EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels,
SANCO C/6 TB/gcs D(2006) 360387

Meeting of Competent Authorities

On Blood and blood components

26 September 2005

Summary report

The meeting of competent authorities as foreseen by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, was convened on 26 September 2005 under the Chairmanship of Mr Tapani PIHA, Head of Unit, Sanco C6.

All Member States were present at the meeting; were also present: Iceland, Norway, Bulgaria and Romania.

Item 1 and 4 Welcome and introductory remarks by the Chairman of the Committee

The Chairman welcomed the delegations (list of representatives appended in annex I). The aim of the meeting was to review the responsibilities of the competent authorities under Article 4, 5 and 8 of Directive 2002/98/EC; and to discuss the progress and the difficulties encountered in the transposition of the Directive.

Item 2 Adoption of the agenda

The revised draft agenda was adopted.

Item 4 Introduction by the competent authority of each Member State

Each delegation presented a brief overview of its structure, related responsibilities etc. A document on the relevant paragraphs of the Blood Directive was circulated (Annex II).

<u>Item 5</u> Specific issues to be addressed to the implementation of Directive 2002/98/EC and Directive 2004/33/EC

Directive 2002/98/EC

<u>Note 1</u>

A common electronic notification system for the transmission by Member States of the reports on serious adverse reactions and serious adverse events to the Commission in a standard data transmission format would be welcome. For the design of such an electronic data reporting system a look will be taken at existing systems in Member States and others. The Commission cannot promise a timetable however.

<u>Note 2</u>

There is a need for further guidance (despite the existing guides) on standards and specifications relating to inspection and control measures for blood establishments, hospital blood banks and facilities of any kind where blood is collected, tested, processed, stored and distributed for transfusion and other therapeutic purposes. The format of such guidance needs to be discussed in the next meetings of the competent authorities.

Directive 2004/33/EC

<u>Note 1</u>

Annex IV requires autologous blood and blood components to be labelled as required by Annex III of Directive 2002/98/EC. The means that autologous blood preparations are to be labelled with the ABO blood group and Rhesus factor. A concern has been raised that this measure does not necessarily guarantee that autologous blood transfusions will not, under any circumstances, be given to persons other than the patients who have donated the autologous blood.

Conclusion: the Commission invited the competent authorities to make concrete proposals on this issue.

<u>Note 2</u>

Annex V requirement that the protein content of fresh-frozen plasma should be higher than 45 g/l has been questioned, because this makes quality control for fresh-frozen plasma unnecessarily cumbersome and expensive without any measurable increase in safety and quality. The Commission will convene a small meeting of experts to come up with a recommendation that can be presented to the Regulatory Committee for an opinion and possible amendment of the Directive.

Item 6 General Discussion

Issues raised by the competent authorities dealt with the exchange of blood components across borders; the ECDC's role in relation to blood safety; the issue of for-the-profit centers; and safe levels of haemoglobin in donors. In particular, the required haemoglobin levels before donation lead to an exclusion of around 15% of female donors in France (and around about 28% in La Réunion). France is investigating the problem and elaborating protocols and will transmit the results to the Commission when ready.

Item 7 Corrigenda

The Commission is aware that there are linguistic errors in certain language versions of the Directives. The competent authorities are invited to send the proposed corrections to the Commission so that the appropriate corrigenda can be introduced.

Tapani PIHA

Chairman of the Committee

ANNEX I

List of Participants

Member State		
BE **Belgique / België**	SPF Santé publique, Sécurité de la Chaîne Alimentaire et Environnement Direction générale Médicaments	SPF Santé publique, Sécurité de la Chaîne Alimentaire et Environnement Organisation des Soins de Santé
CZ **Česká Republika**	Department of Pharmacy Ministry of Health	Institute of Clinical and Experimental Hematology
DK **Danmark**	Indenrigs- og Sundhedsministeriet, 4 s. kontor	
DE **Deutschland**	Paul-Ehrlich-Institute	Regierungspräsidium Darmstadt
EE **Eesti**	Department of Biologicals State Agency of Medicines	
EL **Elláda**	National Center for the Production of Blood Products 'Elias Politis' General Hospital of Nikaia,	
ES **España**	DG Salud Pública. Ministerio de Sanidad y Consumo.	Centro Vasco de Transfusión Hospital de Galdácano
FR **France**	Ministère de la Santé, de la famille et des personnes handicapées Direction générale de la santé Bureau des produits de santé d'origine animale	Agence Française de Sécurité Sanitaire des Produits de Santé Ministère de la Santé
IE **Ireland**	Irish Medicines Board	
IT **Italia**	Ministerio di Sanità Dirigente Ufficio VIII-Direzione Generale della Prevenzione Sanitaria	
CY **Kypros**	Medical and Public Health Services Ministry of Health	
LV **Latvija**	Division of Health Care Organization Department of Public Health Care	
LT **Lietuva**	Personal Health Division Ministry of Health	
LU **Luxembourg**	Division de l'Inspection Sanitaire Direction de la Santé	Service de la Transfusion Sanguine de la Croix-Rouge Luxembourgeoise
HU **Magyarország**	National Blood Supply Service	National Blood Supply Service
MT **Malta**	Ministry of Health, the Elderly and Community Care EU and International Affairs Department	Ministry of Health, the Elderly and Community Care EU and International Affairs Department
NL **Nederland**	Health Care Inspectorate	Dept. of Pharmaceutical Affairs and Medical Technology
AT **Österreich**	Medicines & Medical Devices Inspectorate Federal Ministry of Health and Women	
PL **Polska**	Pharmaceutical Inspectory *sent regrets*	Institute of Hematology and Blood Transfusion
PT **Portugal**	Portuguese Blood Institute Parque de Saúde de Lisboa	

Member State		
SI **Slovenija**	Directorate for Health Care Ministry of Health of the Republic of Slovenia	National Blood Transfusion Centre of Slovenia
SK **Slovensko**	Best Practice Inspection, State Institution for Drug Control	
FI **Suomi/Finland**	National Agency for Medicines	National Agency for Medicines, Enforcement & Inspection
SE **Sverige**	SoS National Board of Health and Welfare	Medical Products Agency
UK **United Kingdom**	Medicines and Healthcare Products Regulatory Agency (MHRA)	Department of Health

OBSERVERS

EFTA Countries		
IS **Iceland**	Ministry of Health	Ministry of Health
LI **Lichtenstein**	Liechtensteinische Landesverwaltung Kontrollstelle für Arzneimittel beim Amt für Lebensmittelkontrolle und Veterinärwesen	
NO **Norvege**	Ministry of Health and Care Services	Directorate for Health and Social Affairs

Applicant countries		
BG **Bulgaria**	Regional Center of Transfuzion Hematology	Bulgarian Drug Agency
RO **Romania**	Regional Blood Transfusion Centre, Constanta	
TR **Turkey**		

ANNEX II

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Consumer Protection
C6 – Health Measures

Luxembourg,
D(2004)
FMD/24.09.2005

AGENDA ITEM 4 –COMPETENT AUTHORITIES

1.1. Roles and responsibilities of the Competent authorities

Article 4

- paragraph 1 requires Member States to designate the competent authority for implementing the requirements of Directive 2002/98/EC – as well as the technical requirements established under Commission Directives.

Article 5

- paragraph 1 requires that only blood establishment that are designated, authorised, accredited or licensed by the competent authority may undertake activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage and distribution when intended for transfusion.
- paragraph 2 requires that blood establishments submit information listed in Annex 1 of Directive 2002/98/EC to the competent authority.
- paragraph 3 requires the competent authority to verify that the blood establishment complies with the requirements set out in Directive 2002/98/EC and indicate to it which activities it may undertake and which conditions apply.
- paragraph 4 requires that the competent authority provide written approval for any substantial changes in activities by blood establishments before they can be undertaken.
- paragraph 5 gives the competent authority the authorisation to suspend or revoke the designation, authorisation, accreditation or licence of a blood establishment if inspection and control measures demonstrate that the blood establishment doe not comply with the requirements of Directive 2002/98/EC – and the Relevant Commission Directives.

Article 8

- paragraph 1 requires the competent authority to organise inspections and appropriate control measures in blood establishments to ensure that the requirements of the Directive are complied with.
- Paragraph 2 requires that the competent authority organise the inspection and control measures on a regular basis with the interval between two inspections and control measures not exceeding two years.

– Paragraph 3 requires that the inspections and control measures are carried out by officials who represent the competent authority. These officials have powers entrusted to them.

– Paragraph 4 requires that the competent authority organise inspection and other control measures as appropriate inn the event of any serious adverse event or reaction or suspicion thereof in accordance with Article 15.

Article 15

– Paragraph 1 indent 1 requires that the competent authority be notified of any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and safety of blood and blood components.

Article 25

– Requires that the Commission hold regular meetings with the competent authorities designated by the member States … to exchange information on the experience acquired with regard to the implementation of this Directive.