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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C6 - Health measures

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Meeting of the Competent Authorities on blood and blood components (Art. 25 Dir. 2002/98/EC)

13 September 2006

9.30 – 17.00

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 13 September 2006 under the Chairmanship of Mr Tapani PIHA, Head of Unit, Sanco C6.

23 Member States were present at the meeting and also Iceland, Norway, Liechtenstein, Bulgaria and Romania. EMEA attended the meeting as well. The list of participants is appended in annex I.

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.

2. BRIEF INTRODUCTION BY COMPETENT AUTHORITIES OF EACH MEMBER STATE

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

3. ADOPTION OF THE AGENDA

The agenda was adopted with addenda proposed by Austria (use of coding standard ISBT 128; use of anti Hepatitis C tests), Romania (inspections) and Belgium (data to include in the annual report on adverse events).

4. APPROVAL OF THE MINUTES OF THE LAST MEETING (26 SEPTEMBER 2005)

The minutes were approved by the participants to the meeting.

5. FOLLOW UP TO THE LAST MEETING

5.1. Computerising blood reports (Article 8 Directive 2005/61/EC)

The design of an electronic system for yearly reports of adverse events and reactions is in the Commission's work plan for 2007, in order to have a system available by the date of first reporting obligation by the Member States, i.e. June 2008. The participants to the meeting agreed with the approach and timeframe proposed by the Commission.

Belgium suggested that in this frame the definition of "Serious Adverse Event" is precised to better take into account specific types of events such as "near missed events", which could be relevant quality/security markers to be circulated among the Member States. This proposal was supported by several delegations, but a careful look should be given first to the existing national and European blood/drugs reporting systems (rapid alert systems, pharmacovigilance) to avoid duplication of efforts.

The participants agreed on the following:

- The Commission to map the existing haemovigilance networks as a starting point for shaping the future electronic reporting system.

- Belgium to send to the Commission a note explaining their expectations on the content of the Serious Adverse Events section in the yearly report.

5.2. Haemoglobin levels (Point 1.2 - annex III – Dir. 2004/33/EC)

The participants discussed a suggestion to include an addendum to point 1.2 of the annex III of Directive 2004/33/EC (threshold for haemoglobin levels in donor blood lies at 125g/l for women and 135g/l for men) letting a capped leeway to the Member States to lower the haemoglobin level, in order to decrease the exclusion rate of donors in some countries or regions due to their specific populations.

A majority of competent authorities confirmed that the haemoglobin levels as set in the directive lead to the exclusion of many potential donors, especially in young women, specific sub-populations or geographical areas. The principle of granting more flexibility to countries concerned by these high exclusion rates was broadly supported.

The Commission will clarify what legal options are available to modify the requirements of Directive 2004/33/EC on this matter.

Afterwards the Commission will consult the Member States in writing on the scope and wording of a possible proposal for addendum to the point 1.2 of the Annex III of Directive 2004/33/EC.

5.3. Protein content in fresh frozen plasma (point 2.4 - annex V – Dir. 2004/33/EC)

At the last meeting of the competent authorities on 26 September 2005, the requirement that the total protein content of fresh-frozen plasma should be higher than 50 g/l[1] has

[1] *Annex V Directive 2004/33/EC*

been questioned by some Member States. It was argued that this parameter makes quality control for fresh-frozen plasma unnecessarily cumbersome and expensive without any measurable increase in safety and quality.

The Commission presented the outcome of a small meeting of experts in May 2006, who concluded that the 50g/l threshold for total protein content in fresh frozen plasma is not unnecessarily cumbersome.

The participants broadly agreed with this conclusion and recommended that no other measures are necessary. Germany promised to send a note to the Commission summarising its intervention on this matter.

6. REPORTS FROM THE COMMISSION

6.1. Commission report on the transposition of Directive 2002/98/EC

6.2. Commission report on voluntary unpaid donation

The Commission presented the two reports. The participants expressed their interest for the information collected, which would constitute as a good basis for future discussion, especially with regards to voluntary unpaid donations.

6.3. Public Health Programme 2006

The Commission informed that five projects dealing with Substances of Human Origin are likely to be funded under the Public Health Framework Programme in 2006. Two out of these five projects directly concern blood and blood components (optimal use of blood and blood components; guidelines for inspections of blood centers). The Commission will give an overview of the projects progresses at the next meeting of the Competent Authorities.

6.4. Questionnaire on Transposition of the Blood Directive

The Commission distributed a preliminary version of the questionnaire on the updated level of transposition of the Blood directive and implementing directives by the Member States. New contributions were provided during the meeting. The document will be published on the internet after all answers were received.

7. SPECIFIC ISSUES RELATED TO THE IMPLEMENTATION OF THE BLOOD DIRECTIVES

7.1. Epidemics of Chikungunya

A severe epidemic of Chikungunya fever is currently affecting several countries of the Indian Ocean, including the French island of La Réunion. In Europe, occurrences of the virus among persons returning from the Indian Ocean area have been reported in the past months by several Member States.

Based on this particular epidemiological situation, the French health authorities have adopted nationwide (France and overseas departments) specific control measures on blood, tissues and organs donations, to secure the collection and distribution chain from a contamination by the Chikungunya virus.

The French authorities communicated to the Commission a note describing these measures. With France's agreement, the Commission distributed this note to the EU

Member States on 3 August 2005. At the meeting the French delegation further detailed the actions carried out at national level, as well as other Member States exposed to the disease.

The national delegates were of the opinion that point 2.3 of Annex III of Directive 2004/33/EC (deferral for particular epidemiological situation) is sufficient to ensure a satisfactory level of safety for blood and blood components at the current stage of the Chikungunya epidemics, since the risk of diffusion of the disease in the EU is limited.

The Commission recommended the Member States to carefully consider implementing measures comparable to France's, taking into account their national specific epidemiological situation and/or exposure to the disease.

7.2. NAT Testing for HIV/AIDS

Two cases of HIV infections were reported in March 2006 in Greece after transfusion of the blood originating from the same donor, who was seronegative by standard techniques, but positive by Nucleic Acid amplification Testing (NAT).

The Commission consulted experts on the benefit of including HIV NAT into the compulsory testing requirements. Conclusions were that, due to the heterogeneity of epidemiological and socio-economical situations among the Member States, there is no proof at this stage of the efficiency of systematising the use of such test at European level.

A large part of the Competent authorities confirmed that the decision to use NAT testing for HIV largely relies on national, and even regional, epidemiological and socio-economical contexts, sometimes even on political developments.

The Commission invited the competent authorities who have an experience in using the NAT testing for HIV to share their knowledge and expertise with the other countries by sending information to the Commission, who will circulate it.

The Commission concluded by urging the competent authorities to ensure that their donors screening and testing procedures as a whole are efficient and optimal, as laboratory tests – including NAT HIV tests – are only one step in the entire blood safety check process. Feed-back on national screening measures will be done at the next meeting of the competent authorities.

7.3. White cells in bone marrow transplants

The Donor Leukocytes for Infusion (DLI)[2] explicitly fall under the Blood Directive, while they are exclusively used in the frame of bone marrow transplants, which are regulated by the Tissue and Cell Directive. This situation leads to multiple interpretations among Member States regarding the legal framework to apply to the DLIs. This may result in bone marrow transplants centres having to be registered and inspected under both directives. The European Group for Blood and Marrow Transplantation (EBMT)

2 Donor Leukocytes for Infusion (DLI) are a routine therapy for patients post-allogeneic HSC transplant. DLI are taken from the same donor as the stem cell transplant according to the same standards and using the same collection techniques. DLI are intended as "transplant" products for long-term engraftment and effect in contrast to donor granulocyte transfusions which are intended for transient effect and which may not be donor specific.

regrets this situation and is calling for having the DLIs regulated only by the Tissue and Cell Directive.

Several competent authorities confirmed that they face difficulties indeed in choosing which legal framework should be applied to DLIs (origin vs. destination legal approach), leading to differing national practices.

The Commission asked the UK to share its legal analysis on this case to feed the discussion and the UK agreed to send a note. The Commission will further reflect on how to tackle this matter.

7.4. Inspection of mobile blood establishments (article 8 – Directive 2002/98/EC)

EMEA and some Member States reported to the Commission that the provisions of article 8 of Directive 2002/98/EC on inspections of blood establishments require clarification for actual and smooth implementation, especially with regards to the frequencies of inspections of mobile collection sites.

After several contacts with the Biologic Working Party in EMEA and experts on this topic, the Commission presented to the competent authorities a proposal for "memorandum of understanding" of the Blood Directive's provisions on inspection of mobile sites as follows:

Mobile collection sites are operated and managed under the quality system of the reference blood establishment. The equipment used is supplied by the reference blood establishment, and its maintenance and calibration is performed by the reference blood establishment. Full information regarding mobile collection sites' operation and management, as well as their equipments, are reviewed during the inspection of the reference blood establishment. The inspections of mobile collection sites' premises are done as necessary.

The representatives of the competent authorities broadly agreed with the approach proposed by the Commission, which fully respects the legal requirements of the Blood Directive and the feasibility of inspections in the field. Slight changes in the wording were suggested by some participants.

Based on the outcome of the discussion, the Commission will formally answer to the EMEA request for interpretation of the Blood Directive provisions on inspections of mobile collection sites (dated 23 August 2006), in time for the EMEA ad hoc meeting of GMP inspection services in December 2006.

8. ANY OTHER BUSINESS

8.1. Use of Anti-HBc test

The Competent authorities had an exchange of views on the potential benefit of the use of HBc testing, which is required by the Tissues and Cells Directive but not in the Blood Directive. The Commission concluded that further reflection is needed on this topic, as well as on the Blood directive testing requirements more generally, to take into account the technical and scientific progress since the Blood Directive was adopted.

8.2. Coding of blood and blood components

The Competent authorities had an exchange of views on the different national coding systems in place or in preparation for blood and blood components. The Commission

informed the participants about the activities of the working group on coding for tissues and cells, and will provide an update on its progresses at the next meeting of the competent authorities.

Annex 1: List of participants

Countries	Organisation
AT	Bundesministerium fur Gesundheit und Frauen
BE	SPF Santé publique, Sécurité de la Chaîne Alimentaire et Environnemen
BG	Bulgarian Drug Agency
CY	Cyprus Ministry of Health, Medical and Public Health Services
CY	Cyprus Ministry of Health, Medical and Public Health Services
CZ	Dept. of Pharmacy, Ministry of Health
CZ	Institute of Haematology and Blood Transfusion
DE	Paul-Ehrlich-Institut
DE	Regierungspräsidium Darmstadt
DK	Ministry of the Interior and Health
EE	State Agency of Medicines
EMEA	EMEA
ES	Ministerio de Sanidad y Consumo, DG Salud Pública
FI	National Agency for Medicines, Lääkelaitos
FI	National Agency for Medicines, Lääkelaitos
FR	Agence Française de Sécurité Sanitaire des Produits de Santé
FR	Ministère de la Santé
HU	National Blodd Supply Service (OVSZ)
Iceland	Ministry of Health and Social Security
IE	Compliance Department, Kevin O' Malley House
IT	Azienda Ospedaliero Universitaria "Ospedali Riuniti di Trieste"
Lichtenstein	Kontrollstelle für Arzneimittel beim Amt für Lebensmittelkontrolle und Veterinärwesen

LT	Health Care Division, MoH
LV	Latvian Blood Centre
LV	Health Care Organization
MT	Ministry of Health, the Elderly & Community Care - Department of Institutional Health
Norway	Directorate for Health and Social Affairs
Norway	Ministry of Health and Care Services
PL	Institute of Hematology and Transfusiology
PL	Main Pharmaceutical Inspectorate
PT	Portuguese Blood Institute
RO	Regional Blood Transfusion Centre of Constanta
SE	The National Board of Health and Welfare
SE	The National Board of Health and Welfare, Communicable Diseases Prevention and Control
SI	Agency for medical Products and Medical Devices of the Republic of Slovenia
SI	Ministry of the Republic of Slovenia
SK	Best Practice Inspection, State Institution for Drug Control
UK	Medicines and Healthcare products Regulatory Agency
UK	Department of Health