



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/IPK/ac ARES (2017)

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

### **Meeting of the Competent Authorities for Tissues and Cells**

**15 November 2017, 10.00 - 18.00**

**16 November 2017, 9.00 – 12.30**

*Location: Albert Borschette Conference Centre, Room CCAB 1B*

*Rue Froissart 36, B - 1040 Brussels*

## **AGENDA**

### **Day 1**

- 1. ADOPTION OF THE AGENDA**
- 2. LEGAL MATTERS**
  - 2.1. Transposition of Tissue and Cells Directives**
  - 2.2. Organisation of the oversight of the ART sector – update from Spain**
- 3. EVALUATION OF THE TISSUE AND CELL LEGISLATION**
  - 3.1. State of play**
    - 3.1.1. Feedback on Open Public Consultation and Stakeholder event of 20/9/2017
    - 3.1.2. External study – update from ICF
  - 3.2. Issues relevant for NCAs in the context of BTC evaluation**

#### **4. PRESENTATION OF ACTIONS UNDER THE PUBLIC HEALTH PROGRAMME**

**4.1. Update on the Joint Action ARTHIQS - 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 on the Joint Action VISTART - Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation**

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

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

4.3.2. European Cornea and Cell Transplantation Registry (ECCTR)

**4.4. Public Health Programme – update**

4.4.1. *TRANSPPOSE (TRANSfusion and transplantation: PrOtection and SElection of donors)*

4.4.2. *GAPP (Facilitating the Authorisation of Preparation Process for blood and tissues and cells)*

#### **5. CODING – UPDATE ON IMPLEMENTATION**

#### **DAY 2**

#### **6. SURVEILLANCE AND VIGILANCE**

**6.1. Update on infectious disease risks**

6.1.1. Epidemiological – general update and testing protocols (ECDC)

6.1.2. Other – Member State update

**6.2. RATC alerts**

6.2.1. General overview

6.2.2. Member State update on recent RATC alert(s)

**6.3. Vigilance**

6.3.1. SARE reporting - – state of play and issues identified (EDQM)

6.3.2. Vigilance expert subgroup

## **7. INTERNATIONAL DEVELOPMENTS**

### **7.1. Council of Europe update**

### **7.2. WHO update**

## **8. INTERACTION WITH STAKEHOLDERS**

### **8.1. Update on DG SANTE/B4 meetings with stakeholders**

### **8.2. Meeting with ART stakeholders (16/11/2017)**

## **9. UPDATE ON OTHER RELEVANT EU POLICY AND LEGISLATION**

## **10. ANY OTHER BUSINESS**

## **11. 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.*