



**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/IP/imc/ARES (2019)

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

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

22 October 2019, 10.00 - 17.00

23 October 2019, 9.00 - 13.00

*Venue: Albert Borschette Conference Centre,  
Rue Froissart 36, B - 1040 Brussels  
Room 0.B*

**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.** 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**

*Update on the work of the Inspection Expert Subgroup (IES)*
  - 5.2. AUTHORISATION**

*GAPP WP5 and GAPP WP6*

### **5.3. TRACEABILITY**

5.3.1. Update on the work of the Coding Expert Subgroup (CES)

5.3.2. Proposal for improving traceability of tissues and information to patients (ES)

### **5.4. SURVEILLANCE AND VIGILANCE**

5.4.1. Update on infectious disease risks

a) Epidemiological - general update (ECDC)

b) Other - Member State updates

5.4.2. Rapid alerts (DG SANTE)

5.4.3. SARE (EDQM)

5.4.4. Update on the work of the Vigilance Expert Subgroup update (VES)

### **5.5. CLINICAL OUTCOME DATA**

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

5.5.2. GAPP WP8 – Use of clinical data for preparation process authorisation

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

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

**6.2.** GAPP Joint Action – other WPs

## **7. INTERNATIONAL DEVELOPMENTS**

**7.1.** Council of Europe update

**7.2.** WHO update

## **8. Specific topics raised by Member States**

**8.1.** Survey on sharing of surplus tissues (IT)

**8.2.** Preparation of starting materials of human organs and extracorporeal chemotherapy products (FR)

### **8.3. Survey on oversight cord blood banking (NL)**

## **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.*