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/DF/imc ARES (2019)

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

Meeting of the Competent Authorities on Blood and Blood Components

18 June 2019, 10:00-17:00
19 June 2018, 9:00-16.00

BRUSSELS

Venue: CCAB (Centre de Conférence A. Borschette, Rue Froissart 36, 1040 Bruxelles, Belgium)
Room AB-3A

DRAFT AGENDA

FIRST DAY

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 MSM update from Denmark

3.3 Other Member State legislative updates?

4. EVALUATION OF THE BLOOD LEGISLATION

4.1 Progress summary

4.2 Related political events

5. INSPECTION AND AUTHORISATION

5.1 Update from the Inspection Expert Sub-group (IES)

5.2 Other Member State updates on inspections?

5.3 Update on the GAPP work packages 5 and 6 (section on blood) on preparation process authorisation

6. VIGILANCE AND SURVEILLANCE

6.1. ECDC update

6.2. RAB alerts - General overview

6.3. Member State surveillance updates

6.4. SARE reporting – preliminary data 2018 exercise - EDQM

6.5. Feedback from Vigilance Expert Sub-group (VES)

6.6. Delegation of national vigilance activities by CAs to professional bodies

7. THERAPY SPECIFIC TOPICS

7.1 Feedback from the T&C competent authority survey and discussion

7.2 Issues related to PRP/PRF – DK

7.3 General discussion on the scope of 2002/98/EC and any regulatory gaps

8. COUNCIL OF EUROPE UPDATE – OTHER ACTIVITIES

SECOND DAY

9. CLINICAL OUTCOME DATA FOR SOHO

9.1 Feedback from registries meeting of February 20, 2019

9.2 Presentation of SCANDAT registry

9.3 Presentation of German Haemophilia registry

9.4 Update on GAPP work packages 8 and 9

9.5 GDPR – questions and answers for the SoHO sector

10. CONTINUITY OF SUPPLY AND EMERGENCY PLANNING

10.1 Feedback from the Plasma Supply Symposium January 29-31, 2019 – EDQM

10.2 Report on Kreuth meeting June 2019 on PDMP indications and use (tbc)

10.3 Developing guidance on continuity of the blood supply – EDQM

10.4 Impact of DEHP ban on supply of blood bags - Updates from the Commission and from stakeholders

11. RESEARCH AND DEVELOPMENT

11.1 RTD presentation on Horizon Europe

11.2 Stakeholder presentations on research priorities

11.3 EBA presentation on PBM conference results

12. PRESENTATIONS OF OTHER EU-FUNDED ACTIVITIES

12.1 Other GAPP work packages

12.2 Transpose project

13. EMA UPDATE (TBC)

14. WHO UPDATE

15. ANY OTHER BUSINESS

16. FINAL REMARKS

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.