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Meeting of the Competent Authorities for Tissues and Cells

8 – 9 December 2011

Summary Report

The meeting of the Competent Authorities on Tissues and Cells was convened on 8 and 9 December 2011. The previous meeting of National Competent Authorities (NCAs) took place on 23 and 24 June 2011.

PARTICIPATION:

All Member States except Romania and Spain were present at the meeting of the Competent Authorities (CA). Liechtenstein, Norway and Croatia, 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) attended the meeting.

European Commission:

Chairman: Mr D. SCNNICHELS (SANCO)

Ms I. SISKA, Ms H. LE BORGNE, Ms. S. VILLANUEVA, and Mr. S. VAN DER SPIEGEL (SANCO)

1. ADOPTION OF THE AGENDA

The agenda was adopted without changes. Minutes of the previous meeting were approved.

2. UPDATE AND INFORMATION ON THE TRANSPOSITION CHECK OF THE TISSUES AND CELLS DIRECTIVES

Member States are under the legal requirement to transpose the directives into national law one year after adoption and the Commission has the duty to check the transpositions.

The Commission gave an update on the state-of-play concerning the transposition check of the tissues and cells directives. The Commission launched the web-based questionnaire was on 1 July 2011. The deadline for submitting replies to the questionnaire was 15/10/2011. The deadline was extended by a month, and 24 full

submissions at that time. Other submissions are to be finalised and submitted before the end of the year.

The Commission presented an overview of the replies submitted until December 2011, based only on the yes/no answers. Additional requests for information and clarification from MS may be requested after the first analysis of the replies. Following an in depth evaluation of the replies provided by the MS, the Commission preliminary report will be presented as soon as possible. The Commission informed delegates it is currently awaiting the arrival of a lawyer in the team.

3. European Parliament initiave report on the Tissues and Cells Directive

In July 2011, the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament decided to prepare a report on the T&C Directives in order to identify possible issues requiring clarification/revision of Directive 2004/23/EC. The Committee appointed Ms. Marina Yannakoudakis (UK, MEP ECR) as rapporteur. Ms Yannakoudakis expressed an interest to meet the competent authorities. Several issues were debated:

- Principle of voluntary and unpaid donation
- Application to assisted reproductive technologies
- Principle of self-sufficiency and how to address shortages.
- Cord blood banks (tension between private and public tasks)

Additional comments and/or suggestions can be sent in writing to Ms Yannakoudakis. and/or Commission/SANCO. Ms Yannakoudakis will also engage in bilateral contacts with some NCAs.

4. Debrief from the Joint Conference & Workshop on human transplants identification and monitoring in European Union - Quality and Safety Standards – Katowice (PL), 6-7 October 2011

The meeting, jointly organised by the Polish CAs for T&C and Organs, was the first to gather MS Competent Authorities for Tissues and Cells and Competent Authorities for Organs to discuss quality and safety standards in the transplantation field in EU.

A brief overview of the presentations given during the meeting, as well as main discussion points and conclusions were presented by the PL representative.

It was concluded that similar initiatives from other NCAs, building bridges between organ and T&C transplantation communities, would be welcomed also in future.

5. Debrief from the Joint informal meeting of the Committee for Advanced Therapies (CAT) and the National Competent Authorities – "ATMP hospital exemption in Europe", Utrecht (NL), 21-22 November 2011

An informal CAT meeting was organised by the Head of the Dutch Medicines Agency to share experiences and to foster a common understanding on the issue of ATMP hospital exemption (HE) in the MS. The meeting was also attended by two

representatives who are also NCAs for T&C (DK, EE). The DK representative gave a brief overview of the main discussion points and conclusions of the meeting.

While definitions of ATMP and T&C are not always agreed and should be further clarified, the participants shared the concern for safety and quality. Every product/substance, with or without a HE, should be subject to the most adequate safety and quality measures. In addition new innovative applications of these products/substances should be subject to adequate protocols.

Participants were positive towards a harmonised approach on HE at EU level and towards the active involvement of T&C NCAs in this debate. It was questioned whether an exemption from the pharmaceutical legislation, makes HE products again subject to the Tissues and Cells legislation.

It was underlined that there is a need of collaboration between T&C competent authorities and CAT in order to ensure safety and quality for hospital exempted ATMPs using tissues and cells. The Commission recalled that during the T&C NCAs meeting in June 2011, and during the CAT meeting of October 2010, it was decided to organise a Joint Working Group including interested T&C NCAs and CAT members in order to discuss common borderline issues between T&C Directives and Pharmaceutical legislation. The following MS expressed their interest to join this work: AT, DK, IE, IT, PL, SE. A first meeting with CAT members is foreseen in February 2012.

It was also suggested to put these issues on the agenda of the pharmaceutical committee.

6. PROJECT PRESENTATIONS: EUROGTP

The European Good Tissue Practices (EuroGTPs) project is funded under the 2nd Public Health Programme and started in September 2008, running for 36 months. The final report was presented by the coordinator, from the Transplant Services Foundation in Barcelona.

Several NCAs acknowledged the project's valuable output and underlined that Good Tissue Practices could be an important tool for professionals in the field of T&C transplantation (IT, AT). Council of Europe representative welcomed the participation of EuroGTP in the CD-P-TO expert group responsible for drafting the new Guide to the Safety and Quality Assurance for the Transplantation of Tissues and Cells (guidelines to be published in 2012). The main outputs of the EuroGTP project could be included in this guide.

The Commission expressed its support to the work of Council of Europe and agreed to follow up the work of CD-P-TO expert group in order to further decide on the status/relation with EU Directives of the new Guide to the Safety and Quality Assurance for the Transplantation of Tissues and Cells.

7. SURVEILLANCE AND VIGILANCE

7.1. Update on infectious disease risks

7.1.1. Epidemiological update – ECDC

ECDC presented an epidemiological update focused on Q fever and WNV and their future plans for developing epidemiological protocols and assessment of infection risks.

Since 21 June 2011, ECDC published on its website weekly updates on geographical distribution of WNV fever cases in the EU MS and neighboring countries. Substantial efforts have been made to strengthen the level of detection in the affected countries and raise awareness of WNV fever in the neighboring countries. Blood Safety Risk estimation tool (EUFRAT), launched for testing during the ESCAIDE conference, will become available in the near future.

Concerning Q fever, ECDC noted that there is epidemiological evidence for the effectiveness of control measures in some countries, such as NL in which a strong decline of human infections was recorded. However, preliminary data indicate a slight increase of incident cases in some countries (e.g. DE).

Starting with 2012, ECDC plans to assess the feasibility of epidemiological data collection in MS in order to evaluate the usefulness of setting up a system for EU-wide data collection. ECDC would propose to develop surveillance, analysis and reporting protocols for EU data collection in cooperation with the NCAs for T & C (through the establishment of a Working Group).

Several NCAs (AT, DK, IT) acknowledged the usefulness of the weekly updates provided by ECDC and declared their support for the ECDC initiative to develop a comprehensive list of communicable diseases potentially transmitted through tissue and cell transplantation (IT, IE, NL). It was suggested that EUROCET project could contribute to data collection.

The Commission acknowledged the support provided by ECDC and welcomed the recruitment of new scientific officers at ECDC.

7.1.2. Update on reported cases of Q-fever and West Nile Virus

NL representative confirmed that there were no outbreaks of Q fever in 2011 and there were no elements to add to the overview given during the T&C CAs meeting in June 2011.

GR representative provided a short overview of the WNV outbreak in Greece in 2011 and the measures taken at national level.

IT NCA presented an update of the epidemiological situation in Italy for 2011 and the preventive measures taken by the Italian National Transplant Centre (CNT) in order to prevent WNV transmission.

The Commission reminded that a European preparedness plan for anticipated

outbreaks of WNV has been developed by a working group of NCAs for blood in collaboration with ECDC, which was made available also to the T&C NCAs via the CIRCA platform.

7.1.3. Other additional information or updates reported by MS

Member States did not report any additional information on infectious diseases.

7.2. Serious adverse reactions and events: Preliminary analysis of the 2010 Annual report - presentation by the Commission

The Commission presented a draft report of the SARE reporting for 2010. A full report should be presented in June 2012. It was mentioned that a partial quality check was performed with the help of members of the SOHO V&S project, which revealed that more work is needed to improve the annual SARE reporting. The results of this check will be distributed by the Commission to the NCAs, offering them the possibility to revise/update their submissions accordingly.

Several MS have acknowledged an improvement of the data collected for 2010 and supported the ongoing refining of the SARE reporting template and Common Approach document. It was suggested to involve EUROCET in providing some denominators in the reporting template prepared by the Commission and sent to the MS to be filled out with 2011 data.

The Commission reminded that a major update is ongoing for the next data collection exercise in 2012. Further suggestions from NCAs for the next reporting/data analysis/data presentation are welcomed.

7.3. RATC – Current status of RATC-Defects; development of the RATC-Health

The Danish Competent Authority presented the status and summary of activities of Rapid Alerts Tissues & Cells (RATC) for the period of January to December 2011. The RATC system is operational and as yet no formal "rapid alerts" on Quality & Safety defects have been issued so far between Member States and the Commission. Since its launch, three Information Notices related to medical devices have been issued and seven Communications relevant for human tissues and cells have been circulated between the MS and the European Commission.

The Danish Competent Authority proposed updating the format and structure of the sub-folders in the CIRCA-RATC database. These proposals were accepted by the other Member States. The Commission will operate these changes in the CIRCA RATC system and organise a meeting of all NCAs interested in contributing to the further development of RATC system (DE, DK, NL, PL) probably in the first half of 2012. Delegates were invited to comment on the draft annual report on the operations and activities of the CIRCA-RATC system which had been circulated in advance of this meeting. After its finalisation it was planned to be placed at the Commission's website for information.

The Commission informed about the preliminary consultations with other SANCO units to develop/upgrade the current CIRCA-RATC platform in order to cover also

the alerts on communicable diseases (RATC HEALTH); this topic is planned to be discussed within the RATC Working Group. The Commission will debrief NCAs about this issue during the next NCAs meetings.

7.4. Update on the development of the EU support for tissues and cells

7.4.1. Information on the call for tender for the development of EU coding compendia

The Commission informed the NCAs about the results of the public procurement procedure EAHC/2011/Health/03 concerning reference compendia for the application of a single European coding system for human tissues and cells, which was launched on 5 September 2011. Only one proposal was submitted by a consortium formed by CNT and ICCBA and subsequent to its evaluation, was selected for funding. The contract was expected to be signed until the end of 2011. It was underlined that T&C NCAs will be regularly updated during the next meetings on the advancement of this work.

7.4.2. Information on the governance of the EU support for tissues and cells

The Commission updated the group of T&C NCAs on its efforts related to the set-up and running of the EU vigilance and traceability support for tissues and cells. The concrete set-up with the involvement of two European agencies (EMA, ECDC) was discussed in October 2011 with the Steering Group including members of the EMA and ECDC Management Boards, Competent Authorities for Tissues and Cells, EMA and ECDC representatives, as well as DG SANCO. During this meeting significant reservations on the proposed allocation of tasks to the Agencies were expressed by some participants. In order to avoid further delays, the Commission decided to explore other options, in particular to carry out the tasks within DG SANCO.

Several NCAs endorsed the need for the EU support for tissues and cells and acknowledged that the Commission approach would provide for a faster solution for the setup and implementation of the system. A transfer of the system to the agencies - at a later stage - was considered. The Commission will come back to this topic during the next T&C CAs meeting in June 2012.

8. INTERPRETATION QUESTIONS

8.1. Interpretation of the requirements regarding HTLV testing in high risk donors

Point 1.2 of Annex II and point 2.4 of Annex III of Commission Directive 2006/17/EC state *"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."*

NCAs and Commission were asked by the UK Competent Authority whether the 2006/17/EC Directive requires repeated HTLV testing in the absence of a NAT test and if yes, what the supporting scientific arguments are.

ECDC stated that current scientific data are not conclusive and a full risk assessment would be needed for a comprehensive answer. It was decided to seek advice from the SANCO legal unit and to ask ECDC to provide an official opinion; both responses should be discussed during the next meeting in June 2012.

8.2. Transplantation of face

The question whether composite tissues, such as facial transplant should fall under the Organs or T&C Directive was introduced by the Swedish Competent Authority.

This question was already discussed at the meeting of T&C NCAs in October 2009, however without reaching a conclusion. In the meantime Directive 2010/53/EU was adopted and provides for a definition for "organs" in Art 3 (h).

Several NCAs considered that facial transplants require similar processing and have similar safety issues to organ transplantation. It was suggested that Commission should have the same interpretation for other multi-tissue transplantation procedures (e.g. hand transplantation). It was decided to consult the SANCO legal team and provide feedback to NCAs during the meeting in June 2012.

8.3. Amniotic membrane: regulatory classification

During the meeting of competent authorities on tissues and cells of 29 and 30 May 2008, there was unanimous consensus between the CAs to consider the use of amniotic membrane for cornea replacement as homologous, and therefore in the scope of Directive 2004/23/EC. This was based on the fact that the use can be considered as homologous because the function it performs is the same whether on the placenta or on the eye and the processing is completely equivalent to other tissues in terms of complexity and scale.

Amniotic membrane is also used as a wound dressing and/or barrier for treatment and management of burn wounds and wounds of various etiology, its preparation and use being similar to the one mentioned above. In this regard, the Belgian Competent Authority called for a confirmation that amniotic membrane used as a wound dressing and/or barrier for treatment and management of burn wounds and wounds is covered by the Directive 2004/23/EC.

It was concluded that amniotic membrane used as a wound dressing and/or barrier for treatment and management of burn wounds is covered by the Directive 2004/23/EC and that this view should be also communicated to CAT.

8.4. Apheresis of mononuclear cells for preparation of ATMPs: regulatory classification

In order to produce some ATMPs (e.g. autologous tumour vaccines) peripheral blood mononuclear cells are collected by an apheresis procedure. These procedures

can be carried out in hospitals and in blood establishments. The question is whether the cell product is in the scope of the Blood Directive or in the scope of the T&C Directive (or both). In Belgium, mononuclear cells are usually collected in hospitals and the cell product is considered to be in the scope of the tissue and cell legislation. Therefore, the Belgian Competent Authority requested the opinion of the Committee on whether mononuclear cells collected for the preparation of ATMPs are considered to be in the scope of the tissue and cell legislation.

Following discussions, it was agreed that, similar with Donor Lymphocyte Infusion, mononuclear cells collected by apheresis are considered to be in the scope of the EU tissue and cell Directives, and that this view should be also communicated to CAT.

9. AMENDING OF DIRECTIVE 2006/17/EC – DISCUSSION ON DRAFT AMENDMENTS (TESTING REQUIREMENTS FOR PARTNER DONATION - NOT DIRECT USE, HTLV – HIGH PREVALENCE AREAS)

9.1. Testing requirements for partner donation - not direct use

Taking into account the recommendations in the ECDC's risk assessment on change of testing requirements for reproductive cells in partner donation and following the discussions with NCAs during the meeting in June 2011, the Commission presented a draft proposal for amending the current legal testing requirements for partner donation as laid down in Annex III of Directive 2006/17/EC.

All participants agreed with the draft proposal with the rectification that biological screening planned in point 2.2 should be performed within 3 months before donation. Following discussions, the Commission will prepare a legal proposal for amendment by the next meeting of the Committee, foreseen in June 2012.

In addition to the proposed text by the Commission, the Competent Authority from BE, has presented a proposal concerning the determination of biological markers for sperm donations (other than by partners). Other NCAs (IT, UK, FR, AT) supported BE proposal and confirmed that sperm donations are quarantined for 180 days, thus safety is ensured. In addition, sperm is now processed (washed) before storage, and some eggs are also stored by vitrification.

In this regard, it was agreed that Commission should ask ECDC to provide a risk assessment also for testing requirements in case of fresh eggs donations other than between partners. The Commission will also consult the legal unit in DG SANCO and put forward another draft text for discussion with T&C NCAs in the next meeting.

9.2. HTLV - high-prevalence areas

Following the discussion of the WG on HTLV testing (UK, IT, DE, ES, FR) and based on ECDC's risk assessment on HTLV transmission by tissue/cell transplantation, during the NCAs meeting in June 2011, it was suggested to amend Annex II and III of the Directive 2006/17/EC by changing from high "incidence" to high "prevalence". In this regard, EC had presented a draft text stipulating that

HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

All participants group agreed with the proposed text, but some questioned whether the questionnaires used by all MS refer to "donor's parents originate from those areas". It was agreed for MS to check and confirm to the Commission the wording in the donation questionnaires, and also to proceed with the other actions proposed during the meeting held on 23-24 June 2011.

The Commission will prepare a legal proposal for amendment by the next meeting of the Committee, foreseen in June 2012.

10. ART:

10.1. ART activities in Member States

10.1.1. Donation of gametes - The UK perspective

The UK representative updated the NCAs about the new decisions taken by the Human Fertilisation and Embryology Authority's (HFEA) regarding the financial compensation for gamete donors and the benefits in kind allowed by the UK legislation (egg sharing). It was highlighted that without these approaches, UK would face a major shortage of eggs. 40% of the eggs currently donated in UK are ensured through egg sharing, the rest of 60% being provided by known donors (friends, relatives). It was also mentioned that UK has a registry of all gametes donors and that counselling before donation is compulsory. Regarding the "egg lottery" issue which was brought to the attention of the public by several media, the UK representative confirmed that, due to the HFEA intervention, this lottery never took place.

During the following discussions, some MS provided input on their national legislation and in particular on the types of financial compensation for gametes donation or benefits in kind.

Discussions have also addressed the issue of financial compensation vs. incentive. Commission reminded the NCAs about the requirements of the Charter of Fundamental Rights of the EU, which clearly prohibits on "making the human body and its parts as such a source of financial gain". It was agreed that UK representative will provide to EC a copy of the legal opinion document regarding compensation and benefits in kind for gametes donors.

10.1.2. Organization and activities of the Bulgarian Executive Agency for Transplantation (BEAT)

The Bulgarian representative presented the structure and main activities of the Bulgarian Executive Agency for Transplantation (BEAT) which is the national competent body in charge of management, coordination and control of transplantation (organs and tissues & cells, including the reproductive ones).

Regarding the ART sector, in Bulgaria there are 29 ART centres (2 public and 27 private) which are authorised and regularly inspected by BEAT. Concerning the issue of illegal egg collection which was raised in the Bulgarian media in the summer of 2011, it was mentioned that recently a new ordinance entered into force, which introduced clear and strict requirements for donation of gametes.

The Commission and other NCAs invited BEAT to engage in more activities and projects organised by the EC and EAHC. There was a specific invitation to participate actively in the 2011 and 2012 Joint Actions on organ transplantation, led by ES/FR (for twinning) and IT respectively as well as in the Black Sea Area project initiated by Council of Europe. The Bulgarian authorities are reminded of the importance of their presence in the Competent Authorities for tissues and cells, blood as well as organs (organised and funded twice per year by the Commission).

11. CORD BLOOD BANKING IN EU

Following the new developments in the area of cord blood transplantation and also due to the growing interest of the public and media in cord blood banking, the Commission proposed a first exploratory discussion with the T&C NCAs, aiming to identify the issues of interest to be further analysed by the group.

NCAs raised the following issues:

- The need to have a comprehensive view on the state of the art in cord blood banking at transplantation with cord blood stem cells,
- Comprehensive scientific data on the use of cord blood stem cells for both autologous and allogeneic therapies.
- The need to distinguish discussions on (a) public versus private cord blood banks (CBB) and on (b) storage of cord blood for autologous vs allogeneic use.
- All CBB, public and private are to be subject to the safety and quality provisions laid down in the EU legislation and enforced by the national competent authorities.
- There is need for objective and fact-based information to donor families on the potential benefits and the still limited probability of these benefits. Current information is often too commercial in nature. On the other hand there is need to build public awareness on the possibility and value of donating CB.
- Allowing private CBB and autologous storage is a national decision. Where MS allow exclusively the existence of public CBB, cross-border activities are seen.
- While it is encouraged to promote public CBB, it is in particular important to have as much CB as possible available for potential allogeneic utilisation. To ensure optimal availability of CB for allogeneic use, registries of available CB are to build/coordinated on European/international level.
- Collection and storage prove to be costly and a potential barrier for public activity, in particular when HLA-typology is required. The Commission noted that some private CBBs seem to do very well in collection and storage. The existence of mixed models can be explored, where CB stored by private actors is made available for allogeneic use. In the rare case of an autologous match, the costs of original autologous storage should be reimbursed to the donor family.

It was agreed that the Commission will propose discussions on the above mentioned topics or others suggested by NCAs during the following meetings of the Competent Authorities for T&C.

12. PROJECT PRESENTATIONS – SOHO VIGILANCE& SURVEILLANCE (WP 9)

The SOHO Vigilance& Surveillance (V&S) project is funded by the Public Health Programme and aims to support EU MS in the establishment of effective vigilance and surveillance systems for T&C used in transplantation and in assisted reproduction.

WP9 is responsible for drafting the "V&S Guidance for clinical entities that apply tissues and cells" by December 2012. The guidance document will be printed and provided to all Competent Authorities for tissues and cells in an electronic version as well as a hard copy version. MS may translate the document for national distribution to their hospitals directly or via tissue establishments.

The work of WP9 was presented by the PL representative. The partners in WP9 have already organised several editorial/drafting meetings and plan to consult both T&C NCAs and professional associations before issuing the final draft. NCAs will be probably asked for their feedback on the guidance document in July-September 2012.

13. AOB

13.1. Management of commercial demineralised bone substitutes (DBMs) - exchange views with the Commission and NCAs (DK)

The issue was brought up by the Danish CA who had received several applications from national commercial distributors for authorisation as a Tissue Establishment for "storage" and "distribution" of DBMs. Most often these DBMs are processed outside Europe (USA) and imported through one European country (i.e. the point of entry), where the donor history file review and product release takes place. When distributed in Europe from this point of entry flexibility in relation to qualifications for the designated Responsible Person should be considered.

During discussions NCAs shared their experience and problems encountered with commercial distribution of DBMs (e.g. UK, IT, PL). One concern was raised: the possibility that some of the DBMs may enter into some MS as medicines, and thus avoid the national controls by NCAs for tissues and cells.

In this regard, the Commission reminded the NCAs that a Working Group to work on import-export legal requirements is being created and called for volunteers. The following countries have expressed their interest to contribute: AT, DK, FR, HR, IE, PL, PT, UK. It was agreed that the Commission will be asking for a written confirmation from NCAs in order to finalise the composition of the WG.

13.2. Interpretation of the exclusion criterion of "*transplantation with xenografts*" for tissue and cell donation (DK)

The Danish Competent Authority has informed the T&C NCAs about a recent publication including international consensus viewpoints regarding the evaluation

of risks and benefits of xenotransplantation, how this differs from the widespread use of xenografts, and the current status of recommendations and laws in several healthcare sectors. The publication "Interpretive conundrum on the exclusion criterion of "*transplantation with xenografts*" for tissue and cell donation" is available in Cell & Tissue Banking Journal 2011 (DOI: 10.1007/s10561-011-9264-2)

13.3. Mutual recognition of the site (authorisation) certificates for distributors of bone substitutes (DBMs).

The topic was introduced by the Danish CA who suggested that the site certificates issued by the National Competent Authorities for distributors of bone substitutes should be more informative so they are mutually recognised within EU.

When a commercial distributor in one MS receives DMBs from a tissue establishment in another EU country, the site certificate of the latter could attest that the specified activities (e.g. donation, procurement, testing, processing, storage, distribution) were authorised and therefore the appropriate regulatory requirements have been fulfilled. The minimum information of name and site address of the tissue establishment, the list of the specified activities and the product descriptions/codes to which it is applicable, should be included and thus, these types of site certificates can assist the principle of mutual recognition and transparency in EU.

Several MS supported the above proposal. It was also suggested that the principles of the model certificate in the "Manual on inspection of tissue and cell procurement and tissue establishments" published by the Commission in August 2010 should be applicable for all site certificates.

13.4. Information: 2012 Conference of the European Tissue Bank Association/EATB

NCA from Austria informed the group about the organization of an Informal Meeting of the Competent Authorities for T&C, with participation of the DG SANCO, back to back to the EATB meeting in November 2012. The availability of the former EUSTITE project to organise more training sessions for inspectors was also reiterated.

Dominik Schnichels