



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Products: Quality, Safety, Innovation

Brussels, 24 May 2023
SANTE.D.2/MA

Joint Meeting of the Competent Authorities on: Blood and Blood Components Tissues and Cells Organs

24 May 2023, 09:00 - 13:00 (CET)

**BRUSSELS
Virtual event**

Minutes

PARTICIPATION

The meeting was attended by Competent Authorities from 26 Member States, Norway, Liechtenstein, Bosnia Herzegovina, and Turkey. The European Directorate for the Quality of Medicines (EDQM), the European Centre for Disease Prevention and Control (ECDC), the World Health Organization, the European Medicines Agency (EMA), the European Health and Digital Executive Agency (HaDEA), the European Health Emergency Preparedness and Response Authority (HERA), and DG RTD attended the meeting as observers.

1. Welcome, introductory remarks and adoption of the agenda

Participants of the meeting were welcomed by the DG SANTE, Head of Team SoHO (D2). Meeting attendees were informed on the agenda, including other AOB points, namely, a short presentation by on SightSoHO, and a presentation on the EC/EDQM/ECDC networks. Speakers were asked to respect their allocated time for presentation, to allow for discussion.

The draft agenda for this meeting was shared with the participants. Documents were uploaded in CIRCABC upon receipt from participants.

2. Regulatory matters: Points for information / discussion

Proposal for a SoHO regulation

DG SANTE, SoHO team provided an overview of the ongoing process and timeline for the upcoming adoption of the BTC legislation. It was highlighted that the legislation is currently being negotiated simultaneously in both the European Council and the European Parliament. The team shared the next steps in the political process with the participants, particularly focusing on the final text trialogues. These trialogues involve the European Council, the European Parliament, and the European Commission coming together to reach an agreement on the final version of the legislation.

Implementing EU SoHO legislation

DG SANTE, SoHO team gave a short introduction on the EU SoHO platform set-up, more specifically, ‘the Wheel’ and its specific components. An overview of the developing SoHO-X platform was also presented together with an overview of the early insights and concerns to address.

Proposed revision of the EU pharmaceutical legislation

DG SANTE, SoHO team informed participants of the Commission proposal for a new pharmaceutical legislation, for which discussions are going to be held in both the parliament and council. Overall objectives of the legislation, numbering six in total, revolve around enhancing access to improve the single market and considering budgetary and affordability aspects. Addressing the issue of antimicrobial resistance (AMR) will also be given significant, and most immediate attention. Additionally, some SoHO relevant requirements were mentioned.

3. Presentations on EU-funded activities

3.1 RTD funded activities on personalised medicine

Commission colleagues from RTD gave a presentation on the European partnership on Personalised Medicine. The EU's support for advancements in personalized medicine, including funding initiatives was discussed, the Commission's expectations regarding personalized medicine and the anticipated outcomes from their efforts in this field. A new approach to the European Partnership was presented, emphasizing its key features, policy objectives, rationale, and potential candidates. The strategic priorities and the potential impact on the field of personalized medicine was also discussed.

3.2 EU Funded activities

DG SANTE, SoHO team gave a wrap-up of the activities funded through EU4Health.

3.3 SightSoHO

The SightSoHO team presented the objectives of the service, regarding the training program, content and the upcoming events and deadlines.

4. Presentation from HERA

DG SANTE, SoHO team gave a brief introduction to set the scene. The overall framework for emergency preparedness was presented with a link to SoHO. A reference was made to the resilience of supply of critical SoHO.

After, HERA presented their department and the topic of HERA threat assessment and intelligence gathering. They will start developing an IT system (ATHINA) for data collection and functional analysis, which will support HERA activities.

5. WHO Update

The World Health Organization (WHO) presented an update on the activities on Blood and OTC Transplantation. The WHO action framework for blood products was explained together with the proposal to include PR Cryoprecipitate in the WHO Essential Medicine List. For the other sector, attention was given to the global action framework on tissue transplantation (GAFTT) as well as to WHO-ESOT joint project on organ transplantation.

6. ECDC Update

The ECDC demonstrated the currently and updated situation on communicable diseases in Europe. This was followed by a presentation on the SoHO network activities and the coordination committee. The idea of the expert panel together with the influence on the guideline development process was explained.

7. EMA Update

The EMA gave a presentation on the different active working parties. They briefed the NCA's on the March meeting of EMA/HMA on shortages of medicines. The meeting primarily centred around the importance of financial assistance from the EC to Member States and the coordinated strategies for enhancing plasma collection. Discussions also revolved around the necessity for harmonizing donor eligibility criteria, fostering closer

collaboration among stakeholders, and raising awareness about the significance of donating whole blood or plasma.

8. Council of Europe EDQM Update

The EDQM presented information about the intergovernmental structure, including committees and working groups in the SoHO field. An update was given on the technical guideline development and publications.

9. Any Other Business

EC ECDC EDQM networks

DG SANTE, SoHO team gave an overview of the future (legal) collaboration between EC, EDQM and ECDC.

The next planned meeting at the end of October will not take place. There will be a face-to-face meeting in Santander and extra virtual meetings can be planned if needed.

10. Final Remarks

DG SANTE thanked all participants attending the meeting.