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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate D - Health Systems and Products  
D4 – Substances of Human Origin and Tobacco Control

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## Meeting of the Competent Authorities for Tissues and Cells

7 – 8 June 2012

### Summary Report

The meeting of the Competent Authorities on Tissues and Cells was convened on 7 and 8 June 2012. The previous meeting of National Competent Authorities (CAs) took place on 8 and 9 December 2011.

#### PARTICIPATION:

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

European Commission:

Chairman: Mr D. SCNNICHELS (SANCO)

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

Administrative assistant: H. PREROVSKA

#### **1. ADOPTION OF THE AGENDA**

Minutes of the previous meeting were approved. The agenda was adopted with minor changes:

- point 2 "Debrief from the Regulatory Committee meeting 7 June a.m" was cancelled, because the CAs meeting started immediately after the Regulatory Committee meeting with the same attendance;
- at the request of several CAs point 12.3 " Bone marrow registries in Spain" was re-scheduled for the first day, under point 5;

The German representative requested to the Commission to clarify the legal basis for the meetings of the CAs according to Directive 2004/23/EC and also to present the set of Rules of Procedure for these meetings.

## **2. EUROPEAN PARLIAMENT INITIATIVE REPORT ON THE TISSUES AND CELLS DIRECTIVE – UPDATE**

Following the publication by the Commission of the "Second Report on Voluntary and Unpaid Donation of Tissues and Cells" in June 2011, the European Parliament (ENVI Committee) has decided to prepare an initiative report on this topic. In this regard, a discussion/exchange of views between the Rapporteur (Ms. Marina Yannakoudakis, MEP) and CAs took place during the meeting in December 2011, and it was agreed that Commission will inform the CAs about the conclusions of the ENVI report.

The Commission presented the recommendations in the Draft ENVI Report and informed the CAs that the report should be voted in June or September 2012.

National CAs welcomed the interest of the European Parliament for the field of tissues and cells transplantation and appreciated the acknowledgement of EURO CET and its activities. It was considered that the issue of cord blood banking (e.g. public awareness, advertising over internet, autologous vs. allogeneic use, etc.) would require further consideration from both Member States and Commission. CAs emphasized that ethical issues should not be addressed by the EU legislation which is limited to safety and quality aspects.

Council of Europe expressed its regret that none of the comments and suggestions provided jointly with the European Blood Alliance during the public consultation of the draft ENVI report, were taken into consideration, especially because some of the issues raised in the report have been broadly examined by the EDQM Committees (e.g. ethical issues).

It was agreed that during the next CAs meeting the Commission will present the final version of the ENVI report as adopted by the European Parliament.

## **3. DEBRIEF FROM THE MEETING ON BORDERLINE ISSUES BETWEEN TISSUES, CELLS AND ADVANCE THERAPY MEDICINAL PRODUCTS - BRUSSELS, 13 FEBRUARY 2012**

Following the discussions in the CA meeting of December 2011, the Commission organised a meeting between the CAs for tissues and cells and members of the Committee of Advanced Therapies/CAT in EMA. The aim of the meeting was to identify and discuss borderline issues between the area of tissues and cells for transplantation purposes and the field of advanced therapy medicinal products (ATMP).

A debrief from this meeting was presented by the DK CA. The main topics of discussion included: definitions and classification, consistency in regulatory approaches, hospital exemption and other (e.g. issues related to the third-country origin of tissues and cells in case of their use for ATMPs). It was mentioned that both groups welcomed the concept of this meeting which allowed them to list the topics and questions of mutual concern. It was agreed that there is a lot of potential for sharing experience and building collaboration between the fields of tissues and cells and of ATMP. In this regard, the Commission will provide reports and outcomes of the most relevant projects and initiatives in the field of tissues and cells that can be useful for both professionals in the field of ATMP and CAT members. The group of CAs

considered that hospital exemption is a complex matter to be addressed by the national authorities.

CAs indicated an interest that similar meetings be organised in future. The Austrian CA mentioned that some of the issues debated during the February meeting will be further discussed during an informal meeting of CAs to be held in Vienna in November 2012. It was agreed that Commission services will invite CAT representative(s) whenever relevant issues for both T/C and ATMP are to be debated and will inform the CAT secretariat about interpretations examined during the CAs meetings.

#### **4. ILLEGAL AND FRAUDULENT ACTIVITIES IN THE TISSUES AND CELLS AREA – UPDATE (FR)**

The FR CA presented the approach of French authorities on a special case regarding a private commercial company aiming to prepare, store and distribute dehydrated human placenta to be consumed by mothers, while claiming therapeutic advantages for its products. Based on the French legislation, the product was considered a medicinal product with all consequences related to this status.

The FR representatives noted that EU legislation is not clear for such products and made the following remarks:

- 1) EU Directive 2004/23 provides that: “it shall apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications. Where such manufactured products are covered by other directives, this Directive shall apply only to donation, procurement and testing”. The FR point of view was that for procurement, testing and processing, the provisions of Directive 2004/23/EC may be applied.
- 2) For the other activities, such as preservation, storage and distribution, other EU laws could be applied such as the legislation about medicinal products or medical devices or in this specific case (e.g. placenta for human consumption) the food legislation.

During the subsequent discussions it was noted that the same topic was debated during the CAs meeting in December 2010, when the Commission, after consulting the Unit responsible for EU Food legislation, presented the legal framework and its preliminary analysis, as following:

- 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<sup>1</sup> 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.

CAs highlighted the need of a consistent approach regarding such products (e.g. placenta for human consumption, stem cells from human milk, etc). It was also emphasised that more information on these products would be needed (evidence-base

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<sup>1</sup> REGULATION (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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.

on therapeutic effects, clinical trials, etc) and the public should be made aware about the lack of evidence concerning its therapeutic effects.

The Group of CAs concluded that based on the current information, human placenta for human consumption seems to fall outside the Tissues and Cells Directives. French authorities were suggested to bring this file also to the agendas of the Pharmaceuticals Committee and the Food Committee.

## **5. BONE MARROW REGISTRIES IN SPAIN (ES)**

The ES CA presented their position on the activities launched in Spain by DKMS, a private donor recruitment body from Germany. In their view, DKMS started its activity without fulfilling all the requirements of the Spanish legislation. The follow-up of the dispute between DKMS and the Spanish Ministry of Health and the National Transplantation Organisation was also presented.

During the subsequent discussions, several issues were raised, such as:

- DKMS practices in other EU Member States (e.g. Poland)
- co-existence of private organisations such as DKMS with public national recruitment organisations within the specific context of MS healthcare systems;
- authorisation procedure for the activities performed by such an organisation when starting similar activities in another EU Member State;
- donors' recording in national donor registries.

The DE representative underlined that DKMS is a non-profit organisation and asked/suggested some legal clarifications. He asked the Commission for legal clarification if the ES approach may be against article 56 of the Treaty on the functioning of the EU regarding freedom of services. The ES CA stressed that the position of Spain is based on the article 12 of 2004/23/EC directive.

The Group of CAs concluded that more information on DKMS activities would be needed, and asked the Commission to provide additional data and a compilation of issues that were raised by CA at the meeting for a potential discussion at the next CA meeting. The issue if "brokering-like activities" are sufficiently covered by the Directive will be clarified by the Commission.

## **6. INTERPRETATION QUESTIONS**

### **6.1. Interpretation of the requirements regarding HTLV testing in high risk donors – update**

NCA's and Commission were asked by the UK CA 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.

Following the CAs meeting in December 2011, the SANCO legal unit was asked to provide its opinion on this issue. It was stated that according to provisions under point 1.2 of Annex II and point 2.4 of Annex III of Commission Directive 2006/17/EC repeated HTLV testing is required. It was also noted that in case of appropriate scientific arguments, these provisions may be adapted to scientific and technical progress as laid down in Article 28 of Directive 2004/23/EC. It was

agreed that the UK representative should send additional scientific data and the Commission should request a full risk assessment from ECDC.

## **6.2. Transplantation of face – update**

Following the adoption of the Directive 2010/53/EU which provides for a definition for "organs" in Art 3 (h), the question whether composite tissues, such as facial transplant, should fall under the Organs or T/C Directive was re-discussed at the meeting of T&C NCAs in December 2011. During the meeting it was suggested that Commission should have the same interpretation for other multi-tissue transplantation procedures (e.g. hand transplantation).

After consulting the SANCO legal team it was concluded that a thorough analysis of the technical aspects of such procedures is needed. Several CAs provided arguments in support of including the transplantation of composite tissues under the Organs Directive (e.g. long term storage – possible for tissues and cells, but not valid for organs/composite tissues). Other CAs stated that they have already included composite tissues in their national legislation when transposing the Directive 2010/53/EC (ES). Council of Europe representative mentioned that it was agreed to include transplantation of composite tissues in the last edition of the Guide for Organ Transplantation to be published next year. Following discussions, it was agreed that Commission should consult the CAs for Organ Transplantation during their next meeting in September 2012. The final adoption of the interpretation should take place during the next meeting of the CAs for Tissues and Cells in December 2012.

## **6.3. Endocell**

The NL CA asked the Commission and the CAs for Tissues and Cells whether the co-culture of autologous endometrial cells to support embryo transfer at blastocyst stage (ENDOCELL®/ Laboratoire Génévrier) may fall under the provisions of Directive 2004/23/EC and about its use in other EU Member States.

The FR CA stated that Endocell is considered an ancillary therapeutic product in France, requiring authorisations from both ANSM and ABM (Bioethical law). It was mentioned that Laboratoire Génévrier has not received a renewal of the authorisation for this product because they failed to provide data on efficacy, feasibility and safety of this product.

CAs agreed that there is no clear regulatory framework yet for such a product (e.g. endometrial tissue) which is produced in one Member State for use in patients in other Member States, In particular supervising is difficult. It was suggested that as long as Laboratoire Génévrier has no authorisation from the FR authorities, ENDOCELL should not be used in other Member States. The issue of mutual recognition of processing authorisations could be discussed during one of next meetings.

Some MS considered that in this case rather the process in the different sites of utilisation are to be authorised, and not the single product. Therefore national authorities responsible for ART establishments should authorise the processes in which ENDOCELL is used and validate it. It was also underlined that in the ART

field, beside quality and safety there is also the issue of efficacy, therefore it was suggested that such a process would require full authorisation from the CAs for Tissues and Cells in order not to compromise the embryo and the subsequent pregnancy. It was stated that authorisation for such processing falls under Directive 2004/23/EC.

#### **6.4. Faecal transplantation**

The NL CA asked the Commission whether faeces donated by partner or close relative transplanted as treatment for *Clostridium difficile* infection may fall under Directive 2004/23/EC and what would be the safety and quality issues to be considered in this case.

The group of CAs concluded that bacterial flora does not fall under the provisions of the Directive 2004/23/EC.

#### **6.5. Transplantation of islets of Langerhans**

The NL CA asked the Commission whether transplantation of Langerhans islets for the treatment of type 1 diabetes combined when pancreas transplantation is not a valid option, falls under the Tissues and Cells or Organ Transplantation Directives.

It was recalled that this question was already discussed during the CAs meeting in May 2009, when it was agreed that due to the complex banking process, islets of Langerhans should fall under the provisions of the Directive 2004/23/EC. Some CA recalled that the Committee of Advanced Therapies in EMA was also asked to provide its opinion on the classification of a suspension containing human islets of Langerhans, autologous or allogeneic. This recommendation which states that the product does not fall within the definition of an advanced therapy medicinal product as provided in Article 2(1)(a) of Regulation (EC) No 1394/2007 is available at:

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2011/08/WC500110643.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/08/WC500110643.pdf)

A "Reflection paper on classification of advanced therapy medicinal products" prepared by the Committee of Advanced Therapies in EMA is also available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2012/04/WC500126681.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500126681.pdf)

### **7. SURVEILLANCE AND VIGILANCE**

#### **7.1. Update on infectious disease risks**

##### *7.1.1. Epidemiological update – ECDC*

ECDC presented an overview of the communicable disease threats related to tissues and cells in the first 6 months of 2012, a summary of the Viaspan® alert (potential contamination with *Bacillus cereus*, and its consequences on recipients of solid organ transplantations), as well as future activities envisaged by ECDC in the area of tissues and cells.

ECDC representative emphasised the aim of the agency to become a recognized authority in providing Member States and EU Commission with the scientific advice on demand and infectious risk assessments in relation to most, if not all communicable diseases relevant to substances of human origin. Among its short-term priorities, ECDC included the development of an evidence-based comprehensive review of potential risks of transmission for infectious diseases relevant to the area of substances of human origin. In this regard, it was mentioned that ECDC will organise a MS expert consultation meeting to identify and prioritise infectious diseases which may be transmitted via tissues and cells, blood or organs and asked CAs to recommend national experts, either in the field of tissues banking or epidemiology and communicable diseases.

The Commission acknowledged the support provided by ECDC and underlined the need to identify the needs in this area, to provide risk assessments and eventually to recommend response measures. It was agreed that CAs interested to send national experts to the group organised by ECDC will provide their names to EC-SANCO D4.

Several NCAs acknowledged the usefulness of the data provided by the Commission also to Tissues and Cells CAs during the Viaspan® alert, and expressed their support for a communication platform linking the current RATC system with alerts concerning organs and blood.

#### *7.1.2. 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**

### *7.2.1. Analysis of the 2010 Annual Report*

The draft 2010 Annual Report presented during the December 2011 meeting was revised following re-submissions from some MS, and the Commission presented a brief analysis of the data.

It was highlighted that data collection regarding the number and classification of SARE and especially the number of tissues and cells distributed and processed at national level, continues to be a difficult exercise. Even though some of the data were corrected following the quality check, several submissions were incomplete, making the overall totals inaccurate. Another important issue which contributed to the lack of data precision is the different interpretation of the data to be collected. The continuous work to improve the Common Approach document with the help of the SOHO V&S project was emphasized and appreciated.

The Commission should send a final version of the draft 2010 Annual SARE Report to the CAs for their feedback/approval by October 2012, with the aim of publishing it on the Europa website by the end of this year.

### *7.2.2. 2012 SARE reporting exercise – Update*

Following the feedback requested during the meeting in December 2011 on the SARE reporting exercise, the Commission received comments and suggestions from 11 MS. Taking into account this feedback, as well as proposals from the SOHO V&S project, the Commission has revised both the reporting template and the Common Approach document. With this revision, the Commission aimed to make the template more self-explanatory and user-friendly and to improve the structure and data definitions in the Common Approach document.

The Commission informed the group that the 2012 reporting exercise, for data collected from 01/01/2011 to 31/12/2011, will be launched in early July, with a deadline for submission in September 2012 (to be confirmed by email). The first results should be presented during the CAs meeting in December 2012. In the meantime, the template should be presented to MS inspectors and vigilance contact points during the SOHO V&S training course to be held in Ireland in June 2012.

### **7.3. Update on the development of RATC**

During the meeting on 8-9 December 2011, the Commission informed the CAs about its efforts related to the creation of an EU vigilance and traceability support for tissues and cells, and about its decision to explore new options in order to put it in place by the end of 2012.

Starting with January 2012, the Commission analysed several solutions for an IT platform, developed and hosted by the Commission services, to ensure rapid and secure communication between CAs and Commission for the transmission of cross-border rapid alerts related to tissues and cells intended for human application. Because the re-use of similar rapid communication systems (e.g. EWRS) was not considered feasible and the current CIRCA/CIRCABC system was not designed as a rapid communication platform, it was decided to develop a new system taking into account the specificities of the T&C field for the alert notification and reporting, while ensuring appropriate user friendliness, performance, system reliability and security. During the first steps of the development of this new RATC platform, the Commission consulted the RATC Working Group and the SOHO V&S project.

The SANCO IT project manager explained the user roles and the main features of the system, also introducing the prototype of the new RATC platform. The relation with EURO CET128 was also explained. It was mentioned that it was envisaged to start the acceptance phase in September 2012 with a launch in production foreseen for November-December 2012.

The CAs warmly welcomed the solution proposed by the Commission and commented some of the new features (e.g. possible links with other sectors, library, search function, statistics). Commission was asked about a potential training/webinar to be organised for the CAs to speed up the exploitation of the

new platform. The Commission agreed to reflect on the possibility to organise such a training course and called for CAs to express their availability for testing the new platform during the acceptance phase.

#### **7.4. Update on the development of the new European code for tissues and cells – EURO CET128 tender**

During the meeting in December 2011, when the Commission presented the results of the public procurement procedure EAH C/2011/Health/03 concerning reference compendia for the application of a single European coding system for human tissues and cells, it was agreed that CAs will be regularly updated about the progress of this work. Therefore, the EURO CET128 consortium representatives briefly presented the overall project and provided details regarding the activities planned for 2012 which require close collaboration with CAs (WP1 – building the compendium of all EU tissue establishments and WP2 – building a compendium and tissue and cells products used in EU).

CAs welcomed the work of the consortium and expressed their readiness to collaborate. Regarding the template designed by EURO CET128 to be fulfilled by CAs for the development of the TEs registry, CAs suggested several adjustments in terminology and data to be provided.

It was stated that the implementation of the new EU code in all MS by 2014 may be challenging, therefore CAs asked the Commission whether a transition period will be envisaged. The Commission agreed to reflect on this issue which should be addressed during the next meeting of the CAs.

### **8. IMPORT/EXPORT FROM/TO THIRD COUNTRIES**

#### **8.1. Grafton alert (ES)**

The Spanish CA provided details about an alert issued by the the Spanish National Transplant Organization following an alert from the international company “Medtronic” and his Spanish distributor about the derived human tissue products called Grafton® and Xpanse®, in which they were recommending an immediate recall of all affected batches.

This alert triggered a debate on the import of tissues from third countries by a tissue establishment in a Member State where the product is not stored and/or used, but considered in transit to another Member State.

The need for clear and common requirements concerning import-export of tissues and cells from/to third countries was emphasized. The need for adequate tools for CAs on illegal and fraudulent activities was also underlined.

The Commission recalled that a new WG for Import-Export was initiated and this topic could be debated during its first meeting to be held in September 2012.

## **8.2. Brokers selling T&C without storage; online advertising of demineralised bone products (IE)**

The IE CA raised the question about authorising/licensing "broker companies" which are not involved in tissues/cells storage, but just import/export of products from third countries and their subsequent distribution in EU Member States. Criteria for authorising/inspecting were discussed.

In addition, advertising DBMs over internet with the possibility of ordering and their direct distribution to EU hospitals/professionals was also debated.

Due to the important quality and safety aspects related to the issues above, it was agreed that they should be put up in discussion to the Import-Export Working Group with the aim to finding a harmonised approach across EU Member States.

To facilitate the first session Import/Export Working Group some Member States volunteered to prepare some discussion papers:

- Activities to be authorized (IE)
- Which competent authority supervises what (PL, ES)
- Check list and procedures on equivalent standards of safety and quality (NL)

## **9. PROJECT PRESENTATIONS: SOHO V&S**

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. The coordinator, the IT CA, updated the group about the most recent achievements. The following outputs were highlighted:

- Contribution to the NOTIFY WHO project;
- New section on EURO CET website dedicated to rapid alerts, including a forum on vigilance issues;
- WP 7 deliverable "Communication and Investigation of SARE associated with human tissues and cells" was sent to the CAs for feedback, with deadline end of August 2012;
- WP 8 is organising two training courses in vigilance and surveillance of tissues and cells for CAs in the field in July and October 2012; it was mentioned not all Member States have sent representatives to this course.
- The final conference of the project will be held in UK in January-February 2013.

The Group of CAs acknowledged the valuable work and outputs of the SOHO V&S project.

## **10. FIRST EDITION OF THE COUNCIL OF EUROPE GUIDE TO SAFETY AND QUALITY ASSURANCE FOR TISSUES AND CELLS – UPDATE FROM THE EDQM SECRETARIAT**

The Council of Europe representative updated the group about the drafting process of the first edition of the CoE Guide dedicated only to safety and quality issues for human tissues and cells intended for human application. The leaders of the drafting group are Italy (for tissues) and France (for cells) with the drafting process under the aegis of the

CD-P-TO. The aim to align the CoE requirements to the EU directives for Tissues and Cells was highlighted, also taking into consideration and including the valuable output of several EU-funded projects (EUSTITE, SOHO V&S, EuroGTPs).

It was mentioned that the full text will undergo public enquiry before publication in the summer of 2013, hence national CAs were encouraged to provide their feedback on the draft text.

## **11. REVISION OF THE MEDICAL DEVICES DIRECTIVE – UPDATE**

The SANCO Medical devices unit presented a short overview of the changes foreseen in the revised version of the Directive focusing on products manufactured utilising non-viable tissues or cells of human origin. The presentation highlighted the scope of the new Regulation proposed by the Commission, the essential safety and performance requirements, as well as provisions related to conformity assessment.

It was mentioned that the current draft text was under consultation by the other Commission services with the target date - September 2012 for submission to EP and Council and 2014 for adoption. Documents and the development of the legislative decision-making process are available at: [http://ec.europa.eu/health/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm)

Several CAs welcomed the Commission proposal, but expressed their concerns regarding the conformity assessment provisions which include an EU reference laboratory designated to check that the requirements relating to the donation, procurement and testing and/or the benefit/risk of the incorporation of the human tissues or cells into the medical device have been complied with by manufacturer and properly assessed by notified body. Other issues of concern were human DBM (demineralised bone matrix) products which may include both viable and non-viable cells, as well as human DBMs combined with carriers (e.g. gel/syringe), which may be produced by the same tissue establishment producing non-combined DBM. Some CAs questioned the added value of transferring products manufactured utilising any tissues or cells of human origin under the Medical Devices Directive.

It was recalled that the regulatory status of commercial human bone substitutes had already been discussed during the CAs meetings in October 2009 (when it was agreed that commercial bone substitutes in all Member States need to comply with the EU legislation) and June 2011. Some CA's highlighted that the present draft revision required further considerations, in particular to reflect the emergence and operation of new regulatory frameworks which currently fulfils some of the earlier identified gaps.

It was agreed that CAs interested to provide feedback to the Commission should send their comments to SANCO D4 at their earliest convenience.

## **12. AOB**

### **12.1. Presidency meeting of National CAs for Tissues and Cells 2012 (AT)**

The AT CA informed the group about the organization of a meeting of the CAs for T&C, under the Cypriot Presidency on 21-23 November 2012 in Vienna. Several topics of potential interest will be presented, such as regulatory aspects for import-export of human tissues/cells, legal framework for composite tissues in EU, issues requiring clarification or scientific update in the EU legislation for Tissues and Cells, etc.

### **12.2. Organisation and access to fertility clinics in the Northern part of Cyprus (CY)**

The CY CA informed the group about the need to properly inform patients originating from EU Member States of the status of IVF centres in Northern part of Cyprus.

CY CA received complaints from EU citizens regarding the quality of the IVF treatment in the northern part of Cyprus and was also informed about medical services proposed by these centers via the media in some EU Member States (e.g, gender selection, buying of donor gametes). Therefore, the Ministry of Health in Cyprus wanted to inform the CAs that tissue establishments in the Northern part of Cyprus are not authorised/licensed and are not inspected by the CY CA according to the Tissue and Cells Directives.

### **12.3. Other issues (IE)**

The IE CA informed the group about the meeting "Making Gene and Cell Therapy Medicines a Reality to be held in Dublin on 10-11 July 2012. The meeting was jointly organized by the Parenteral Drug Association (PDA) and the Irish Medicines Board (IMB) being focused on outlining the regulatory framework and challenges of translating the exciting basic science discoveries related to molecular and cell biology into novel, commercial gene and cellular therapies.

DOMINIK SCHNICHEL