EUROPEAN COMMISSION
HEALTH AND FOOD DIRECTORATE GENERAL

Directorate D - Health systems and products
D4 – Substances of Human Origin and Tobacco Control

Brussels,
SANTE D4/RM/ac ARES (2015)

Meeting of the Competent Authorities for Tissues and Cells

3 December 2015, 10.00 - 18.00

Location: Albert Borschette Conference Centre, Room AB-4B

Rue Froissart 36, B - 1040 Brussels

4 December 2015, 9.30 – 16.00

Location: Albert Borschette Conference Centre, Room AB-4B

Rue Froissart 36, B - 1040 Brussels

AGENDA

Day 1

1. ADOPTION OF THE AGENDA

2. LEGAL MATTERS

2.1. Update on the transposition of the Tissues and Cells Directives

2.2. **Transposition of Directives (EU) 2015/565 (Coding) & 2015/566 (Import) – Progress and planned use of exemptions *(Members will be asked to provide oral updates of progress)***

2.3. Interpretation questions

2.3.1. Lymphocyteimmunotherapy

2.3.2. Direct distribution of sperm

2.4. Mapping by the Commission of the more stringent safety and quality requirements in the Member States – Presentation of results

2.5. Organisation of the oversight in the ART sector in Spain (ES ART CA) (to be moved to day 2)

3. REPORTS

3.1. Update on the implementation of the Tissues and Cells Directives and the third survey on the implementation of the principle of voluntary and unpaid donation for tissues and cells – main conclusions and state of play

4. PRESENTATION OF PROJECTS, JOINT ACTIONS AND STUDIES UNDER THE HEALTH PROGRAMME (AND HORIZON 2020)

4.1. Update on the 2013 Joint Action on good practices on donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies and of haematopoietic stem cells for transplantation (ARTHIQS)

4.2. Update on the 2014 Joint Action on Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation (VISTART)

4.3. Update from the study into the economic landscape of the tissues and cells sector

4.4. Presentation of current tissue & cell-related Horizon 2020 calls for proposals (DG RTD)

DAY 2

5. SURVEILLANCE AND VIGILANCE

5.1. Update on infectious disease risks

5.1.1. Epidemiological update – ECDC

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

5.2. Update on the development of the EU coding platform

5.2.1. Update on the agreements with the organisations managing ISBT128 and Eurocode

5.2.2. Debrief from the meetings of the Expert Sub-Group on Coding

5.2.3. Preparations for the roll-out of the SEC
- Update on the EU Tissue Establishment Compendium
- External communication plan

5.3. Rapid alerts for tissues and cells (RATC)

5.3.1. Debrief from the meeting of the RATC Working Group

5.3.2. Update on alerts

5.4. Serious adverse reactions and events (SARE)

5.4.1. Preliminary Results of the 2015 SARE annual reporting exercise (2014 data)

5.4.2. Presentation of a national vigilance system- potential topic for next CA meetings, starting with June 2016 (for discussion)

6. INTERNATIONAL DEVELOPMENTS

6.1. Update from the Council of Europe

6.2. Other developments

7. UPDATE ON THE REVISION OF THE EU MEDICAL DEVICES LEGISLATION

8. ANY OTHER BUSINESS

8.1. Traceability & anonymity – transplantation cards (DK CA)

8.2. HTA guidance on cord blood banking (UK CA - HTA)

8.3. Mitochondrial donation in the UK (UK CA – HFEA)

8.4. Discussion on CA group interaction with stakeholders

8.5. Other points

9. CONCLUSIONS OF THE MEETING

Please note that all supporting documents will be sent to you via the CIRCABC site before the meeting. We kindly ask you to bring a copy with you as copies will not be provided during the meeting.