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 INTRODUCTIONARY 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 date 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.