EUROPEAN COMMISSION
HEALTH AND FOOD DIRECTORATE GENERAL

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

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

Meeting of the Competent Authorities for Tissues and Cells

3 June 2014, 10.00 - 18.00

Location: Albert Borschette Conference Centre, Room AB-3C

Rue Froissart 36, B - 1040 Brussels

4 June 2014, 9.30 – 14.00

Location: Albert Borschette Conference Centre, Room AB-3C

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. Debrief from the Joint meeting of Tissues and Cells Competent Authorities, National Competent Authorities for Human Medicines and representatives of the Committee for Advanced Therapies in EMA

2.3. Interpretation questions

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

2.5. Debrief from the DG SANTE D4 visit to FDA-CBER

2.6. **Mapping of the US FDA vs EU requirements for tissues and cells (UK HTA) –**

Postponed to DAY 2

2.7. Organisation of the oversight in the ART sector in Spain (ES)

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 – discussion of the main conclusions

4. PRESENTATION OF PROJECTS, JOINT ACTIONS AND STUDIES UNDER THE HEALTH PROGRAMME

4.1. Update of 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

4.2. Update from the study into the economic landscape of the tissues and cells sector (Rathenau Institute)

4.3. Presentation of the results of the Eurobarometer survey for blood, tissues and cells

4.4. Presentation of the output of the 6th EUSTITE course for EU MS inspectors

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

5.3. Rapid alerts for tissues and cells (RATC)

5.4. Serious adverse reactions and events (SARE)

5.4.1. Results of the 2014 SARE annual reporting exercise (2013 data)

5.4.2. Launch of the 2015 SARE annual reporting exercise

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

7. VAT ON TISSUES AND CELLS

8. 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.