COMMISSION OF THE EUROPEAN COMMUNITIES
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health Law and International

Meeting of the Competent Authorities on Tissues and Cells

6 -7 December 2010

Summary Report

PARTICIPATION:

All Member States except Germany were present at the meeting of the Competent Authorities (CA) on 6 and 7 December. Iceland, Liechtenstein, and Croatia, as well as the European Directorate for the Quality of Medicines and Health Care of the Council of Europe (EDQM), WHO and the European Centre for Disease Prevention and Control (ECDC) also attended the meeting.

Commission:

Chairman: Mr Antti MAUNU (SANCO)

Ms B. KALTENBRUNNER BERNITZ, Ms I. SISKA, Ms O. SOLOMON, Mr Stefaan VAN DER SPIEGEL (SANCO)

Day 1

1. ADOPTION OF THE AGENDA

The agenda was adopted without change

2. SURVEILLANCE AND VIGILANCE

2.1. Update on infectious disease risks: latest news (ECDC and Member States)

2.1.1. Q-fever in the Netherlands

The ECDC and the Netherlands updated the Member States on the Q-fever outbreak in the Netherlands and measures taken since the last CA meeting in May. The seasonal Q-fever peak is over in the Netherlands. ECDC noted that the epidemic seems under control, but it is still 10 times higher compared to historical baseline. The Netherlands considers vaccination of high risk patients (Advice of the Health Council) and the advice of the Health Council on screening of tissue donations is expected. The Netherlands expect to finalise a report on preventing Q-fever by March 2011.

Austria and Belgium have taken measures to reduce the potential risks for Q-fever transmission as discussed in the meeting of the CA in 20-21 May 2010. These entail a deferral during a period of 6 weeks (rather than 5 weeks, as suggested by ECDC) after having visited an affected farm or after having spent a night in the affected areas in the Netherlands.

The ECDC will assess the need for precautionary risk reduction measures for tissue and cell transplantation during the 2011 Q-fever period (expected to start in March), on the basis of data from the first weeks in 2011. The NL CA committed to inform the Commission promptly on any new measures and evolutions. The NL CA will also forward the advice of the Dutch Health Council (expected January 2011) and the report on prevention (expected March 2011).

2.1.2. West Nile Virus

The Commission and ECDC gave an update on the West Nile Virus (WNV) outbreak over the summer and the measures taken with regard to blood safety. ECDC highlighted that the outbreak in Greece was the largest outbreak reported since 1996. There are recent changes in the transmission dynamics and epidemiology of this disease which may be related to climatic variations and/or the new lineage 2 of the virus in mosquitoes. The 2010 situation is particular with regard to 1) new geographical area of spread 2) its early onset 3) the wide spread circulation and human cases and the lineage 2 of the virus.

Member States in general found the Commission communication to the Competent Authorities on the WNV outbreak very useful. Some Member States took similar risk reduction measures for tissue and cells as for blood (28 day deferral period after leaving an area with ongoing transmission of WNV). The situation needs to be monitored closely, since an important outbreak could be expected in 2011, and response measures similar to blood have to be reflected upon.

The meeting was informed that a subgroup of the Competent Authorities on Blood will be created to develop a preparedness plan for next year's anticipated WNV outbreak with regard to blood safety. A first meeting of this group will take place on 26 January 2011 in Thessaloniki, Greece. The results of discussions in this group will be communicated at the next meeting of the Competent Authorities on tissues and cells.

2.1.3. Other – Member States will be asked whether they have additional information or updates to report

Member States did not report any additional information on infectious diseases. ECDC informed about the first occurrence of autochthonous Chikungunya fever in France and highlighted a general increase of transmission of mosquito-borne diseases and called for improved preparedness and surveillance.

2.1.4. General discussion on communication of infectious diseases

During the summer of 2010, the Commission has received and forwarded to the Competent Authorities a number of alerts on infectious disease outbreaks which may

have implications on tissues and cells safety. The Commission thanked the concerned Member States and stressed the importance of these proactive communications. Member States also gave very positive feedback regarding the ECDC inputs.

Overall, Member States were content with the communication approach (forward alert messages by email) taken over the summer by the concerned Member States and the Commission and underlined the importance of receiving the epidemiological information as early as possible.

2.2. Feedback on the Rapid Alert System

The Danish Competent Authority presented the status and summary of activities of Rapid Alerts Tissues & Cells (RATC) for the period of January to December 2010. The RATC system is operational but no formal "rapid alerts" have been issued so far between Member States and the Commission. Two "Information notices" were issued. The Danish Competent Authority suggested some changes in the relevant Circa database and made some proposals for the RATC System, including annual review of the template, protocol and database at a working group meeting of appointed CA vigilance representatives. The recommended changes will be subject to peer review by the Commission and the Competent Authorities. These proposals were accepted by the other Member States. The Commission will make the changes of the circa database and a meeting of the CA vigilance representatives will be organised during 2011.

It was clarified that two CIRCA systems are in use to date. A first one specifically supporting the RATC system, and a second one to distribute the documents related to the Competent Authority meetings. It is important that every Member State gives the right contact persons and coordinates for each of the two systems.

2.3. Serious adverse reactions and events: Annual report 2009- presentation by the Commission

Article 7 of Directive 2006/86/EC requires that Member States shall report serious adverse events and reactions every year to the Commission. The Commission sent out a report template during the spring of 2010 for reporting data collected in 2009.

The Commission presented the preliminary report on collected data. It was emphasised that the data is partial and incomplete and therefore no consistent analysis can be carried out for the 2009 reporting period. There is also lack of consistency and harmonisation of data which makes the overall review and interpretation difficult. It was underlined that the report template should include clear definitions and that we should aim for as straightforward and concise approach as possible. It was agreed to review the reporting template and develop further the common approach document for definitions of reportable serious adverse events and reactions. The SOHO V&S project will take up this work under Work Package 7 with the aim to draft guidance on investigation and communication of Serious Adverse Events and Reactions.

Member States were invited to send to the Commission by 15 January:

- Comments and or corrections to the draft report
- Remarks and problems they encountered in relation to the collection and reporting of data for the 2010 period (2009 data)
- Any objections on making available to the SOHO V&S project the individual country reports (data and comments) with the view to analyse them and get elements for developing further the common approach document.

2.4. Update on the development of a European vigilance and traceability system

2.4.1. Information on work progress of the Working Group on coding of tissues and cells

The technical progress of the Coding Working Group was presented to the Competent Authorities. The objective is to develop a simple system that is as compatible as possible to the different systems and situations in the Member States.

Previous conclusions were confirmed regarding the donation nomenclature, allowing to trace all substances of the same origin. The Working Group sent a questionnaire to all Member States which has indicated that, to date, in most countries donor/donation identifications are not granted at national level, but at a more local level (e.g., tissue establishment). The proposed system should work with nationally as well as with locally allocated donor/donation identifications. In addition, the Working Group has developed an illustration of how the donation identification can work in practice.

Regarding product nomenclature the Working Group has defined that the future system should allow for both, Member States applying a general high level of product descriptions and codes, as well as Member States applying a detailed level of product descriptions and codes. A member of the Working Group is discussing with different Member States, in order to compare systems and help prepare a basis for a 2-level system of product nomenclature (general/detailed).

The Commission plans to contract external service providers to help take forward both elements of the code (donation nomenclature, product nomenclature), in particular to establish a reference database for each. Some historical concerns were expressed regarding involvement of potential service providers. However it was clarified that service providers are not involved so far. It is first up to the Commission and Competent Authorities to define the needs. Only later in the contracting process, potential service providers can offer solutions on how to address these needs.

It was clarified that partner donation of reproductive cells will not be subject to this coding system.

2.4.2. Information on developments for establishment of a European system for vigilance

The Commission explained the activities in order to involve a European Agency (ECDC/EMA) in the set-up and running of the EU vigilance and traceability system for

tissues and cells. The Competent Authorities urged for progress and reminded that several national systems are waiting for progress at EU level.

2.5. SoHO V&S project on vigilance and surveillance-developments, presentation by project leader

The project leader gave an update to the Competent Authorities about the SoHOV&S project, which is co-funded by the Second Programme of Community Action in the Field of Health.

The overall objective of the project is to support Member States in the establishment of effective vigilance and surveillance systems for tissues and cells used in transplantation and in assisted reproduction, through:

- Standardisation of principles and practices in the inspection and certification of tissue establishments, including definition of current best inspection practice, formulation of inspection guidelines and development of training for inspectors;

- Development of a model for the reporting and investigating of adverse events and reactions associated with the quality and safety of tissues and cells in the EU.

Within the latter objective the project will complete the common approach document for reporting serious adverse events and reaction (see also point 2.3).

3. INTERPRETATION QUESTIONS

3.1.1. Follow up HTLV I/II testing requirements (40 min)

Directive 2006/17/EC, Annex II - Laboratory tests required for donors (except donors of reproductive cells) states that "*HTLV-I antibody testing must be performed for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas*".

The American Association of Tissue Banks (AATB) has recently voided systematic HTLV testing for donations of tissues and cells occurring on US territory. AATB board agreed to align with FDA's line not to impose an HTLV test for tissues with an absence of viable leukocytes e.g. corneas and highly processed tissue.

Following recommendation by the Regulatory Committee on tissues and cells the Commission asked the assistance of ECDC to assess the possible risks of the change in HTLV testing for human tissues and cells imported from US into the EU. The UK Human Tissue Authority (HTA) organised a technical meeting on 9 July 2010 on the impact of the change in US testing requirements on import of tissues from the US.

During the meeting, HTA presented the developments since the last Regulatory Committee meeting in May 2010. The HTA expert explained that agreement on the way forward may be achieved through: 1) a consistent approach to testing requirements, 2) identification of high risk areas and 3) if necessary revision/updating of Annex II of Directive 2006/17/EC.

ECDC presented the draft risk assessment on HTLV transmission by tissue/cell transplantation. It was clarified that the ECDC work on the assessment is ongoing, but

only part of the questions have been addressed so far. Questions on HTLV-I/II epidemiology, evidence for transmission linked to certain viable cell types, transmission thresholds and the effectiveness and availability of diagnostic tests has been reviewed, but the literature search is not yet complete, therefore results should be considered preliminary. The following conclusions could so far been drawn:

- General population prevalence in US and Europe is likely to be fairly low and probably less than 0.1%;
- Available evidence does not support an objective classification of the US or North America as an area of high-incidence or high prevalence of HTLV-I/II infection;
- The exclusive transmission of HTLV by lymphocyte cells is valid for blood donations, but uncertain for tissues and cells;
- The power of conclusion for a threshold of transmission of 10^8 viable leucocytes is not sufficient. Therefore no classification can be made in low-risk/high-risk tissues on the basis of this threshold value;
- There are effective tests for HTLV-I/II infection available globally;
- Approval for diagnostic use is lacking in US market.

The following next steps were agreed:

- to form a joint ECDC / CA ad-hoc expert group to address questions related to cell content of (selected) tissue materials and their infectiousness;
- on the basis of ECDC terms of reference Member States to propose experts for the ECDC ad-hoc expert group;
- ECDC to organise a meeting of the ad-hoc expert group early 2011 to review evidence and complete Risk Assessment;
- After finalisation of the ECDC risk assessment to set up a Competent Authority working group consisting by the UK, IT, DE, FR and possibly ES, as agreed at the CA meeting on 20-21 May 2010, to discuss possible ways forward with regard to HTLV testing requirements in the EU legislation. The work of the group will be co-ordinated by the UK and the Commission.

3.1.2. Interpretation of Directive 2004/23/EC with regard to the processing of pancreatic islets in another establishment during an autologous transplantation in the same surgical procedure

The Human Tissue Authority in the UK raised a question in relation to an autologous and single surgical procedure of pancreatic islet transplantation, where the pancreas is removed, transported to a separate laboratory for processing and returned to the operating theatre where the pancreatic islets are transplanted back into the same patient. The patient remains in theatre the whole time while processing takes place.

The question raised was whether this procedure would be excluded from the scope of Directive 2004/23/EC according to its Article 2, and hence not covered by the

requirements of this Directive. In addition, the meaning of the term "banking" in recital 8 was questioned in relation to the above mentioned surgical procedure.

Following the discussion at the meeting of Regulatory Committee in May 2010 the Commission examined the provisions relating to the terms "banking" and "same surgical procedure" and presented the applicable framework and other considerations.
THE LEGAL FRAMEWORK

- The scope of Directive 2004/23/EC as laid down in Article 2, paragraph 1, covers the *"donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications (...)."*
- Article 2, paragraph 2(a), of the Directive excludes from this scope *"tissues and cells used as an autologous graft within the same surgical procedure".*

- Recital 8 of the Directive, when referring to this exclusion, however mentions a second criterion:
"(...) *Tissues and cells used as an autologous graft (tissues removed and transplanted back to the same individual), within the same surgical procedure and without being subjected to any banking process, are also excluded from this Directive. The quality and safety considerations associated with this process are completely different".*

- "Processing" is defined in Article 3(g) as *"all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications.*

- The definition of "tissue establishment" provided in Article 3(o) of the Directive is *"a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken (...)".*

- In the initial Commission proposal the term 'tissue bank' was used and defined as the "*establishment, public or private, that is responsible for the activities of processing, preservation, storage, and distribution of tissue and cells. It may also be responsible for the procurement of tissues and cells*".
In Directive 2004/23/EC, as adopted, this term was deleted and incorporated into the definition of "tissue establishment".

-The Explanatory Memorandum of the Commission proposal, referred to the Recommendation R 94/141[1] of the Council of Europe (CoE) which refers to activities relating to the banking of human tissues (and cells) as: "…..*Activities related to the banking of human tissue be divided into the following separate functions, it being understood that such functions in no case extend to the collection of such tissue:*
- organisation;
- processing;
- preservation;

[1] *Council of Europe. Recommendation No R (94) 1 of the Committee of Ministers to Member States on Human tissue banks. Adopted by the Committee of Ministers on 14 March 1994, at the 509th meeting of the Ministers' Deputies)*

- internal quality control;
- storage;
- distribution; "

ANALYSIS

Tissues and cells used as an autologous graft within the same surgical procedure are excluded from the scope of Directive 2004/23/EC.

However, recital 8 explains that the exclusion is justified only because the quality and safety considerations associated with this process (autologous same surgical procedure without any banking process) are completely different (from 'normal' tissues and cells). The considerations are different because it was assumed at the time that in an autologous transplantation within the same surgical procedure, the cells would remain during the whole process in the operation theatre, hence there would be no risks in this case for cross-contamination or mix-up of the cells during transport or during processing. During the discussion several Competent Authorities referred to the next case as a typical example for exclusion: dissection and use of a peripheral vena for immediate use as bypass during cardiovascular surgery.

It would go against the legislator's intention to exclude from the scope of the directive autologous grafts for which the quality and safety considerations are the same as for "normal" tissues and cells. As all exclusions, this one must also be interpreted in a restrictive way.

The term « banking process » is not defined in Directive 2004/23 but needs to be interpreted in the light of COM initial proposal and of the CoE recommendation R(94)/141.

Based on the above consideration the Commission concluded that:

- The term « banking process » cannot be considered only as storage and preservation. Interpreted in the light of the notion of *'tissue bank*' -replaced in the directive by 'tissue establishments'-it would extend to the activities carried out by the establishments under discussion in this question.

- The processing of autologous grafts in other establishments with a view to their application within the same surgical procedure is within the scope of Directive 2004/23/EC, as well as the storage (if relevant), transport and distribution operations that are carried out with a view to this processing.

However, it was highlighted that the above analysis represents the views of the Commission services; it is for the Court of Justice to decide on the correct interpretation of Union Law.

This conclusion was generally accepted by the Competent Authorities.

A question was raised during the meeting about the status of tissues and cells used as autologous grafts within the same surgical procedure which are processed in another

department of the same hospital. Many Member States indicated that a cautious and pragmatic approach is needed so that any department of a hospital where some processing takes place does not become a tissue establishment. In addition, it was stated that the scope of the Directive should not be extended though an interpretation to the clinical field. It was suggested that the risks of mix up, cross contamination etc remain low when the tissues and cells are processed in an "operation area" in a wider sense than the "operation theatre" and that in this case the exclusion should apply. It was also proposed to consider establishing hospital tissue banks in analogy to hospital blood banks.

3.1.3. Human placenta tissues for human consumption (Question raised by the UK Human Tissue Authority)

The UK Human Tissue Agency raised question about the legal status of human placenta tissues for human consumption. Human placenta are consumed by some birth mothers either raw (placenta smoothies) or cooked and dehydrated (capsules) or by the baby in a form of tincture.

The placenta derived products are prepared by a) the birth mother at her home b) a "placenta expert" at mother's home c) third party (commercial service). The questions raised were 1) whether the placenta processing falls within Directive 2004/23/EC and its implementing measures and 2) whether placenta derived products are covered by the Food Law?

The Commission presented the legal framework and its preliminary analysis:

- The placenta products under question although derived from human tissues and cells are not intended for human applications and therefore not covered by Directive 2004/23/EC on tissues and cells;

- The placenta derived product under question are intended to be ingested by humans hence they are covered by the definition of 'food' in Regulation 178/2002/EC[2] on general food law;

- Whether the placenta derived products under question are covered by Regulation 178/2002/EC, it would depend on the way the products are prepared and used.

It was stressed that this preliminary unofficial analysis represents the views of the Commission services; it is for the Court of Justice to decide on the correct interpretation of Union Law.

It was agreed that:

- More information on products on the market is needed
- The issue should be addressed by the Food Standards Agency in the UK

[2] REGULATION (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

- If deemed necessary by the Member States, the matter could be brought to the attention of the Standing Committee on General Food Law.

Day 2:

4. ART:

4.1.1. Feedback from expert group meeting on testing requirements for partner donation (not direct use)

As laid down in Annex III of Directive 2006/17/EC, donors of gametes, including partners (not for direct use), shall be subject to testing at the time of each donation (for HIV and Hepatitis B & C).

At the Competent Authority meeting of 19-20 October 2009, it was argued by a number of Member States that the current testing requirements are cumbersome and costly, and do not necessary add to the safety of human substances[3]. Following the discussion at the meeting, it was agreed to set up an expert working group to review and discuss the evidence base for testing requirements for partner donation of gametes (not for direct use), and a possible legal change of testing requirements - from testing at each donation to periodic testing. In addition, DG SANCO has requested the assistance of the ECDC to assess the potential health risks of changing the current testing requirements.

The ECDC presented the draft risk assessment on change of testing requirements for reproductive cells in partner donation to the Competent Authorities. It underlined that given the limited data available the findings of the risk assessment should be treated with caution.

The Commission asked the Competent Authorities to review and provide comments on the ECDC risk assessment by 31 January 2011. The finalised ECDC risk assessment and possible approaches on how to take this issue forward should be further discussed with the expert working group and at a forthcoming meeting of the Competent Authorities. In addition, ECDC agreed to assist the Commission and the expert working group in identifying and summarising which data would need to be collected in order to further assess the potential risks of changing the current testing requirements for partner donation (not for direct use) and the related conditions for such change. The Competent Authorities will be asked to, as far as possible, provide the Commission with the required data.

4.1.2. Presentation of the results of the ESHRE study

Isabel de la Mata (Principal Adviser with Special Interest in Public Health, DG SANCO) presented the main findings of the study "Comparative Analysis of Medically Assisted Reproduction in the EU: Regulation and Technologies", conducted by the European Society of Human Reproduction and Embryology (ESHRE) and funded by the European Commission. This study has been commissioned by DG SANCO to map existing practices on medically assisted reproduction in the Member States as well as the interface with the EU Directive on Tissues and Cells (which includes reproductive cells) in terms of quality and safety. However, it should be underlined that this is an

[3] http://ec.europa.eu/health/archive/ph_threats/human_substance/documents/ev_20091019_mi_en.pdf

ESHRE study and its findings do not necessarily represent the official position of the Commission.

Key findings of the ESHRE study concern legislation, activity level, access to fertility treatment, donation of gametes, and cross-border movement and reproductive care. The study is available on DG SANCO's homepage[4].

5. REPORT ON THE PROMOTION OF VOLUNTARY AND UNPAID DONATIONS (ARTICLE 12.1 OF DIRECTIVE 2004/23/EC)

In accordance with Directive 2004/23/EC, article 12, the Member States shall report on the practice of voluntary and unpaid donation of tissues and cells to the Commission every three years.

The Commission sent out a report template to the Competent Authorities for tissues and cells during the summer of 2010. Based on the responses from the Competent Authorities, the Commission is currently finalising its second report on voluntary and unpaid donation of tissues and cells.

The Commission presented the main findings of the draft report to the Competent Authorities, and asked them to send any comments on the report to the Commission by 15 January 2011.

6. FOLLOW UP ON INSPECTION GUIDELINES AND OPERATIONAL MANUAL FOR INSPECTIONS

The Commission informed Member States that following the meeting of the Competent Authorities in May the inspection guidelines decision 2010/453/EU[5] was published on 3 August 2010.

After the agreement in the Regulatory Committee in May 2010, the manual on inspection of tissue and cell procurement and tissue establishments has been translated and sent to Member States on 21 October for linguistic comments. Linguistic comments may be submitted until the end of January 2011. After review by the Commission Translation services, the manual will be published in all Union languages on DG SANCO 's homepage.

7. UPDATE AND INFORMATION ON THE TRANSPOSITION AND IMPLEMENTATION OF THE TISSUES AND CELLS DIRECTIVES

The Commission gave an update on the state-of-play concerning the transposition checks of the tissues and cells directives. The Commission explained the main areas that were identified in the directives as being important in the transposition checks. Member States were informed of the new web-based tool the Commission intends to launch in order to check whether Member States have transposed tissues and cells

[4] http://ec.europa.eu/health/blood_tissues_organs/docs/study_eshre_en.pdf.
[5] 2010/453/EU COMMISSION DECISION of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council.

directives into their national legislation. Further information on this web-based tool that aims to facilitate transposition checks will be provided in due course.

It was suggested to cover import/export provisions in the transposition check.

8. INTERACTION WITH ADVANCED THERAPIES MEDICINAL PRODUCT REGULATION

The point was postponed to the next meeting of the Competent Authorities, as Mr Christian Schneider, chairman of the committee on advanced therapies (CAT) in EMA was not able to attend the meeting.

9. PROJECT PRESENTATIONS

9.1. Poseidon on Haematopoietic Stem Cell Transplantation

The Poseidon project aims to improve the safety of unrelated haematopoietic stem cell transplantation (HSCT), optimise HSC donation policy, and promote equal access to this therapy throughout the EU.

The project leader presented the main findings of the project, which finished on 30 November 2010. The final report is being prepared and will be available early 2011.

In relation to this project the issue of accreditation of cord blood banks, notably of private cord blood banks was raised. It was agreed that this is an issue that merits a separate discussion in a future Competent Authorities meeting.

9.2. Euro-GTPs on European Good Tissue Practices for European tissue establishments

The project coordinator presented the developments of the project. European Good Tissue Practices (Euro-GTPs) project started in September 2008 and is running for 36 months and is led by Transplant Services Foundation based in Barcelona.

The project aims:

- To develop detailed European Good Tissue Practices for the activities carried out in tissue establishments (TE), contributing to the harmonization of these activities among European TEs.
- To develop a training model for TE personnel based on the GTPs.

The Good Tissue Practices, as well as the Training Model should contribute to the harmonization of tissue banking activities and specific procedures in Europe, in order to provide tissues for transplant of high quality and safety.

A discussion took place with regard to the further use of the outputs of this project, notably the possibility to develop guidance for good practices for tissue establishments. Such EU-level guidance document will also be valuable as reference document in case of discussions between inspectors and tissue establishments. The document could also be useful when discussing borderline cases between tissues, cells and advanced therapies.

It was agreed that collaboration would be explored with the EDQM steering Committee of the Council of Europe for developing such guidance similar to the blood quality manual of CoE.

10. AOB

Austria announced that new EUSTITE training sessions will be organised in spring 2011, on a self-covering cost basis.

11. FOLLOW-UP ACTIONS

2.3 Serious adverse reactions and events: Annual report 2009- presentation by the Commission

Member States (MS) to send to the Commission (COM) by 15 January:

- comments and or corrections to the draft report
- Remarks and problems they encountered in relation to the collection and reporting of data for the 2010 period (2009 data)
- Indicate whether have objections on making available to the SOHO V&S project the individual country reports (data+comments) with the view to analyse them and get elements for working on /refining the common approach document.

3.1.1 Follow up HTLV I/II testing requirements

- ECDC to send to the Commission (COM) by 14 December, Terms of Reference for experts to participate in a joint ECDC / CA ad-hoc expert group to address questions related to cell content of (selected) tissue materials and their infectiousness.
- COM to send the ToR to MS immediately
- MS to propose experts for the ECDC ad-hoc group on the basis of the ToR, by 15 January 2011
- Finalisation of ECDC risk assessment by the end of February 2011
- After finalisation of the ECDC risk assessment to set up a CA working group (UK, IT, DE, FR and possibly ES, as agreed at the CA meeting on 20-21 May 2010) to discuss possible ways forward with regard to HTLV testing requirements. The work of the group will be co-ordinated by the UK and COM.

4.1.1 Feedback from expert group meeting on testing requirements for partner donation (not direct use)

MS to sent to the COM by the end of January:

- comments with regard to the results of the ECDC risk assessment and
- any comments for the foreseen Working Group reflection on a proposal for (a) temporary testing (once per year, once per 2 year) provided that (b) quality procedures are ensured with the ART establishment.

5.0 Report on the promotion of voluntary and unpaid donations (article 12.1 of Directive 2004/23/EC)

- MS to send comments to the draft report by 15 January.

6.0 Follow up on inspection guidelines and operational Manual for inspections

- MS who haven't sent linguistic comments to the manual for inspections and still wish to do so, must send their comments in track changes at the latest by end January 2011

These points of action were communicated to the Member States also by e-mail on 10 December 2010.