EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels, 01 February 2008
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Meeting of the Competent Authorities on blood and blood components (Art. 25 Dir. 2002/98/EC)

18 October 2007

9.30 – 17.00

SUMMARY REPORT

The third 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 18 October 2007 under the Chairmanship of Mr Tapani PIHA, Head of Unit, Sanco C6 (Health measures).

26 EU Member States were present at the meeting, Iceland, Liechtenstein, Switzerland, Croatia and the former Yugoslav Republic of Macedonia. The World Health Organisation attended the meeting as well. The list of participating organisations is appended in annex.

1. WELCOME AND INTRODUCTORY REMARKS

The Chairman welcomed the delegations. The aim of the meeting was to discuss the progresses and difficulties encountered in the transposition and implementation of the Blood Directive in the Member States, to have a discussion on a number of proposals by the Commission related to the implementation of the Blood Directive, and to share information on programmes and initiatives in and outside the EU related to blood transfusion.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. BRIEF INTRODUCTION BY COMPETENT AUTHORITIES OF EACH MEMBER STATE

Each delegation presented a brief overview of its structure and related responsibilities.

4. GENERAL DISCUSSION ON THE TRANSPOSITION AND IMPLEMENTATION OF THE BLOOD DIRECTIVE

4.1. Status of transpositions.

The Commission updated the EU Member States on the latest status of transposition of the Blood Directive. The Commission urged the remaining late Member States to finalise the transposition of directives 2002/98, 2004/33, 2005/61 and 2005/62 very rapidly as infringement procedures have been launched already for the four of them.

4.2. Update from the Commission on the next reporting deadlines.

The Commission provided the participants with the timeline for reporting according to the Blood Directives.

The report by Member States on activities undertaken in relation to the provisions of the Directive (Art. 26-1 of Directive 2002/98) will have to be sent to the Commission at the occasion of the next meeting of the competent authorities (autumn 2008). The Commission will report to the European Parliament and the Council of Ministers in 2009.

The report on voluntary and unpaid donation of blood and blood components (Art. 20-2 of the Directive 2002/98) is planned for 2009 (jointly with the report on voluntary and unpaid donation of tissues and cells).

The annual reports by the Member States to the Commission on serious adverse reactions and events (Art. 8 of 2005/61/EC) will have to be communicated to the Commission every year on 30 June, starting from June 2008 with the data for the year 2007.

4.3. Findings of the questionnaire sent to Member States regarding the transposition and implementation of the blood and blood components regulatory framework.

The Commission presented a preliminary summary of the finding of the questionnaire on the transposition and implementation of the Blood Directive (at the date of the meeting, answers received from 26 Member States, Croatia, former Yugoslav Republic of Macedonia, Turkey, Iceland, Liechtenstein, Norway and Switzerland).

The Delegations welcomed the questionnaire as a useful source of information. The asked the Commission to repeat this information gathering exercise for the next meeting of the competent authorities in 2008. The Commission agreed with this proposal and precised that the 2008 questionnaire will be considered as the reporting obligation according to article 26-1 of the Directive 2002/98/EC (see point 4.2).

The delegations were given five more weeks after the meeting to review and/or confirm their initial answer to the questionnaire, before it is made publicly available on the website of the European Commission.

5. SPECIFIC ISSUES RELATED TO DIRECTIVE 2002/98/EC, 2004/33/EC, 2005/61/EC AND 2005/62/EC

5.1. Discussion on a proposal for modification of the Donor's Haemoglobin levels (Point 1.2 - annex III – Dir. 2004/33/EC)

The delegations had a discussion regarding the proposal done at the second meeting of the competent authorities in 2006 to include an addendum to Point 1.2 of the annex III of Directive 2004/33/EC (thresholds for haemoglobin [Hb] levels in donor blood lie at 125g/l for women and 135g/l for men) so that the Member States have a controlled possibility to lower Hb levels to decrease exclusion rates of donors in some countries or regions due to their specific populations.

While at the time of the 2006 meeting the proposal raised no specific concern, a Member State stressed afterwards the importance of further addressing the potential impact of this approach on importation from third countries that apply different Hb levels requirements.

During the discussion, several delegations stressed the importance of considering the Directive's provisions on Hb levels at donation time in view of the amount of Hb in finished blood products, as these are linked.

In conclusion, the Commission asked the Member States to send comments in writing on their preferred approach(es) to amend the Blood Directive on this matter by mid December 2007.

The amendment is planned to be submitted to the agreement of the Regulatory Committee in the course of the first semester of 2008 and be adopted by the Commission thereafter.

5.2. Recent outbreak of Chikungunya virus in Italy - Exchange of views on early warnings

Dr. Giuliano Grazzini, representative of the Italian competent authority, presented an update on the safety measures for blood and blood components undertaken in Italy since the occurrence of a Chikungunya outbreak in the Emilia-Romagna region, during the summer 2007.

The competent authorities agreed on the fact that this first outbreak of Chikungunya within the European continental territory does not justify at this stage to include the disease in the list of permanent or temporary deferral criteria (annex III of Directive 2004/33/EC). However careful scrutiny should be maintained in 2008 and after because many factors tend to demonstrate that the disease is likely to appear another time in Europe in the future.

This event emphasized the importance of rapidly exchanging information amongst the Member States and with the Commission for the sake of human substance's safety across the EU. Therefore the Commission proposed to create an e-mailing list for circulating quick alert messages, which would contains the coordinates of a contact person(s) in the Commission and a contact person(s) per competent authority. All the delegation agreed with the proposal.

The Commission will coordinate with the European Center for Disease Prevention and Control (ECDC) in Stockholm to ensure complementarities between the blood quick alert mailing list and the Early Warning and Response System on communicable diseases. Moreover, the Commission will contact the ECDC and explore the creation of online, up-to-date maps of at risk areas in the EU (for Chikungunya and other communicable diseases), which could be consulted directly by the competent authorities or the blood establishments.

WHO Europe offered to share their network of National Authorities contact points on communicable diseases.

5.3. Notification of Serious Adverse Events and Reactions - Discussion on a draft discussion document for the first annual reporting to the Commission in June 2008.

Serious Adverse Events and Reactions to be notified are often interpreted differently in different Member States. Therefore the Commission consulted the Member States on a draft common approach regarding the scope and definitions of the Serious Adverse Events and Reactions to tackle in the first annual report to send to the Commission in June 2008.

This common approach would aim to ensure the comparability of the information sent to the Commission from 27 different sources. Its goal would also be to avoid overburden for all the concerned parties (blood establishments, competent authorities, the Commission) by answering as much as possible questions in advance to the information gathering exercise.

The competent authorities reacted positively to the proposal. They agreed to send written comments on the draft document within 5 weeks. The Commission invited any interested competent authorities to join a small working group to finalise the common approach that will be made available in due time for the collection of data in early 2008.

DG SANCO will coordinate with DG Enterprise with regards to serious adverse events linked to medicinal products and medical devices.

5.4. Exchange of views on national implementations of the donors deferral rules based on sexual behaviour (Annex III – 2.1 of Directive 2004/33/EC)

In the last months the Commission has received several questions from Members of the European Parliament on the donors deferral rules applied to persons having sexual behaviours putting them at high risk of acquiring severe infection diseases that can be transmitted by blood[1].

The Commission included a specific question on this matter in the questionnaire to have a better understanding of the policies applied in this field. During the meeting some delegations completed the information

[1] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2006-5739+0+DOC+XML+V0//EN&language=EN
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2006-4492+0+DOC+XML+V0//EN&language=EN
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2006-2278+0+DOC+XML+V0//EN&language=EN

provided in the questionnaire. It appears that the national situations are rather different, depending of national epidemiological situations. The Commission and the Member States agreed on the fact that this issue necessitate further consideration in the future, keeping in mind the work already done in other international organisations such as the Council of Europe or the World Health Organisation.

The Commission concluded the discussion by emphasizing that the donor deferral principles in the Blood Directive primarily aim to guarantee the safety of the recipient. However, the Member States should apply safety measures in a proportionate way. One important element to consider in this context is that the donor selection rules are based on national, up-to-date epidemiological data. In any case, it is fundamental to properly inform the public and specific populations about the factors on which donor selection criteria is based.

6. PUBLIC HEALTH PROGRAMME

6.1. Presentation of projects in relation to blood and blood components

Dr Christian Seidl, coordinator of the EU-Q-BLOOD SOP Project (European Standard Operating Procedure methodology reflecting European best practice – Funded under the European Public Health programme in 2004) presented the final outcome of the project to the delegations. Several Member States showed interest for using the proposed methodology to issue standard operating procedures at national level.

The new EUBIS project (pan-European standards and criteria for the inspection of blood establishments – funded under the European Public Health programme in 2006) was introduced as well to the participants. The project is still in an initial phase. The project coordinator (Dr Christian Seidl) invited the interested competent authorities to answer a questionnaire on inspection of blood establishments, which sets the basement for the next steps of the project. The overall objectives of the project were welcomed by the participants and a majority of delegation agreed to contribute to the questionnaire. Some delegations offered to contribute in a more substantial way to the project.

6.2. Update on the new 2008 - 2013 Public Health Programme and on priorities for the 2008 call for proposal

The Commission updated the competent authorities on the new Public Health Programme 2008-2013 and consulted them on priorities to consider for human substances in the 2008 work programme.

7. OTHER BUSINESS

7.1. Presentation of the South Eastern Europe Health Network's project on blood safety

Dr. Alina Mirella Dobrota (Romania), Project coordinator, presented an interesting status report on the South Eastern Europe Health Network's project on blood safety.

7.2. Preliminary report of the SCENHIR on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers

The Commission informed the competent authorities about a preliminary report of the Scientific Committee on Emerging and newly-Identified Health Risks (SCENHIR) on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.[2] Blood and blood components collection, storage and transfusion devices are considered in the report.

The Commission invited the competent authorities to comment on to the SCENHIR preliminary report by the end of the public consultation period on 26 November 2007.

[2] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_cons_05_en.htm

Annex : List of participants

Country	Surname	Name	Organisation
BELGIUM	MUYLLE	Ludo	Federal Agency for Medicines and Health Products
BULGARIA	GAYDAROVA	Lyubina	Bulgarian Drug Agency
BULGARIA	TODOROV	Ivan	Bulgarian Drug Agency
CROATIA	ŠARLIJA	Dorotea	Croatian Institute of Transfusion Medicine
CROATIA	JUKIĆ	Irena	Croatian Institute of Transfusion Medicine
CYPRUS	KIOUPI	Stala	Blood Establishment, New Nicosia General Hospital
CYPRUS	SIDERA	Zoe	Blood Establishment, New Nicosia General Hospital
CZECH REPUBLIC	STÁRKOVÁ	Dana	Ministry of Health
CZECH REPUBLIC	TUREK	Petr	Fakultni Tomayerova nemocnice
DENMARK	KRISTENSEN	Hanne	Danish Medicines Agency
DENMARK	TOLDAM	Maria	Danish Medicines Agency
ESTONIA	RIKK	Tiina	Ministry of Social Affairs
ESTONIA	ORLOVA	Svetlana	State Agency of Medicines
FINLAND	LEINONEN	Eeva	National Agency for Medicines
FRANCE	SANDID	Imad	Agence Francaise de Sécurité Sanitaire des Produits de Santé (Afssaps)
FRANCE	WORMS	Bernadette	Direction Général de la Santé (DGS)
GERMANY	HEIDEN	Margarethe	Paul-Ehrlich-Institute
GREECE	KARATZA	Ekaterini	Ministry of Health and Social Solidarity
GREECE	ECONOMOU-PETERSEN	Effrossini	Hellenic National Blood Center
HUNGARY	BARÓTINÉ-TÓTH	Klára	Hungarian National Blood Transfusion Service
IRELAND	COSTELLO	Patrick	Irish Medicines Board
IRELAND	CUNNINGHAM	Grace	Irish Medicines Board
ITALY	DE ANGELIS	Vincenzo	Italian National Blood Centre - National Institute of Health
ITALY	GRAZZINI	Giuliano	Italian National Blood Centre - National Institute of Health
LATVIA	DAUGAVVANAGA	Anita	Health Statistics and Medical Technologies State Agency
LIECHTENSTEIN	BATLINER	Brigitte	Amt fur Gesundheit
LITHUANIA	NAUJOKAITE	Alvyda	Ministry of Health
LUXEMBOURG	HUBERTY-KRAU	Pierrette	Ministère de la Santé, Direction de la Santé
MALTA	ZAMMIT	Richard	Ministry of Health, the Elderly and Community Care
POLAND	RADZIWON	Piotr	Regional Centre for Transfusion Medicine
PORTUGAL	LOPES CORDEIRO	Alice	Autoridade para os Servicos de Sangue e Transplantacao
ROMANIA	DOBROTA	Alina Mirella	Regional Center for Blood Transfusion - Constanta county
SLOVAKIA	OVADEKOVA	Renata	State Institute for Drug Control
SLOVENIA	KOBLAR	Vesna	Agency for Medicinal Products and Medical devices
SPAIN	MORO DOMINGO	Elena	Ministerio de Sanidad y Consumo, DG Salud Publica
SPAIN	VESGA CARASA	Miguel	Vocal Comite Cientifico para la Seguridad Transfusional (CCST), Ministerio de Sanindad
SWEDEN	AXELSSON	Monica	The National Board of Health and Welfare
SWEDEN	ÅKERLIND	Britt	The National Board of Health and Welfare
SWITZERLAND	SCHNEEBERGER	Urs	Federal Office of Public Health

SWITZERLAND	JUTZI	Markus	Swissmedic, Swiss Agency for Therapeutic Products / Federal Office of Public Health
The former Yugoslav Republic of Macedonia	DUKOVSKI	Risto	Institute of Transfusion Medicine
The former Yugoslav Republic of Macedonia	DAUTI	Hanif	Mission of the Republic of Macedonia to EU
THE NETHERLANDS	KOK	Liisa	Ministry of Health, Welfare and Sport - Department of Pharmaceutical Affairs and Medical Technology
UNITED KINGDOM	GOULDING	Nigel	Medicines and Healthcare products Regulatory Agency
UNITED KINGDOM	TAYLOR	Clare	NHSBT/SHOT
	HAFNER	Valentina	WHO EU
	ABU AMIN	Noryati	WHO
	SEIDL	Christian	Blood SOP Project / EUBIS Project
	PIHA	Tapani	European Commission
	FERNANDEZ-ZINCKE	Eduardo	European Commission
	ZARDOYA-MARTINEZ	Maria	European Commission
	BRÉGEON	Thomas	European Commission