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C6 - Health Law and International

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

**12-13 April 2010**

**SUMMARY REPORT**

The sixth meeting of Competent Authorities as foreseen by article 25 of 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 12 and 13 April 2010.

All Member States except Slovakia were represented at the meeting; were also represented: Norway, Iceland, Liechtenstein, Croatia, the European Directorate for the Quality of Medicines and Health Care of the Council of Europe (EDQM), WHO Head Quarter, WHO Euro, the European Centre for Diseases Prevention and Control (ECDC) and the European Medicines Agency (EMA).

**1. ADOPTION OF THE AGENDA**

The agenda was adopted with the request to add a point on testing of fresh frozen plasma in section 3.3, and on the draft resolution on availability of blood and plasma derived medicinal products to be discussed at the next World Health Assembly in section 8.

**2. DIRECTIVE 2009/135/EC ON BLOOD SUPPLY IN THE CONTEXT OF THE INFLUENZA A(H1N1) PANDEMIC**

Article 3 of Directive 2009/135/EC, allowing temporary derogations to certain eligibility criteria for donors of whole blood and blood components in the context of a possible risk of shortage caused by the Influenza A(H1N1) pandemic, provides that it shall apply until

30 June 2010. The Commission and the Member States had a discussion to assess the need for a prorogation of the Directive beyond this cut-off date.

Several elements were considered.

- (1) As of 12 April 2010, no Member State had notified the Commission of having triggered the Directive 2009/135/EC.
- (2) Coverage of vaccination campaigns: The WHO has included the A(H1N1) strain in the recommendation for the seasonal flu vaccine 2010-11. The Committee of Human Medicinal Products of the European Medicines Agency (CHMP) has endorsed this recommendation. Therefore the next seasonal flu vaccination campaign will address A(H1N1). In addition, there are possible remaining stocks of monovalent vaccines. This should ensure that the immunity thresholds of the population are reached.
- (3) ECDC provided the latest data on the A (H1N1) flu pandemic: (1) The transmission rates are back to a low basic level; (2) No second wave of increased transmissions was observed in the southern hemisphere after the winter wave; (3) It is unlikely that the EU will experience a second spring/summer wave during 2010; (4) Still some sporadic infections are likely to occur during the spring/summer 2010, with particular impact on high risk groups; (5) The A/H1N1 influenza strain is most likely to be the predominant seasonal influenza virus in 2010/2011.
- (4) The emergency procedure followed to adopt Directive 2009/135/EC demonstrated the capacity of the European Commission to act swiftly in case of need.

Based on the above elements, the committee unanimously concluded that it was not necessary at this stage to renew the derogation.

Greece presented the results of a study on the impact of the A(H1N1) pandemic on blood donors and blood supply in Greece.

### **3. REGULATORY MATTERS**

#### **3.1. Minimum Hb levels in Donors Blood**

The Competent Authorities agreed on the usefulness to review the binding Haemoglobin thresholds set by Directive 2004/33/EC in order to better take into account the variations of these levels in the population of the Member States. However, in order to ensure the health of the donors, any decision to decrease the thresholds should be well documented and based on firm scientific evidence. This relates in particular to the potential impact on donors' iron stores. Also the differences between using venous or capillary punctions for measuring Hb levels should be further assessed.

In spite of the Commission's request for inputs, little documentation and evidence was collected.

Therefore the Committee concluded that there was currently no conclusive evidence to justify a change of the Hb levels laid down in the EU legislation.

In case sufficient evidence becomes available, the topic could be discussed again.

### 3.2. Maximum pH levels for platelets at end of shelf life

9 Member States answered to the questionnaire, which was circulated by the Commission in December 2009, on the impact of the maximum pH 7,4 threshold for platelet concentrates at end of shelf life. According to their answers:

- Available national findings seem to confirm the conclusions of the BEST study that pH above 7,4 does not influence in-vivo recovery and efficiency of platelets.
- The discard of platelets concentrates that do not meet the specifications can be important;
- The evolution of collection methods and storage bags may increase the number of non-compliant units.

The Committee concluded that it was not justified to maintain the upper pH limit laid down in Annex V of Directive 2004/33/EC. This will require a future amendment of the Directive, through the regulatory procedure. The Commission made no commitment on timing.

### 3.3. Others

#### 3.3.1. *Electronic signature of donors' questionnaires*

Denmark had a question regarding the possibility for donors to sign electronically the pre-donation questionnaire.

The Commission clarified that the Blood Directive does not precise whether the donor's questionnaire should be on paper or in an electronic format. It only specifies that (1) the chosen format contains the information listed in annex Annex II of 2004/33/EC, Part B, and (2) the questionnaire is signed by both the donor and the health care staff member responsible for obtaining the health history. Logically, if the questionnaire is in an electronic format, the signature will have to be digital. This is compliant with the Blood Directive provided that (1) the document read and signed by the donor/health professional contains the information listed in the item 3 of Annex II of 2004/33/EC, Part B, and (2) the electronic signature process is in line with Directive 1999/93/EC of 13 December 1999 on a Community framework for electronic signatures<sup>1</sup>.

Furthermore, the Commission took the view that information records according to article 13 and 14 of Directive 2002/98/EC can be stored in electronic form.

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<sup>1</sup> [http://eur-lex.europa.eu/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&numdoc=31999L0093&model=guichett&lg=en](http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&numdoc=31999L0093&model=guichett&lg=en)

### 3.3.2. *Proteins levels in donors' blood (Directive 2004/33/EC Annex III Item 1.3)*

Annex III.1.3 requires that protein levels of plasmapheresis donors are checked at least annually. Denmark considered that this obligation is useful to monitor donors' health when they donate around 30 times per year, but is disproportionate in countries, like Denmark, where they are not allowed more than 4 to 6 aphaeresis per year. Therefore they suggested that there should be a lower limit to the number of plasmapheresis donations (e.g. 6 per year), above which the annual protein analysis annually should be mandatory.

The Commission took note of Denmark's concern, but stressed that their proposal goes beyond the interpretation of Directive 2004/33/EC.

The Committee concluded that the issue should be further discussed within the framework of EDQM.

### 3.3.3. *Testing of fresh frozen plasma*

UK will submit to the Committee a written question regarding testing requirements applying to imported fresh frozen plasma intended for transfusion, which will be circulated to all Member States. This point will be addressed at the next meeting of the Competent Authorities.

## 4. TRANSPOSITION CHECKS

In order to adequately monitor the transposition of the Blood Directive, a "Report template: Transposition concordance table" was sent to the Member States in March 2009.

Based on the information sent to the Commission by the Member States, DG SANCO has started the transposition checks. A preliminary analysis of the data revealed that the Member States provided the Commission with insufficient information: Either the legislation sent to the Commission contains missing information or the transposing laws have not been sent at all. In addition to this general problem, the Commission identified certain main problem areas, including record keeping, traceability, notification of serious adverse events and reactions, eligibility of donors and testing of donations.

The Member States that have not yet sent the completed concordance tables to the Commission were urged to do so by 30 April 2010. It was also mentioned in the meeting that the Commission would contact the Member States to request additional information and clarification. It was underlined that failure to fully transpose the blood directives may lead to infringement procedures.

## 5. REPORT ON THE PROMOTION BY THE MEMBER STATES OF VOLUNTARY UNPAID DONATION (ARTICLE 12 OF DIRECTIVE 2002/98/EC)

The principles governing voluntary and unpaid blood donation are set out in article 20 of Directive 2002/98/EC. It states that *Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.*

In accordance with the Directive, Member States shall report to the Commission on the practice of voluntary and unpaid blood donation every three years. An electronic report template on "Voluntary and Unpaid Donation of Blood and Blood Components" will be sent to the Member States during the coming weeks. Deadlines for responses will be mid-June 2010. The collected information will provide the basis for the second Commission report on voluntary and unpaid donation in the field of blood.

## **6. QUALITY SYSTEMS: GOOD PRACTICE GUIDELINES ACCORDING TO ARTICLE 2.2 OF DIRECTIVE 2005/62/EC**

### **6.1. Joint initiative Council of Europe/EDQM and European Commission**

In accordance with Directive 2005/62/EC (Article 2), the Commission shall develop good practice guidelines for the interpretation of quality system standards and specifications.

The Committee was informed about the joint drafting process of guidelines on quality systems in Blood Establishments by the Council of Europe/EDQM and the Commission. The overall aim is to develop quality/safety provisions, taking into account the specific needs of quality systems for transfusion as well as GMP (in accordance with Directive 2005/62/EC).

The Commission insisted on the need for all experts and involved parties to liaise at national level in order to ensure consistency at European level. The Member States welcomed this approach, and a number of Member States volunteered to assist the two Institutions in this process.

### **6.2. Annex XIV of EU GMP on manufacturing of medicinal products derived from human blood or plasma**

EMA and the Commission presented the state of play for Annex XIV of the Good Manufacturing Guide for medicinal products, which relates to medicinal products derived from human blood or plasma.

In case of comments and further questions, the Members of the Committee were advised to liaise with their MS's representative in the Pharmaceutical Committee.

## **7. SURVEILLANCE AND VIGILANCE**

### **7.1. Infectious diseases risks: latest news**

This topic will become a fixed point on the agenda of future meetings.

#### *7.1.1. Q fever outbreak in the Netherlands*

ECDC presented their preliminary risk assessment on Q fever, where they pointed out the risk of transmission of the disease via blood transfusion.

NL provided information on their epidemiological situation, and commented that the Dutch blood transfusion service Sanquin is developing and applying a Q fever test for blood donations.

The Member States expressed concerns about the situation in NL and, pending the final ECDC risk assessment due end of April, they agreed that it would be reasonable to apply at least a 5 weeks deferral period for any potential blood donor having visited a farm or having stayed overnight in the concerned areas in NL. NL was asked to give details on these areas for onward transmission to the other Member States. All MS should keep the Commission informed on any action taken. The Commission will evaluate the need for amending the EU donor selection criterion for Q fever on the basis of the final ECDC risk assessment.

In this context, the Competent authorities were reminded that the Member States should notify the Commission of any blood donor deferrals for particular epidemiological situations (point 2.3 of Annex III of Directive 2004/33/EC).

#### *7.1.2. West Nile Virus (2010 season)*

Italy presented the plan they have prepared to face the 2010 season of West Nile Fever.

#### *7.1.3. Others infectious diseases risks*

Italy raised the attention of the participants on the potential risks posed by the emergence of the Usutu virus in Europe. It also flagged concerns regarding the new human gammaretrovirus xenotropic murine leukaemia virus-like (XMRV).

Greece informed the participants on seven cases of malaria in individuals living around Sparta, in the south of Peloponnesus, in August and September 2009. Precautionary measures were taken for blood collection. Six months later, the precautionary measures have been withdrawn, but further vigilance has been recommended.

The Competent Authorities agreed on the importance of properly monitoring health threats and to share the information having a potential impact on blood safety with the Commission and the other Member States.

### **7.2. Vigilance of human substances: status and next steps**

The Commission provided the Committee with information on the state of play of the steps towards involving an EU agency (ECDC or EMA) in the vigilance activities under the Directives on Blood and Tissues/Cells, in order to avoid any misunderstanding regarding the scope and objectives of this involvement. The Commission made clear that the vigilance activities would only concern blood components, tissues and cells intended for transfusion or transplantation, and would not cover any pharmaceutical products (like Advanced Therapy Medicinal Products or plasma derivatives). The objective is not to build a single European system for vigilance, but to connect the functioning national systems.

The Commission will keep the Competent Authorities informed as the discussions advance in the coming months.

### **7.3. SARE annual reports to the Commission – next steps**

The Commission informed the Member States that they will shortly receive a report template for serious adverse reactions and events (SARE) that occurred and/or were validated in 2009 (from 1st January to 31st of December). The completed report template should be submitted to the Commission by 30 June 2010.

The Commission will elaborate a third version of the "common approach document" during the autumn 2010 with the assistance of the Member States. This updated version will be used for the 2011 SARE annual report (with data of 2010).

**8. ANY OTHER BUSINESS**

The World Health Organization presented a draft resolution on availability of blood and blood products to be tabled at the next World Health Assembly in May 2010.

Chair of the Committee

Patricia Brunko 