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Meeting of the Competent Authorities on Blood and Blood Components

16-17 May 2011

Summary Report

The meeting of the Competent Authorities on blood and blood components was convened on 16 and 17 May 2011. The previous meeting of National Competent Authorities (NCAs) took place in October 2010.

All Member States were present at the meeting. Iceland, Croatia, and Norway as well as the European Directorate for the Quality of Medicines and Health Care of the Council of Europe (EDQM) and the European Centre for Disease Prevention and Control (ECDC) also attended the meeting.

European Commission – SANCO D4:

Chairman: Mr Antti MAUNU

Ms B. KALTENBRUNNER BERNITZ, Ms I. SISKA, Ms S. VILLANUEVA, Ms. H. LE BORGNE, and Mr Stefaan VAN DER SPIEGEL

1. ADOPTION OF THE AGENDA

The agenda was adopted with additional points suggested by FR, AT and PL under the section "Any other business".

MATTERS FOR THE COMPETENT AUTHORITIES

2. SURVEILLANCE AND VIGILANCE

2.1. Update on infectious disease risks

2.1.1. Follow up on the European Medicines Agency's CHMP position statement on Creutzfeldt-Jacob disease (CJD) and plasma-derived and urine-derived medicinal products

In its draft position statement on Creutzfeldt-Jacob disease presented during the NCAs meeting in October 2010, the European Medicines Agency (EMA, not present during this meeting) recommended certain exclusion criteria for blood donors to ensure the safety of plasma-derived and urine-derived medicinal products. Possible additional exclusion criteria included 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.

Following the quite critical opinion of several NCAs, DG SANCO has sent a questionnaire to Member States for information on existing national blood safety measures in relation to Creutzfeldt-Jakob disease and to estimate the impact of EMA recommendations on blood supply at national level.

The Commission presented the replies to the questionnaire provided by 9 Member States (MS). During discussions, several MS have noted that they did not receive the questionnaire regarding national blood safety measures in relation to Creutzfeldt-Jakob disease, and therefore had no opportunity to provide feedback. DG SANCO agreed to re-circulate the questionnaire with an additional question on whether the proposed additional deferral criteria may impact blood supply/plasma fractionation.

It was also stated that a harmonised approach on introducing additional exclusion criteria for vCJD at EU level would be beneficial, but could be difficult to reach due to various degree of impact on national blood supply and plasma required for fractionation.

Several Member States re-expressed serious concerns regarding the impact of such additional deferral criteria on the supply of blood and blood components.

It was also mentioned that EMA will finalise its position statement by end of June, and that this final document will be circulated by SANCO D4 to all NCAs.

It was clarified that the EMA position statement is not legally binding, and provides only recommendations or suggestions, and should be subject to national assessments on impact of blood supply in each MS.

2.1.2. General update on infectious diseases in relation to blood safety

ECDC briefly presented the recent changes in its structure due to the recent reorganisation of the agency. It was mentioned that no changes of mandate were operated.

ECDC provided a general overview on infectious diseases as monitored by the agency on a regular basis.

Following the outbreaks of Q fever which affected some of the MS in the last years, ECDC gave an update on the current epidemiological situations and needs of blood safety measures.

ECDC has also included a short presentation of the EUFRAT project, which will soon provide NCAs an online tool to estimate the risk of blood contamination during outbreaks. This tool will be launched most likely in June and will be

made accessible to NCAs during a pilot phase of one year. This tool should be fully operational by the end of 2012.

2.1.3. West Nile Virus (WNV) - feedback from the working group on West Nile Virus infections and blood safety and the development of a European preparedness plan for 2011

Following the decision of the NCAs in October 2010 to set up a subgroup of Competent Authorities to develop a European preparedness plan for the anticipated outbreak of West Nile Virus in 2011, ECDC co-organised with DG SANCO and the Greek CA a workshop in Thessaloniki in January 2011. This work was led by Greece, in close cooperation with several Competent Authorities (IT, FR, RO), ECDC and the European Blood Alliance (EBA).

ECDC briefly introduced the workshop and some of its key-outcomes. Elements covered include the definition of "affected area", need for real-time sharing of epidemiological overview at EU level for decision making in other EU countries, strengthening surveillance in at-risk and affected countries, further need for guidance on how to apply EU blood directive. ECDC also enumerated its ongoing projects in relation to WNV (e.g. Blood Safety Risk estimation tool (under the EUFRAT project), expected to be available for internal testing in June 2011; regular epidemiological update of publicly available information on WNV on ECDC website).

The topics discussed and the major results of the Thessaloniki meeting were presented by the Greek CA, followed by a presentation from the EBA representative on the conclusions of a survey regarding measures taken in 2010 during WNV outbreak, which was assigned to EBA during the 1st meeting of the WG on WNV in Thessaloniki.

The Greek CA introduced the Draft Preparedness Plan, as well as a proposal for an Action Plan for Protecting the Blood Systems, drew up during the Thessaloniki workshop. Outstanding issues concern:

- NAT testing,
- multi-sector surveillance,
- Definition of an affected area, risk area and free area.

It was mentioned that the preparedness plan will be finalized by mid June 2011 and that ECDC will provide the models and relevant data for risk assessment and that a coordinated tool will be available by the ECDC at the beginning of summer 2011.

After discussions, it was concluded that the WG on WNV should continue its work taking into account the possible contributions from other NCAs in order to finalize the Preparedness Plan as scheduled (mid-June 2011).

SANCO will organize a conference call of the WG consisting of NCAs of affected areas (GR, FR, IT, RO) and of free areas (AT, DK, NO). For the later

countries, the work should also cover identification of and protocols for potential donors who traveled to and returned from “affected areas”.

The updated preparedness plan will be circulated by SANCO to the MS in order to provide competent authorities with guidance on how to conduct quantitative risk assessments for blood safety to be included in national WNV preparedness plans.

2.1.4. Follow-up on reported cases of Q-fever in the Netherlands and Germany.

ECDC noted that the implementation of control measures in 2010 in the Netherlands have resulted in a decrease in number of reported cases in 2011 (only 10 cases confirmed until April). The outbreak reported in Germany was not considered to be linked with the outbreak in the Netherlands. In both countries the situation seemed to remain stable as no abnormal increase in cases has been notified at the start of the lambing period and measures have been taken by the local authorities in charge.

NL representative gave an overview of the situation concerning Q fever and its implications on the supply of tissue, cells, blood and blood products in 2011, summarizing the information sent in May to the European Commission. In summary, in 2011, 24 cases of Q fever in humans have been reported, eight being new cases; one death has been notified. Following the recommendation of Health Council in 2010, the Dutch Government began offering vaccination against Q fever to high-risk patients, in order to limit the number of new cases of infection in high-risk groups. Since 1 November 2010, blood donations from high-risk areas have no longer been tested for *C. burnetii* DNA. It was also mentioned that a report from the Health Council concerning risks of Q fever from tissue, cells and blood products is in its final phase, and its conclusions will be notified to the Commission. Currently, because there are no risk areas, there are no special recommendations to be made to the NCAs group.

The DE representative gave a brief update on the reported cases of Q-fever in Germany. Outbreaks were reported in 2 regions in which Q fever is endemic in sheep, but there is no geographic context between the German and Dutch regions. There was no spread of disease to adjacent districts and specific measures have been taken by local veterinary health authorities. In 2011, 111 Q fever patients were registered, but there was no increase of cases in the region close to the Dutch border. Measures were taken by local health authorities and blood establishments in the concerned regions.

Following a question from BE regarding ECDC's risk assessment method and the lack of a peak in the number of cases registered in 2011, ECDC agreed to make an update of the blood safety related aspects of the risk assessment on Q-fever in 2010. This report will be circulated and might be considered by the MS that indicated during the previous meeting of Competent Authorities to apply a deferral period (AT, BE, CZ, EL, LX, MT, RO, SK and SL). The current situation seems to suggest that the deferral measure is no longer needed.

NOTE: ECDC has provided this update on 26/5 and concluded " *Based on the available data for 2011, the risk for collecting contaminated blood donations in*

the Netherlands, as well as the risk for donors from other EU Member States after travelling to the Netherlands has considerably decreased, compared to 2010. Member States may want to take into account this change of estimated risk in the concerned safety assessments."

NL and DE agreed to keep SANCO informed on future changes in the national situation.

2.1.5. Follow up on discussion on blood safety and XMRV

The XMRV virus and its possible implications on blood donation have been discussed at the Competent Authority meeting for blood in April 2010. Following this meeting, in September 2010 the Commission has requested the support of the ECDC to assess (1) the epidemiological profile of XMRV, (2) scientific evidence of the link between chronic fatigue syndrome and the presence of XMRV in the blood and transmission via blood donation, and (3) to advice the Commission on the possible value and need of introducing deferral criteria and/or testing requirements in the EU.

In reply to this request, ECDC provided a preliminary draft assessment, stating that the work is in its final stage, and the report will be available in the near future. After a comprehensive literature search, ECDC's initial conclusions seem to indicate that the current evidence cannot distinguish whether XMRV is a real human virus or the result of laboratory contamination. There was no concluding evidence of association between XMRV and any human disease. No validated assays that detect infected individuals but do not implicate non-infected individuals have been yet developed. It was mentioned that there are many ongoing studies and their results, when available, will be considered. It was concluded that a critical examination of the existing evidence does not support implementing deferral to address known risk as there has been no study suggesting transfusion transmission. If implemented, the justification for the measure would be applying an approach based only on the precautionary principle.

The final report will be provided by ECDC in the coming months.

2.1.6. Other

The CA from Germany gave a brief update on two cases of HIV transmission via blood transfusion due to HIV-1 NAT failure in donor screening.

The presentation highlighted that HIV-1 RNA donor screening by NAT increases blood safety, but some cases of test failure have occurred with the use of mono-target screening NAT tests. (The underlying reason seems to be the mismatches between test primers and target region sequences; some of these mismatches were not expected to result in test failure.)

As a consequence, a written exchange of information was organised at national level to raise awareness about the test failure and discuss on subsequent measures. In June 2011 a meeting with various experts in this area is convened

for analysing the appropriate corrective measures. DE authorities will communicate the output from this meeting to the National Competent Authorities during the next meeting.

No Competent Authorities raised further epidemiological situations.

2.2. Presentation on findings of the study on proficiency testing

The Council of Europe briefly presented the ongoing project concerning quality systems in the blood transfusion field including inventory visits, audits and proficiency testing scheme (PTS), which is co-funded under the Public Health Programme. In 2010 two pilot studies focused on screening tests by NAT were performed. The preliminary findings were in line with the conclusions stated in the presentation from Germany – there are different results for NAT testing for different HIV genotypes, depending also on technologies used. In 2011, four studies are foreseen: two studies on NAT, one on serology (currently finished with the report under preparation), and one on ABO blood groups (in planning phase).

3. REGULATORY MATTERS

3.1. Points for information

3.1.1. Maximum pH levels for platelets at end of shelf life - adoption of 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

The Commission informed the NCAs that the Draft Commission Directive was adopted on 11 April 2011, with the reference number 2011/38/EU. The Directive and all translations are available on the SANCO website. NCAs did not express concerns regarding the deadline for transposition (30 June 2011).

3.1.2. Transposition checks

The Commission informed the NCAs that the transposition check of the EU Blood Directives is completed for most MS. The Commission also mentioned that updated information from Greece, Latvia, Lithuania and Poland will be requested. Additional information would be also asked for from Austria, Hungary, Germany and Spain. Specific requests for clarifications will be sent by DG SANCO D4 to the concerned NCAs.

3.2. Report on voluntary and unpaid blood donation

The Commission presented the main findings of the recently published "Report on voluntary and unpaid blood donation" with the aim to discuss them with the Member States.

The results of the report were seriously debated. The topics and concerns raised by CAs included: remuneration/payment and the consequences for donation rate and

safety& quality of donated blood; improvement of donor management; the need to disconnect the file on blood/plasma shortage from the file on remuneration of donors; the need to examine also blood wastage in the context of ensuring self-sufficiency at national level; the need to examine optimal use of blood and plasma, including further dissemination of the results of the "Optimal Use of Blood" project which was funded by EC under the Public Health Programme (manual available at <http://www.optimalblooduse.eu/>), as well as the output of other EU-funded projects in the blood area.

The Council of Europe mentioned the work of the Working Group on blood supply management, covering the different topics raised. The CoE and this Working Group agreed to brief this group of Competent Authorities regularly on its progress and findings.

The group confirmed its support for the work of the Council of Europe, as laid down in recital 23 of Directive 2002/98/EC. The Competent Authorities also agreed that the current legal text reflects well the different points of view within the EU and that no legal changes are needed.

It was therefore concluded that no further measures are needed on Voluntary Unpaid Donation at EU level.

3.3. SARE Annual report to the Commission – update and feedback from working group

At the CA meeting in October, it was agreed to set up a working group gathering MS, Council of Europe and International Haemovigilance Network (IHN) to review and complete the current version of the common approach document for reportable serious adverse events and reactions (SARE).

The first meeting of the working group was held on 3 May 2011. The overall aim of this session was to present and discuss the work of the group on the common approach document for SARE.

The Commission briefly introduced the legal obligations of the MS and the objective of SARE reporting, as well as the objectives of the working group. On behalf of the WG, the IHN representative has presented the discussions and output, together with the suggestions put forward by the WG for discussion with NCAs. The WG suggested to carry out its tasks in a stepwise approach:

- step 1 - provide immediate updates/clarifications in the Common Approach document to be taken into account for the 2011 reporting;
- step 2 – consult MS on some issues (e.g. revision of templates, analysis group of SARE reports) and suggest further improvements of the Common Approach document to be used starting with the 2012 reporting;
- step 3 – following the analysis of the last 3 annual SARE reports and inputs from MS, to suggest revisions of current legislation (Directive 2006/86).

The participants came to an agreement on the following suggestions of the WG to be implemented for the 2011 reporting:

- quick preliminary check of the individual MS reports as they are sent in, with potential for some clarifications (anonymized MS reports to be provided by SANCO D4 to the sub-group which volunteered for this task);
- SARE reporting templates should be sent simultaneously to NCAs and to national haemovigilance contact points (list to be filled out by NCAs following a request email from SANCO D4);
- incorporate in the updated version of the Common approach document the explanation on background noise/incidents detected in QS, as provided in the "points under review" text box in version 2.0 of the document.
- It was agreed that EC should liaise with the colleagues in charge of the database to allow the distinction between "0" data from "non-available" data (the template should allow either 0 or NA to be introduced in the appropriate fields).
- It was also decided that an email will be circulated by EC when launching the 2011 SARE reporting, calling for suggestions from NCAs for improving SARE reporting templates.

The WG should report on its activity during the next CAs meeting in order to agree with all MS on the changes to be operated in the Common approach document that should be used starting with next year.

3.4. Interpretation question – Platelet-rich plasma

Irish CA introduced the matter of PRP (platelet-rich plasma) therapy, which is among other things used in orthopaedic or cosmetic therapies. This medical procedure includes the following steps: blood is collected on site and thereafter put into a small centrifuge to separate platelet-rich plasma, which are re-injected into the patient, e.g. in the muscles/tendons. PRP therapy normally takes place in one procedure (thus there is no storage) in an operating theatre or medical office. The Irish CA aimed to clarify whether this medical procedure falls under the scope for collection and testing under Directive 2002/98/EC, and in particular the wide reference provided in article 2 stating that "*this Directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose*".

NCAs considered that as PRP is used for autologous purposes within a single procedure, safety and quality standards laid down in the legislation are not applicable (FR, UK, PT, PL, AT, IT, CZ, SE). Other NCAs supported this view. NL will consult national experts and send eventual comments. It was also mentioned that the centrifuge equipment falls under the safety and quality requirements of the Medical Devices regulation.

4. QUALITY SYSTEMS

4.1. Follow-up on the development of good practice guidelines according to article 2.2 of Directive 2005/62/EC

As set out in Directive 2005/62/EC (article 2), the Commission shall develop good practice guidelines quality system and standards for blood establishments.

Council of Europe and EC have agreed to further enhance cooperation in this field and to develop a common approach for good practice quality system guidelines, largely based on the Council of Europe's "Draft Quality System Manual for Establishments in the Field of Substances of Human Origin". It was agreed to proceed to a joint Council of Europe-Commission drafting process for the next edition of the Council of Europe Guide, within a project jointly supported by Council of Europe and the Commission's Executive Agency for Health and Consumers. The first meeting of the working group was scheduled for 18 May 2011 in Brussels.

Feedback from this group will be given to the MS and the final document will be discussed and approved by National Competent Authorities. The text should be finalised in September 2012 and included in the next edition of the guide.

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

SANCO D3 (Pharmaceuticals) updated the MS on the revised Annex XIV of EU GMP on manufacture of medicinal products derived from human blood or plasma, which was adopted on 10 May.

The Commission clarified the requirements in the revised version of Annex XIV concerning the blood imported for third contract fractionation programs. It was emphasized that testing requirements, as required in the Directive 2002/98/EC, are always to be applied, as well as the technical requirements set up by the Directive 2004/33/EC. However, the legal requirements on traceability and serious adverse events and reactions reporting (Directive 2005/61/EC) and quality systems for blood establishments (Directive 2005/62/EC) have to be applied only when products are intended for distribution in the EU. The revised version also states that for third countries fractionation programmes, consideration should be given to the Community standards and specifications relating to a quality system for blood establishments set out in Commission Directive 2005/62/EC, the traceability requirements and notification of serious adverse reactions and events set out in Commission Directive 2005/61/EC and the relevant WHO guidelines and recommendations.

It was mentioned that Annex XIV should be understood as an interpretation of the legislation for medicines, also providing additional guidance for plasma fractionation. The monographs mentioned in Annex XIV are the ones required for the plasma master file, but other monographs may be used as well.

The issue of applying the same quality and safety standards for EU and non-EU countries was highly debated. It was emphasized that relevant WHO recommendations are coming close to the EU requirements, and if applied for third country plasma fractionation contracts, would provide good quality and safety for patients in those countries. It was mentioned that it is impossible to enforce EU legislation in third

countries and imposing strict criteria may deprive those countries from plasma products. AT Competent Authority noted that imported plasma should be traceable, the blood establishments importing the plasma should have this requirement in the contracts with respective third countries. Furthermore, it was suggested that all products obtained through plasma fractionation should be recorded. Additional operational measures would be needed at national level to trace the flows of products and make sure that residual products are not marketed in EU countries.

Following a question from SE Competent Authority, NCAs agreed that in case of third countries fractionation programmes, it is not mandatory for NCAs to inspect blood establishments from third countries, but just to inspect the premises of the manufacturer. When plasma is imported with the purpose of fractionation and marketing of products in EU-countries, the NCAs should also inspect the blood establishments from the country of origin.

Overall, the NCAs group concluded that currently there is no need to revise the quality and safety requirements related to plasma fractionation as specified in the Directive 2005/61/EC and Directive 2005/62/EC.

5. PRESENTATION OF PROJECTS AND STUDIES

5.1.1. European Up-Front Risk Assessment Tool (EUFRAT)

The EUFRAT is an ECDC-funded project that aims to develop a risk assessment tool to improve blood safety by preventing spread of infectious diseases through blood transmission. The on-line tool should be finalised by 13/06/2011 and should be launched in August 2011. In a first pilot phase, the tool will be available only to competent authorities for approximately one year. After this first year, the decision whether this tool will become publicly available or kept with restricted access, will be re-evaluated by ECDC.

5.1.2. Update on Council of Europe's work on deferral criteria for donors, presentation on risk behaviours having an impact on blood donor management

The Council of Europe is undertaking a study on risk behaviours having an impact on donor management, looking in particular at men having sex with men (MSM). Council of Europe gave an update on this study, which was already introduced at the CA meeting in October 2010.

A study on HIV infection by transmission group and origin in EU/EEA countries during 2004 – 2009 showed that the MSM are the predominant transmission group; an UNGASS report notes that 3-10% of MSM are estimated to be HIV+. In this context, some modelling studies were discussed in order to investigate the risks associated to changing donor deferral criteria and emerging sexually transmitted infections. It was emphasized that there is a need for better information to communities of present and future blood donors and that post-donation information is important, including post-risk interviews (in marker positive donors) and post-donation risk surveys (in all donors) as additional ways to collect information.

MS were informed that the WG will present a proposal of a resolution and a report to the CD-P-TS in Nov 2011. It was underlined that the main impact channels of the work performed by CD-P-TS are a resolution to be adopted by the Committee of Ministers of Council of Europe and the use of the Guide to the collection, preparation and utilisation of blood components (Rec. 1995/15).

5.1.3. DOMAINE - Creating a safe and sufficient donor population in Europe: comparing and recommending good donor management practice

DOMAINE is project financed under the Public Health Programme, aiming to achieve a safe and sufficient blood supply for all European citizens by establishing Good Donor Management practice in all Member States.

The coordinator of the project presented the output of the project, which is now finishing. Major achievements include the publication of the Donor Management Manual (also available online at www.domaine-europe.eu) and the development of a training programme to distribute the manual's knowledge and practice across Europe (to be organised after June 2011).

The need to disseminate the information resulted from DOMAINE and similar projects was emphasized (PT, CY). Several other issues regarding donor population were also discussed: suggestions of an EU-wide action to improve blood donation (GR), on qualified donors (AT), self-sufficiency and promotion of voluntary and unpaid donation (GR).

The European Commission welcomed the idea of collaborating with the Council of Europe on this topic. It was concluded that the results of the DOMAINE project should be made available to the Blood supply management WG in the Council of Europe and the issue of donor management should be addressed within a collaborative effort between Commission, Council of Europe and WHO. More actions at EU level concerning donor management should be discussed next year, when the report prepared by the Blood supply management WG in the Council of Europe will be presented to NCAs.

6. ANY OTHER BUSINESS

6.1. HTLV I/II testing in plasma intended for fractionation

Directive 2004/33/EC sets out permanent deferral criteria for donors of allogeneic donations, including HTLV I/II. Some permanent deferral criteria are excluded for donations used exclusively for plasma for fractionation

At the request of the Plasma Protein Therapeutics Association (PPTA), the EC consulted the NCAs whether HTLV I/II positive donors should also be excluded for donations used exclusively for plasma for fractionation.

It was concluded that the request letter sent by PPTA should be circulated to all NCAs for analysis and that feedback should be provided in writing to the Commission. Answers will be compiled and presented by DG SANCO for discussion during the next CAs meeting.

6.2. Information on launch of tender for inspectors of blood establishments

SANCO D4 informed the NCAs that a call for tender for the organisation of training sessions for inspectors of blood establishments was launched under the Public Health Programme by the Executive Agency for Health and Consumers. The aim of this call for tender is to ensure a more uniform knowledge and way of undertaking inspections, and to further disseminate best practice and expertise in the EU. The training sessions are foreseen for 2012 and will contribute to ensuring the quality and safety of blood and blood components in the EU, allowing for the training of 3-5 inspectors per Member State nominated by the Competent Authorities.

6.3. Clarification of the "qualified practitioner" (acupuncture) term used in Directive 2004/33/EC (NO)

The NO Competent Authority introduced a question related to the different interpretations given to the term "qualified practitioner" in various translations of the Directive 2004/33/EC, Annex III.

Annex III of the Directive 2004/33/EC states under point 2.2.2. that acupuncture should be performed by "a qualified practitioner", otherwise the donor is to be deferred from donating blood for 6 months, or for 4 months provided a NAT test for hepatitis C is negative. Some of the translated versions of the directive are not in accordance with each other when it comes to the term "qualified practitioner". In the English, French, Spanish and German versions, a "qualified practitioner" in the Directives meaning, is not necessarily a doctor/medical practitioner. It can also be other types of health personnel/health workers considered qualified to perform acupuncture in their country. Nevertheless, the Danish and Swedish language versions use the term "qualified doctor" for "qualified practitioner" in the Directive text.

The European Commission noted that all linguistic versions of the Directive are equally valid. NCAs agreed that "qualified practitioner" as used in Annex III of the Directive 2004/33/EC should be interpreted as "qualified healthcare practitioner". Member States can implement stricter provisions.

6.4. Clarification on quality measurements for fresh-frozen plasma (NO)

The NO Competent Authority has raised a question regarding quality control requirements set out in Directive 2004/33/EC. Member States were consulted on their opinion concerning whether the quality requirements for residual cells in fresh frozen plasma are also applicable to plasma for fractionation, or only to fresh frozen plasma for transfusion.

NCAs agreed that the quality requirements set out in Directive 2004/33/EC should apply only to plasma for transfusion.

6.5. Information on a risk assessment for apheresis devices (FR)

The FR CA informed the participants about a tragic event that occurred in France in 2009 resulting in the death of a donor, drawing the attention on the potential risk of use of medical devices used for apheresis procedures in donors and also in patients. The French National Competent Authority (AFSSaPS) organized a collaborative dialogue with all concerned stakeholders to determine corrective measures to prevent such adverse events resulting from use error of these medical devices in France. A letter was also sent to DG SANCO to the unit in charge of medical devices with the suggestion to reclassify the apheresis devices and consumables from class IIb to class III. It was mentioned that similar cases were noted in IT but with no fatalities, with the suggestion that special surveillance of plasmapheresis procedures is required. IT and CZ mentioned that such a change would have a negative impact on the price of plasmapheresis devices and would lead to a dramatic increase of the overall costs of the apheresis procedure. UK stated that they were aware of this issue.

The Commission – SANCO D4 intends to liaise with colleagues from SANCO B2 in charge of medical devices legislation for further discussions and clarifications; the results will be reported to NCAs during the next meeting.

6.6. Enquiry on regulating in-house in vitro diagnostic medical devices (IVDs) (AT)

AT Competent Authority requested the opinion/proposals of the Competent Authorities of Blood on the issue of regulating in-house manufactured IVDs which are produced in health care institutions. This topic is under discussion between MS and EC with regard to the recast of the Directive on In-vitro-diagnostic medical devices 98/79/EC.

Current regulation is that such devices, if not being transferred to another institution outside the production premises, are under a national regulation. Common ground in the recast discussions so far was that such IVDs would have to fulfill the Essential Requirements of Directive 98/79/EC on in vitro diagnostic medical devices. Open question in current discussion is whether in-house produced IVDs also have to undergo a conformity assessment with a notified body.

Concerning a conformity assessment of high risk in-house produced IVDs, relevant for blood safety (e.g. HIV, Hep B and C, blood grouping reagents AB0 and the more important Rh factors), several MS incline to have no conformity assessment for these products, also if used in routine application.

Untouched from the above are research issues like performance evaluation studies of IVDs. These would not be covered by these concerns, as they require separate precautionary measures like in clinical trials.

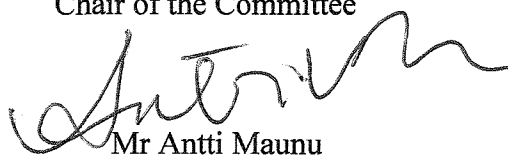
It was concluded that MS should provide their opinions in writing to the EC SANCO/D4. In addition, SANCO D4 should also follow this issue with colleagues responsible for the revision of the Directive on in vitro diagnostic medical devices 98/79/EC (SANCO B2).

6.7. Other clarifications (PL)

In response to three issues raised by the PL Competent Authority the following were concluded:

- EU legislation is setting only minimum safety and quality requirements and MS may introduce more stringent measures. Therefore, PL could maintain the upper maximum pH values for platelets concentrates at the end of the shelf life as initially set in Annex V to Directive 2004/33/EC.
- Infected plasma may be sold to in vitro diagnostics manufacturers for production of standards for viral tests.
- In Poland around 12% of donors are positive for borreliosis (Lyme disease), and the incidence of the disease is approximately 11000/year. Since borreliosis is not included among diseases in Annex III of Directive 2004/33/EC it was agreed that either screening of the population or including a national exclusion criterion for donors positive for Lyme disease may be an appropriate approach.

Chair of the Committee



Mr Antti Maunu