EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels,
SANCO D4/RM/ac ARES (2014)

Meeting of the Competent Authorities for Tissues and Cells

3 December 2014, 10.00 - 18.00

Location: Albert Borschette Conference Centre, Room AB-5B

Rue Froissart 36, B - 1040 Brussels

4 December 2014, 9.00 - 13.30

Location: Albert Borschette Conference Centre, Room AB-5B

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. Update on the draft Commission Directives on import and coding

2.3. Debrief from the first Working Group on the update of the Operational Manual on inspections and presentation of updated version

2.4. Interpretation questions

2.4.1. Feedback on the regulatory status of breast milk and faeces

2.4.2. Lymphocyte immune therapy

3. REPORTS

3.1. Update on the implementation of the Tissues and Cells Directives

3.2. Update on the third survey on the implementation of the principle of voluntary and unpaid donation for tissues and cells

4. SURVEILLANCE AND VIGILANCE

4.1. Update on infectious disease risks

4.1.1. Epidemiological update – ECDC

4.1.2. Update on HTLV mapping

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

4.2. Update on the development of the European coding platform

4.2.1. Hosting of the Eurocet128 database by the European Commission

DAY 2

4.3. Rapid alerts for tissues and cells (RATC)

4.3.1. Follow-up and closing of alerts launched in 2013 and 2014

4.4. Serious adverse reactions and events (SARE)

4.4.1. Preliminary results of the 2014 SARE annual reporting exercise (2013 data)

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

5.1. 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

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

6. INTRODUCTION TO THE ACTIVITIES OF THE COMMITTEE ON ADVANCED THERAPIES (CAT)

7. AOB

7.1.1. Update of the revision of the Medical Devices Directive

7.1.2. Clarification of 'same surgical procedure' by FDA

7.1.3. Prohibition of human placental tablets / capsules

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.