EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products, quality, safety, innovation

Brussels,
SANTE B4/DF/ac ARES (2016)7300931

Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718)

Meeting of the Competent Authorities for Tissues and Cells

21 February 2017, 10.00 - 17.30

22 February 2017, 9.00 – 12.30

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 verification of transposition of the Tissues and Cells Directives

2.2. Transposition of Directives (EU) 2015/565 (Coding) & 2015/566 (Import)

2.3. Regulation of sperm banking in DK – an update (DK)

2.4. Organisation of the oversight of the ART sector – updates from some Member States

3. EVALUATION OF THE TISSUE AND CELL LEGISLATION

3.1. Roadmap

3.2. External study

3.3. Consultation strategy

3.4. Issues identified by CAs in the past

4. EMA UPDATE

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

5.1. 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)

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

- Overall progress on the action

- Specific updates on:

- work package 5b – Principles for CAs for the Evaluation and Approval of Clinical Follow-up Protocols for Blood, Tissues and Cells prepared with newly developed and validated processing methodologies

- Work-package 6 – Inspection Guidelines for Blood, Tissues and Cells Competent Authorities

- Work-package 8 – Establishment of a framework for Joint Inspections.

5.3. Update on projects funded through the 2015 call of the Public Health Programme

5.3.1. Good Practices for demonstrating safety and quality through recipient follow-up (EURO GTP II)

5.3.2. European Cornea and Cell Transplantation Registry (ECCTR)

5.4. 2016 Public Health Programme call for proposals – Update.

6. CODING – UPDATE ON THE STATUS OF THE COMPENDIA, GAPS AND QUERIES

DAY 2

7. SURVEILLANCE AND VIGILANCE

7.1. Update on infectious disease risks

7.1.1. Epidemiological update – ECDC

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

7.2. RATC alerts

7.2.1. General overview

7.2.2. Member State updates on recent RATC alert (Syphilis testing)

7.3. SARE reporting

7.4. Presentation of a National Vigilance system – TRIP (NL)

8. INTERNATIONAL DEVELOPMENTS

8.1. Council of Europe update

8.2. WHO update

9. INTERACTION WITH STAKEHOLDERS

9.1. Update on DG SANTE/B4 meetings with stakeholders

9.2. Briefing for the meeting with selected stakeholders of 22 February 2017

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

11. ANY OTHER BUSINESS

12. 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.