



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/ab ARES (2018)

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

Meeting of the Competent Authorities on Blood and Blood Components

10 October 2018, 14:00-18:00

11 October 2018, 9:00-17.00

BRUSSELS

**Venue: CCAB (Centre de Conférence A. Borschette, Rue Froissart 36,
1040 Bruxelles, Belgium)
Room 2.B**

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

4. EVALUATION OF THE BLOOD LEGISLATION

4.1 Feedback from consultation activities

4.2 Update on the Study by ICF consulting Ltd.

4.3 Next steps

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. PROPOSAL ON ESTABLISHING OF EXPERT SUBGROUP ON INSPECTIONS

7. DIGITAL DATA IN SoHO

8. PRESENTATION OF THE COMMISSION STRUCTURAL REFORM SUPPORT SERVICE (SRSS)

9. SURVEILLANCE AND VIGILANCE

9.1. ECDC update

9.2. RAB alerts - General overview

9.3. Member State surveillance updates

9.4. SARE reporting –EDQM

9.5. Feedback from Vigilance Expert Sub-group

10. CONTINUITY OF SUPPLY/EMERGENCY PLANNING

11. COUNCIL OF EUROPE UPDATE

12. EMA UPDATE

13. WHO UPDATE

14. ANY OTHER BUSINESS

15. FINAL REMARKS