT - Portugal	Portuguese Ministry of Health	Yes (Blood Institute)
SI - Slovenija	***Agency for Medical Products & Medical Devices***	
SK - Slovensko	State Institute for Drug Control	Yes (Ministry of Health)
FI - Suomi/Finland	National Agency for Medicines	
SE - Sverige	The Medical Products Agency and The National Board of Health and Welfare	
UK - United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA)	

EEA/EFTA countries

Liechtenstein	Kontrollstelle für Arzneimittel	
Iceland	Ministry of Health & Social Security	
Norway	Directorate of Health and Social Affairs	

Acceding countries

Bulgaria	Bulgarian Drug Agency	Yes (Ministry of Health)
Romania	Ministry of Public Health	

2. TRANSPOSITION AT 13 SEPTEMBER 2006

Member State	2002/98/EC	2004/33/EC	2005/61/EC	2005/62/EC	Comments
BE - Belgique / België	Yes	Yes	No Sept 2006	No Sept 2006	
CZ - Česká Republika	Yes	Some parts still as non-binding recommendation Finalisation in 2006 (prepared for Parliament now)	Almost completely Finalisation in 2006 (prepared for Parliament now)	Almost completely Finalisation in 2006 (prepared for Parliament now)	
DK - Danmark	Yes	Yes	No Finalisation on 1 Oct 06	Yes	
DE - Deutschland	Yes	Yes	Yes (partially)	Yes	**2005/61/EC:** details on adverse events central reaction collection to be added in March 2007.
EE - Eesti	Yes	Yes	Yes	Yes	
EL - Elláda					
ES - España	Yes	Yes	Yes Publication in Oct 06	No Finalisation planned for Dec 06	
FR - France	Yes *(post meeting inclusion)*	No	No	Yes	**- 2002/98/EC:** The transposition was finished on November 10th, 2006. **- 2004/33/EC:** The transposition will be finished when the decision of the general manager of the AFSSAPS relative to criteria of selection of the donors is published. This publication should intervene before the end of

Member State	2002/98/EC	2004/33/EC	2005/61/EC	2005/62/EC	Comments
					2006. **- 2005/61/EC:** This directive will be transposed in three decisions of the general manager of the AFSSAPS : - The first one relates to the good practices for blood transfusion, which was published on November 10th, 2006 *(post meeting inclusion).* - The second one relates to the notification formats of incidents. This publication should intervene in the beginning of 2007.
IE - Ireland	Yes	Yes	No Finalisation Sept 06	No Finalisation Sept 06	
IT - Italia	Yes	Yes	No Finalisation before end of 2006	No Finalisation before end of 2006	
CY - Kypros	Yes	Yes	No By end of 06	No By end of 06	
LV - Latvija	Yes	Yes	Yes	Yes	
LT - Lietuva	Yes	Yes	Yes (95%) Finalisation 12 Sept 06	Yes	
LU - Luxembourg					
HU - Magyarország	Yes	Yes	Yes	Yes	
MT - Malta	Yes	Yes	No Finalisation end Sept 06	No Finalisation end Sept 06	

Member State	2002/98/EC	2004/33/EC	2005/61/EC	2005/62/EC	Comments
NL - Nederland					
AT - Österreich	Yes	Yes	No Finalisation Jan 2007	No Finalisation Autumn 2006	- **2005/61:** Haemovigilance exists already in the Medicines Act, but the forms have still to be implemented. - **2005/62:** Blood and blood components are pharmaceuticals in Austria and regulated in the Medicines Act. The blood establishments have to follow the EU GMP guide.
PL - Polska	Yes	Yes	Yes	Yes	
PT - Portugal	Yes	Yes	Yes	Yes	All the European Directives are consensually transposed, but not published in the Official Journal yet.
SI - Slovenija	No	No	No	No	Proposal for national law transposing the Blood Directives is at the final stage of the parliamentary procedure and expected to be passed within 1 month. Its implementation regulations will be issued by the end of this year.
SK - Slovensko	Yes	Yes	Yes	Yes	
FI - Suomi/Finland	Yes	Yes	Yes	Yes	The transposition of the "Blood Directives" (4) has been done in Finland by the Blood Service Act (197/2005), Decree (258/2006) and Administrative Regulation 2/2006.
SE - Sverige	Yes	Yes	No Finalisation 1st Nov 2006.	No Finalisation 1st Nov 2006.	
UK - United Kingdom	Yes	Yes	Yes	Yes	

Acceding countries

Bulgaria	Yes	Yes	Yes	Yes	
Romania	Yes	Yes (partially) Nov 1 2006. Drafts submitted for endorsement to the MoH	No Finalisation 1st Nov 2006. Draft submitted for endorsement	No Finalisation 1st Nov 2006	

EEA/EFTA countries

Liechtenstein	No	No	No	No	
Iceland	Yes	Yes	No Finalisation probably during Q4 2006	No Finalisation probably during Q4 2006	
Norway	Yes	Yes	No Passed EEA-Committee 7 July 2006, transposition into force from November 2006	No Passed EEA-Committee 7 July 2006, transposition into force from November 2006	