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Joint meeting of the Competent Authorities and the Regulatory Committee on Blood and Blood Components

27-28 October 2010

Summary Report

The joint meeting of the Competent Authorities and the Regulatory Committee on blood and blood components was convened on 27-28 October 2010.

All Member States except Latvia were present at the meeting of the Competent Authorities and the Regulatory Committee. Iceland, Liechtenstein, Croatia, Turkey and the Former Yugoslav Republic of Macedonia as well as the European Directorate for the Quality of Medicines and Health Care of the Council of Europe (EDQM), the World Health Organization (European Office), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) also attended the meeting.

1. ADOPTION OF THE AGENDA

The agenda was adopted without change.

MATTERS FOR THE COMPETENT AUTHORITIES

2. SURVEILLANCE AND VIGILANCE

2.1. Update on infectious disease risks: latest news

2.1.1. Creutzfeldt-Jakob disease (CJD), EMA position paper

The European Medicines Agency presented its activities relating to Directive 2002/98/EC[1] and its implementing measures. Particular focus was given to EMA's position papers on (1) Creutzfeldt-Jakob disease and plasma-derived and urine derived medicinal products and (2) Creutzfeldt-Jakob disease and advanced therapy medicinal products.

In its position paper, EMA is recommending defining further precautionary measures related to blood safety. Possible exclusion criteria include permanent deferral for donors who have spent a cumulative period of 1 year or more in the UK between the beginning of 1980 and the end of 1996, recipients of blood transfusion, recipients of transplants and donors who have undergone neurosurgery. Member States expressed concerns that the recommendation to expand deferral criteria for blood donors would lead to loss of blood volumes. It was agreed that there is a need for further assessment. EMA will provide more information on the evidence-base for the suggested further exclusion criteria.

In order to get a more comprehensive overview, the Commission will ask the Members States for information on existing national blood safety measures in relation to Creutzfeldt-Jakob disease and to estimate the impact on blood supply of the EMA recommendations by the end of November. Member States are welcome to send additional scientific evidence on deferral criteria.

EMA also presented other areas relating to collection and testing of blood and plasma, including inspections, donor selection in third counties and import. EMA and the Commission will reflect on an approach to address these jointly with the Competent Authorities.

2.1.2. Q-fever outbreak in the Netherlands

The ECDC and the Netherlands updated the Member States on the ongoing Q-fever outbreak in the Netherlands. The Dutch Q-fever situation appears more stable, and there are signs that the outbreak is levelling off.

Following the conclusions on blood safety in ECDC's risk assessment on Q-fever (published in May 2010)[2], it was agreed that it would be reasonable to apply at least a *6 weeks* deferral period for any potential blood donor having visited a farm or having stayed overnight in the identified risk areas in the Netherlands (previously 5 weeks[3]). Austria, Belgium, Czech Republic, Greece, Luxembourg, Malta, Romania, Slovakia and Slovenia apply deferral period for

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[1] DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 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.

[2] http://www.ecdc.europa.eu/en/publications/Publications/1005_TER_Risk_Assessment_Qfever.pdf

[3] http://ec.europa.eu/health/blood_tissues_organs/docs/blood_mi_20100412_en.pdf

such donors. Competent Authorities in Denmark, Finland, France, Germany, Ireland, Italy, Spain and the United Kingdom have conducted a risk-benefit assessment but concluded that deferral measures were not required at the current stage.

The Netherlands informed the Competent Authorities that testing of blood donated in high-risk areas will be terminated on 1 November 2010. The Netherlands agreed to inform the Commission once the approach for 2011 is agreed. The Netherlands is currently considering vaccination of high risk patients.

2.1.3. West Nile virus

The ECDC and a number of Member States affected by the West Nile virus, including Italy, Romania, Hungary, Greece and Spain, gave an update on their national epidemiological situations and blood safety measures taken.

In addition, Romania presented the results of a questionnaire on precautionary measures for West Nile virus in relation to blood safety, which was sent to the Competent Authorities during the spring of 2010.

It is expected that an increasing number of cases of West Nile virus will be reported in 2011. A subgroup will be created to develop a preparedness plan for next year's anticipated West Nile virus outbreak. Elements to consider include impact on volume, geography, deferral criteria, cost and NAT testing. The objective is to have a first meeting in January 2011 in Thessaloniki, Greece. The Commission will follow-up with the ECDC and Greece.

2.1.4. Chikungunya and dengue fever in France

France briefly updated the Competent Authorities on the reported French cases of Chikungunya and dengue fever.

2.1.5. Other - Member States will be asked whether they have any additional information to report

Greece informed the Member States about four reported Greek cases of Malaria.

In addition, a number of Member States underlined the usefulness of having a European map on communicable disease outbreaks, including West Nile virus, which should be continuously updated and made widely available.

2.2. Surveillance and vigilance of human substances: status and next steps

During the summer of 2010, the Commission has received and forwarded a number of messages on infectious disease outbreaks which may have implications on blood safety to the Competent Authorities. The Commission thanked all concerned Member States for their proactive communications.

Overall, Member States seemed to be rather content with the communication approach taken over the summer by the concerned Member States and the Commission. However, a number of Member States underlined the importance

of receiving the epidemiological information as early as possible, and whenever possible clearer guidance on blood safety measures should be given. It was agreed to use West Nile virus as a case study and the work of the planned subgroup (see agenda point 2.1.3) will include suggestions on the communication of alerts and assessments. In addition, Member States pointed out the need of collecting information on communicable disease outbreaks also outside the EU. The WHO should therefore also participate in this group. It was also noted that it would be useful if ECDC could define from all infectious diseases which are relevant for blood safety.

2.3. SARE Annual report to the Commission

The Commission presented the main findings of its annual report template on serious adverse events and reactions (for year 2009), which was sent to the Member States during the spring of 2010. The Commission has received responses from all but one Member State.

In addition, France presented its systems for serious adverse events and reactions.

The Commission clarified that whilst there is a legal requirement to be met, this exercise should support Member States in organising and developing their vigilance systems. The scope (mandatory and voluntary elements) of the SARE reporting was discussed. It was underlined that the report template should include clear definitions and that we should aim for as straightforward and concise approach as possible. This work will be taken forward by a working group (Austria, Belgium, Cyprus, France, Germany, Greece, Ireland, Italy, Portugal and the United Kingdom volunteered to participate in the group. It should also include representatives from the Council of Europe and IHN[4]). The main task of the working group will be to review and complete the common approach document for definitions of reportable serious adverse events and reactions. The working group will also examine and give recommendations as to whether technical adaptation of the Annexes II and III of Commission Directive 2005/61/EC, with regard to the notification of serious adverse reactions and events, would be required.

Member States are invited to send to the Commission their contributions and/or corrections to the SARE draft report by 30 November 2010.

3. PRESENTATION OF PROJECTS FUNDED BY THE EU HEALTH PROGRAMME

The Council of Europe presented the ongoing study on proficiency testing, aiming to assess the performance of laboratories based on interlaboratory comparisons.

The final outcomes of the EU Optimal Blood Use project were presented by Dr McClelland (homepage of project: http://www.optimalblooduse.eu). This project, which is co-financed by the EU Health Programme, aims to improve the quality of the clinical transfusion process through the development of a manual for optimal

[4] International Haemovigilance Network.

blood use. The manual was distributed at the meeting. The project was endorsed by the Member States who welcomed the excellent work undertaken by the project.

MATTERS FOR THE REGULATORY COMMITTEE

1. REGULATORY MATTERS

1.1. Maximum pH levels for platelets at end of shelf life

The draft Commission Directive amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life was presented. Following the presentation, the issue of correlation tables was discussed. It was agreed to keep the reference to correlation tables in article 2 of the draft Commission Directive. The draft Commission Directive got the favourable opinion of the Regulatory Committee with 287 votes in favour. All 27 Member States were present or represented. One Member State voted against the draft Directive and one Member State abstained. That Member State informed the Commission that it would abstain from voting as its Coalition Government is unable to agree to commit resources to transpose into national law a Directive consisting of a single minor technical amendment to Annex V of Directive 2004/33/EC.

The draft Commission Directive will be entered in the Comitology Register, in accordance with the right of scrutiny of the European Parliament (one month period), before it is formally adopted by the Commission and published in the Official Journal of the European Union.

As a general comment, several Member States mentioned the need to review Directive 2004/33/EC[5] in view of recent developments in the field. The Commission encouraged these Member States to send to the Commission more detailed information on specific aspects of the Directive which they believe should be reviewed.

1.2. Follow-up on question from the UK on quality control standards for monitoring fresh frozen plasma

Following the meeting of the Competent Authorities in April 2010, the UK circulated a question on quality control standards for monitoring fresh frozen plasma to the other Member States. More specifically, Annex V of Directive 2004/33/EC requires that Factor VIIIc is measured as a marker of its quality at a frequency determined using statistical process control. Acceptable results for quality measurements are an "Average (after freezing & thawing): 70% or more of the value of the freshly collected plasma unit". The UK asked for input from the other Member States on what they consider as acceptable practice(s) in their blood establishments for the quality monitoring of fresh frozen plasma.

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[5] COMMISSION DIRECTIVE 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.

Given the poor response rate, it was agreed that the UK should re-circulate the question to the Competent Authorities. The collected information should be shared with the EDQM which is currently in the process of reviewing quality control standards for monitoring fresh frozen plasma.

The results of the EDQM work are expected by March 2011 and will be reported to the Committee.

1.3. Deferral criteria for donors, presentation on risk behaviours having an impact on blood donor management

Directive 2004/33/EC foresees permanent deferral criteria for persons whose sexual behaviour puts them at high risk of acquiring sever infectious diseases that can be transmitted by blood. Directive 2004/33/EC foresees a temporary deferral criteria for persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood (defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests.

The Council of Europe is undertaking a study on risk behaviours having an impact on blood donor management, including men having sex with men (MSM). The EDQM presented the first findings of the ongoing work.

A 2008 ECDC survey showed that 21 EU/EFTA countries implement permanent deferral criteria for MSM, while 5 countries exclude persons with high risk sexual behaviours, without specific exclusion of MSM.

First available data for a limited nr of countries indicate a higher prevalence of HIV within the MSM group versus the prevalence of HIV within the general population. A few countries confirm MSM as a major probable cause of infection in verified HIV-positive donors. Comparing countries showed that HIV prevalence in blood donations is higher in countries without specific MSM exclusion criteria. However more data are needed and EDQM will continue the collection of scientific and epidemiological data and assess feasibility, risks and benefits of changes in deferral criteria and testing policies. The results of the study should be presented at a forthcoming meeting of Competent/Regulatory authorities.

Member States showed interest in this study and several mentioned to have received requests to assess and review the national deferral and testing criteria for blood donations by MSM.

The participants of this meeting encouraged further work by EDQM and underlined that changes in deferral criteria and testing policies can only take place after a scientific and epidemiological assessment of its impact on quality and safety of donated blood and blood components.

2. TRANSPOSITION CHECKS

The Commission thanks those Member States that have provided information. The Commission announced that it is currently analysing the information sent by the

Member States on their legislation transposing the Blood Directive. There are question marks in relation to the transposition of the legislation in about 10 countries. The Commission will contact the countries by the end of the year with a request for clarification or additional information.

3. REPORT ON THE PROMOTION OF VOLUNTARY AND UNPAID DONATIONS (ARTICLE 12.2 OF DIRECTIVE 2002/98/EC)

The Commission presented the main findings of the report template on voluntary and unpaid donation of blood and blood components, which was circulated to the Member States during the spring of 2010.

The overall aim of this agenda point was to introduce the main findings and allow for questions and feedback from the Member States. The Commission will send the draft report to give the Member States an opportunity for comments by 1 December. Publication of the report is planned for the end of 2010.

4. QUALITY SYSTEMS

4.1. Good practice guidelines according to article 2.2 of Directive 2005/62/EC

As set out in Directive 2005/62/EC (article 2)[6], the Commission shall develop good practice guidelines for the interpretation of quality system standards and specifications. As announced during the previous meeting, the Council of Europe and the European Commission have agreed to further enhance their cooperation in this field and to develop a common approach for good practice quality system guidelines. The overall objective of this cooperation is to have a joint drafting process of next editions of the Council of Europe's "Guide to the Preparation, Use and Quality Assurance of Blood Components".

The EDQM announced that the first meeting of the joint drafting group should take place in the first months of 2011. The EDQM will provide more detailed information, including a fixed date for this meeting, as soon as possible.

The following 12 countries volunteered to participate in the drafting process: France, Italy, Greece, United Kingdom, Ireland, Cyprus, Portugal, Austria, Romania, Spain, Hungary and Croatia.

4.2. Annex XIV of EU GMP on manufacture of medicinal products derived from human blood or plasma

The Commission updated the Member States on the ongoing revision of Annex XIV of EU GMP on manufacture of medicinal products derived from human blood or plasma.

It was concluded that the draft Annex XIV should progress without making any statement on import criteria for plasma fractionation programmes for third

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[6] COMMISSION DIRECTIVE 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.

countries, other than referring to the import criteria set out in the Blood Directive and its implementing measures. The Commission will pass this conclusion to the drafting secretariat of this Annex XIV within EMA.

The draft Annex XIV will be distributed to the Member State representatives for information.

As a next step, the Commission will set up a joint effort to discuss contract fractionation programmes and import criteria together with the interested Member States (Austria and the United Kingdom), EMA and WHO.

5. ANY OTHER BUSINESS

A Member State asked whether the use of autologous platelet-rich plasma, like for orthopaedic purposes, is subject to the SoHO legislation. The Commission will look at this question in more detail and provide more information at the occasion of the next Competent Authority meeting.

Upon question from a Member State, the Commission explained that confirmations of meetings can only take place 6 weeks before the meeting date itself, given the internal Commission procedures.

Chair of the Committee

Mr Antti Maunu