



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/imc/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 - 18.00

14 May 2019, 9.00 - 16.00

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

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

**5.4.2. Update on the work of GAPP WP 8 on assessing clinical data as
part of a preparation process authorization (FIMEA)**

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

5.4.4. SoHO Registries meeting (SANTE)

6. THERAPY SPECIFIC TOPICS

6.1. Epidermal cell suspensions (EACTB)

6.2. Faecal Microbiota Transplants (UZ Ghent – BE)

6.3. Germ line editing (ESHRE)

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 – overview

7.3. WMDA - S(P)EAR (Serious (Product) Events and Adverse Reactions) for blood stem cell donation and transplantation registries

8. INTERNATIONAL DEVELOPMENTS

8.1. Council of Europe update

8.2. WHO update

9. ANY OTHER BUSINESS

9.1. Media related issues (DG SANTE)

9.2. Health Programme (CHAFEA)

9.3. SoHO Research agenda (DG SANTE/RTD)

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.