



**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/mmm/ARES (2019)

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

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

13 May 2019, 10.00 - 17.00

14 May 2019, 9.00 - 15.00

*Venue: Albert Borschette Conference Centre,*

*Rue Froissart 36, B - 1040 Brussels*

*Room 0.C – on 13 May, Room 5.B – on 14 May*

**DRAFT AGENDA**

- 1. WELCOME AND INTRODUCTORY REMARKS**
- 2. ADOPTION OF THE AGENDA**
- 3. LEGAL MATTERS**
  - 3.1.** Transposition and implementation of Tissue and Cells Directives (DG SANTE)
  - 3.2.** Update on implementation of coding and import legislation (DG SANTE)
  - 3.3.** Danish non-partner donor testing protocol – update (DK)
  - 3.4.** New Medical Device Regulation: interaction with TC competent authorities (DG GROW)
- 4. EVALUATION OF THE EU LEGISLATION ON BLOOD, TISSUES AND CELLS (DG SANTE)**

## **5. OVERSIGHT FUNCTIONS**

### **5.1. INSPECTION AND AUTHORISATION OF TC ESTABLISHMENTS**

*Update on the work of the Inspection Expert Subgroup (IES)*

### **5.2. TRACEABILITY**

*Update on the work of the Coding Expert Subgroup (CES)*

### **5.3. SURVEILLANCE AND VIGILANCE**

#### **5.3.1. Update on infectious disease risks**

**a) Epidemiological - general update (ECDC)**

**b) Other - Member State updates**

#### **5.3.2. Rapid alerts**

#### **5.3.3. SARE**

**a) SARE reporting – final data from 2017 exercise (2016 data)**

**b) Launch of 2019 exercise (2018 data)**

#### **5.3.4. Vigilance Expert Subgroup (VES) - update**

### **5.4. EFFICACY AND CLINICAL DATA**

**5.4.1. Update on the work of GAPP WP 8 (FIMEA)**

**5.4.2. Demonstrating safety and quality through recipient follow up  
(EURO GTP II)**

**5.4.3. Use of registries for clinical follow-up (ECCTR)**

**5.4.4. SoHO Registries meeting (SANTE)**

## **6. THERAPY SPECIFIC TOPICS**

**7. PRESENTATION OF ACTIONS UNDER THE PUBLIC HEALTH PROGRAMME**

**7.1. TRANSPOSE (TRANSfusion and transplantation: PrOtection and SElection of donors)**

**7.2. GAPP Joint Action**

**7.3. WMDA global registry for SAE/SAR in blood stem donation and transplantation**

**8. INTERNATIONAL DEVELOPMENTS**

**8.1. Council of Europe update**

**8.2. WHO update**

**9. ANY OTHER BUSINESS**

*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.*