



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 18 October 2023  
SANTE.D.2/MA

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

**18 October 2023, 09:00 - 13:00 (CET)**

**BRUSSELS**

**(Virtual event)**

**Minutes**

**PARTICIPATION**

The meeting was attended by Competent Authorities from 26 Member States, Norway, Bosnia Herzegovina, Serbia, and Turkey. The European Directorate for the Quality of Medicines (EDQM), the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and the European Health and Digital Executive Agency (HaDEA) 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 another AOB point, namely the SNE / END vacancy. The order of some presentations was modified. EMA and WHO presentations were cancelled. 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**

DG SANTE, SoHO team presented an overview of the ongoing process for the adoption of the SoHO proposal. It was stressed that the EP Plenary followed the ENVI Committee's favourable opinion during the September plenary session and that the Council Working Party conclusions are expected on 25 October 2023. The dialogues with EP and Council are expected to start early

November. Regarding the new pharmaceutical proposal, the participants were informed that it will follow a similar process.

Updates were provided on IES activities (general overview) and VES activities (results on SARE organ pilot), respectively. The latter led to some questions and answers, including an open question on whether the exercise is to be repeated.

DG SANTE gave a short overview on the EU SoHO Platform and updated on its ongoing development, repeating the call for national authorities to engage in the developments.

### **3. Presentations on EU-funded activities**

Following an introduction by DG SANTE, SoHO team on the SoHO activities agenda, speakers presented several EU-funded activities to support the implementation of the new SoHO Regulation. The Italian coordinators in CNS/CNT (ISS/IT) provided presentations on two ongoing projects on training staff authorities (SIGHT-SOHO) and SoHO preparation authorisation (GAPP-PRO). Furthermore, NTT Data presented the new ReaderSHip action on the coordination of new hospital SoHO activities by entities, aiming for recommendations and guidance documents for the management of these SoHO in hospitals.

DG SANTE, SoHO team also gave a brief overview on how these different actions will support the future SoHO regulation. Regarding Clinical Outcome Monitoring Plans for Conditional authorisation, SANTE gave an update on the EuMAR survey (IVF/ESHRE) and the EuroTraCTOR (HSC/EBMT) action. SANTE also mentioned the upcoming grant (submission deadline is October 2023) on the implementation of SoHO Regulation for new SoHO actors preparing FMT and breast milk.

Participants were informed about the objectives, accomplishments, and further steps of each EU-funded activity.

### **4. ECDC and Council of Europe Updates -**

ECDC provided an update on SoHO-relevant communicable diseases and a follow-up from the first meeting of the SoHO-Net TC&MAR group and from the first meeting of the expert panel for ECDC SoHO Guidelines.

### **5. Council of Europe Updates**

EDQM presented an extensive summary of the EDQM Final SARE report 2021 data.

## **6. Cooperation EDQM-ECDC in the new proposal**

Following the two above-mentioned updates, DG SANTE, SoHO team debriefed on the development and alignment of ECDC and EDQM guidelines in the future SoHO Regulation.

## **7. Any Other Business**

DG SANTE, SoHO team gave an update regarding changes to tissue establishments done in EU Coding not mirrored when selecting the same establishments in RAB/RATC from November until July and history of alerts not visible in new release, now both resolved. The Calendar for 2024 was also presented and will be sent to participants, together with a follow-up email. Finally, attendees were informed about a Seconded National Expert vacancy within the SoHO team.