



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation  
B4 – Medical products: quality, safety, innovation

Brussels,  
SANTÉ B4/IP/mnm ARES (2018)

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

## Meeting of the Competent Authorities on Blood and Blood Components

27<sup>th</sup> February 2018, 10:00-18:00

28<sup>th</sup> February 2018, 9:00-13.00

BRUSSELS

Venue: CCAB (Centre de Conférence A. Borschette, Rue Froissart 36,  
1040 Bruxelles, Belgium)

Day 1 – Room AB – 1D

Day 2 - Room AB – 4A

### DRAFT AGENDA

1. WELCOME AND INTRODUCTORY REMARKS
2. ADOPTION OF THE AGENDA
3. REGULATORY MATTERS: POINTS FOR INFORMATION
  - 3.1 Transposition, complaints, court cases and parliamentary questions
  - 3.2 Update on changes to Hungarian legislation
4. EVALUATION OF THE BLOOD LEGISLATION
  - 4.1 Update on the Study by ICF consulting Ltd.
  - 4.2 Preliminary feedback from consultation activities

## **5. PRESENTATIONS OF EU-FUNDED ACTIVITIES**

5.1. VISTART Joint Action on blood and tissues and cells

5.2. New Joint Action on Preparation Process Authorisation for blood, tissues and cells - GAPP

5.3. Transpose project

## **6. SURVEILLANCE AND VIGILANCE**

6.1. ECDC update

6.2. Member State surveillance updates

6.3. RAB alerts - General overview

6.4. SARE reporting – preliminary presentation of 2017 exercise (2016 data) by EDQM

6.5. Feedback from Vigilance Expert Sub-group

6.6. SARE reporting – 2018 exercise

## **7. NEW DATA PROTECTION REGULATION**

## **8. CONTINUITY OF SUPPLY/EMERGENCY PLANNING**

## **9. COUNCIL OF EUROPE UPDATE**

9.1 Update on Council of Europe (EDQM) activities

9.2 Previous questions from Finland on GPG

## **10. EMA UPDATE**

## **11. WHO UPDATE**

## **12. ANY OTHER BUSINESS**

## **13. FINAL REMARKS**