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

Meeting of the Competent Authorities for Blood and Blood Components

11 November 2024 14.00-18.30 (CET)
12 November 2024 09.00-16.00 (CET)

BRUSSELS
(DG AGRI LOI 130 B)

Summary Minutes

PARTICIPATION

The meeting was attended by National Competent Authorities (NCAs) from 23 Member States, EEA countries (NO) and candidate countries (TR). Meeting was also attended by observers from the European Directorate for the Quality of Medicines (EDQM), the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Health and Digital Executive Agency (HaDEA), and the European Blood Alliance (EBA).

1. Welcome, introductory remarks and adoption of the agenda

The meeting was welcomed by DG SANTE's Head of D2 Unit and SoHO Team Leader. No conflicts of interest were declared. The agenda was presented with some adjustments made to accommodate the availability of speakers and was subsequently uploaded to the CIRCABC platform.

DG SANTE outlined the meeting objectives: to share an overview of planned actions supporting NCAs and professionals in implementing the new SoHO regulation (Regulation (EC) 1938/2024), gather feedback on concerns and ideas, and inform attendees of key next steps requiring their further action.

2. Supply of Blood and Plasma

2.1. Supply continuity under Chapter VIII SoHO Regulation and Critical SoHO / SoHO Entities survey

DG SANTE provided an overview to raise awareness and understanding on which new requirements are related to supply continuity expected to be implemented with the new SoHO regulation. DG SANTE informed the participants of the ongoing exercise to support the SoHO Coordination Board (SCB)'s work in fulfilling its obligations under Article 69 (1 (f)) of the SoHO Regulation for the definition of 'Critical SoHO' and 'Critical SoHO Entities'. A survey is running to collect Member States' views on what are considered critical SoHO.

2.2. Blood Supply

2.2.1. Blood supply needs for military services [NATO]

A NATO representative provided an overview of the needs and plans of the military services related to blood supply needs in crisis situation.

It was noted that military services require surge capacity and a reliable supply of blood units to meet *ad-hoc* transfusion needs during crises or conflicts. To address this, military services need to define their specific requirements, while civil services should assess their preparedness. Additionally, supply coordination and funding considerations must also be considered. Options to import from oversees and to have approval for preparing and using freeze-dried plasma were also discussed.

DG SANTE reminded that work on preparedness planning and supply continuity for blood will be included in the new contribution agreement with the Council of Europe.

2.2.2. Critical Entities Resilience (CER) Directive, [DG HOME] and EU act on cybersecurity (NIS-2), [DG CNECT]

The NCAs were briefed on the requirements of the CER and NIS-2 Regulations, with a focus on areas where implementation complements the new SoHO regulation (Chapter VIII).

European Commission representatives presented the two new EU frameworks, which aim to enhance physical resilience and cybersecurity of critical entities. They highlighted that these frameworks are horizontal in scope, extending beyond SoHO and health services.

Participants were informed that, following assessment and identification by Member States (using also the future SCB guidance), blood establishments processing/manufacturing (significant volumes of) blood components for transfusion can be considered 'Critical SoHO entities' and therefore possibly be subject to both CER and NIS-2 Regulations.

The provisions in these two frameworks are considered complementary to the supply requirements in the SoHO regulation, and therefore a comprehensive plan for implementation,

at once allowing to comply with the requirements in the three EU legal frameworks, would be beneficial. These frameworks will therefore be considered in the upcoming work of the Council of Europe.

2.2.3. European blood services [EBA]

The EBA represents the work of its member blood services (from 25 member countries, four candidate countries, and one observer country), which organise around 80% of the European supply of blood for transfusion. EBA typically organizes common work with its members in dedicated working groups, covering, among others, benchmarking, donor studies, emerging infectious diseases, innovation/new products, and EU legislation.
On blood supply, EBA presented the current activities, plans and challenges in view of preparing for blood supply continuity. The importance of developing a common approach to contingency and emergency planning for blood supply was emphasized.

2.2.4. EDQM activities on blood supply

EDQM presented its past work on Blood Supply Contingency and Emergency Plan (B-SCEP) and its plans for the upcoming work under the new Contribution Agreement with the European Commission. These projects aimed to develop practical tools for establishing or strengthening contingency plans in European countries.
EDQM representatives underlined the need for continuing close cooperation with the EU and its bodies, including the EMA, ECDC, and DG SANTE, in the field of SoHO.

The results of a survey report, including recommendations for stakeholders, and a model preparedness plan were presented. Future work will also consider the needs of military services, and of NIS-2 and CER requirements, as well as it will have to cover the requirements at EU level from the new SoHO regulation and address expectations from Member States to develop guidelines at common/EU level. Future work will be endorsed and validated by the future SCB.

2.3. Plasma Supply

2.3.1. SUPPLY Project – EU4Health [EBA]

EBA, as project coordinator of this EU4Health-funded action, presented the outcome of the SUPPLY project. The outcomes highlight the urgent need to build resilience across the entire chain, from (plasma) donor to PDMP recipient, for crisis situations, such as pandemics and trade wars. They emphasized the importance of increasing plasma collection within the Member States, as well as improving patient strategies for plasma derived medicinal products. The SUPPLY project recommended creating plasma collection plans, introducing legal provisions for controlling the allocation of collected plasma that is manufactured into

medicines (PDMP), and optimizing PDMP utilization, among others, by establishing national databases on plasma medicine usage at patient level.

2.3.2. Work SPOC working party [EMA]

EMA presented on the state of play of medicine shortages in Europe, highlighting the pillars of the European Union's strategy to improve availability of medicines: the authorization of the use of medicines - a key priority for the European Medicines Regulatory Network (MRN); the collaboration between regulatory authorities to prevent shortages and mitigate their impact; a joint task force on the availability of authorized medicines; and EMA's extended mandate regulation 2022/123 - which formalizes structures and processes to address medicine shortages and reinforces EMA's role in shortage management.
The Union's list of critical medicines has also been presented, which includes medicines considered most critical for health systems, and the criteria for inclusion, which are based on therapeutic indication and availability of alternatives. Several plasma-derived medicinal products (PDMP) are on this list.

2.3.3. EDQM Activities [EDQM]

EDQM presented its work on plasma supply management and plans for future work, including a stakeholder event in Strasbourg in March 2025, and the activities on plasma supply continuity and plans for upcoming work under the new contribution agreement. EDQM highlighted its work on data collection and data harmonization, the blood guide, and the importance of interoperability and standardization around quality management practices, and the need to address knowledge gaps and evidence gaps, particularly around high-frequency donation, and its effects on donor health.

3. Regulatory matters: Points for information

3.1. SOHO regulation – state of play [DG SANTE]
Participants were divided in breakout groups and invited to discuss articles of the new SoHO regulation, for which doubts have been previously raised by the stakeholders.
Findings and observations of the separate groups have further been shared and discussed in a plenary session. The outcomes of this discussion will be further presented to the future SCB.

3.2. Other EU legal frameworks – update [DG SANTE]

DG SANTE informed the participants of upcoming plans to evaluate the EU legal frameworks on medical devices and diagnostics, which consultation phase will provide opportunities to provide inputs, suggestions, and experiences from the SoHO sector.

DG SANTE informed the participants of ongoing discussions on the EU legal framework on pharmaceuticals. Participants can pass views to their national representatives in the Council Working Party.

4. Communicable diseases

4.1. State of Play [ECDC]
ECDC presented an overview of key activities currently underway in various SoHO field, including an update on communicable diseases (Marburg virus, Mpox, Dengue and West Nile Virus), on the guidelines, and on other ECDC activities, including meetings of the SoHO-Net group.

4.2. US changes in deferral criteria [ECDC]
ECDC presented on U.S. FDA changes to donor deferral criteria, discussing potential EU concerns and actions. The presentation discussed diverse topics that the EU may also need to address, including tattoos, piercings, and high-risk sexual behaviours, and how this revision may prompt EU national authorities to consider similar actions.

5. EU SoHO Platform – State of Play [DG SANTE]

DG SANTE provided a brief update on the development of the EU SoHO platform, highlighting the ongoing testing and consultation exercises for the module on SoHO Entities registration.

6. Blood guidelines and other relevant Blood topics (EDQM/ECDC)

6.1. Presentation [EDQM]
EDQM presented an overview of the new edition of the EDQM guide on the safety and quality of blood, and introduced a proposed working method to develop future guidelines coordinated with the Guidelines from ECDC, the inputs of the SCB, and the features of the future SoHO Platform.

6.2. Presentation [ECDC]
ECDC presented the status of their guideline development activities, highlighting their planning for guidance on additional communicable diseases to be assessed in preparation for the upcoming SoHO Net blood meeting in Stockholm in December.

7. Other topics

7.1. Activities on non-DEHP blood bags

The Istituto Superiore di Sanità-Centro Nazionale Sangue (ISS-CNS) provided an overview of the current actions and plans foreseen for the replacement and out-phasing of the common blood bags, with DEHP free devices. This represents a major change for the activities of the Blood Establishments, as it will impact on storage and quality of the blood components.

A working group, with FR, IT and SE competent authorities is working on how this major change can be timely implemented, validated, and assessed by the NCAs, in the future. Once new blood bags would be available, GAPP and GAPP PRO methodologies will be used to ensure a harmonized approach.

7.2. Support-E action

EBA, the project coordinator, presented the main conclusions of the Support-E action, which was supported by DG SANTE and implemented in collaboration with DG CNECT and DG RTD. This action resulted in the development of a dedicated data register, guidelines, and secured funding for data collection and study on the use of Covid Convalescent Plasma (CCP) in COVID-19 patients. The action, despite facing challenges related to data sharing and protection, provided valuable insights, particularly for highly immune-compromised patients. The study was concluded due to the decline in new COVID-19 cases; however, maintaining the developed CCP database is recommended as a readiness tool for potential future communicable disease outbreaks.

8. Final Remarks

The meeting concluded with a thank you to all participants for their valuable input and participation. DG SANTE provided a reminder of the upcoming tasks and events for NCAs and proceeded to publish the presentations and associated documents on the CIRCABC Platform.