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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

12 May 2022

13:30 – 17:30 (CET)

BY TELECONFERENCE

Minutes

PARTICIPATION

The meeting was attended by Competent Authorities from 22 Member States, Norway, Albania, Montenegro, North-Macedonia, and Turkey. The European Directorate for the Quality of Medicines (EDQM), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) attended the meeting as observers.

1. Welcome, introductory remarks and Adoption of the agenda of the meeting

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

Participants of the meeting were welcomed by the Head of Unit of DG SANTE, Unit B4. Meeting attendees were informed on the agenda, including the interactive session via Slido questions and another AOB point, namely, the short report from the organisers of the conference on "The supply of plasma derived medicinal products in the future of Europe". Speakers were asked to respect their allocated time for presentation, to allow for discussion.

2. Regulatory matters: Points for information

2.1 State of play of the BTC legislation revision

DG SANTE, SoHO team presented the key aspects of upcoming adoption of BTC legislation. The participants were made aware of the status of the legislation which is undergoing the administrative steps before its expected adoption in summer 2022. Participants were reminded of the next steps of the political process, with discussion initiation at the Council of the European Union and engagement with Ministers of Health, health attaché and possibly Member States` Members of the European Parliament.

2.2. Presentation of the pharma revision and plans

DG SANTE informed the participants on the relevance of the ongoing revision of pharmaceutical legislation to the blood sector. Previous this week CA's have received a paper concerning the industrial processing question raised in the revision. SANTE provided a general introduction into the pharmaceutical review and its timeline. The scope of the pharmaceutical legislation covers medicinal products, where blood plasma and blood cells are excluded.

2.3 Change in EMA guidelines for MSM donor deferral and plasma collection

EMA gave a short overview of its initiatives regarding the plasma supply during the COVID-19 pandemic. International travel restrictions, problems of supply and manufacturer inspections all presented major challenges that EMA investigated in order to ensure continuity of the plasma supply in the EU. Thus, a regulatory flexibility of GMP inspection was granted to the EEA and 3rd Country Blood Establishments. Mutual recognition agreement with FDA for PDMP/vaccine is in its implementation phase as well.

2.4. Joint MS validation of any newly available CE marked non-DEHP blood bag set(s)

The EBA updated the participants on the challenges for manufacturers and blood establishments with regards to upcoming ban of DEHP containing blood bags. Following the adoption of the amendment on appendix 14 of REACH, the DEHP blood bags may no longer be produced after May 2024 and no DEHP-containing products are allowed after May 2025. EBA express concern for manufacturing delays associated with the required certification of the DEHP-free blood products and foresee delays in the transition to non-DEHP products due to lack of such capacity of manufacturers. Then EBA gave an overview of the blood banks opinion on the matter, which are mainly concerned with the quality of blood and its components in absence of DEHP and discrepancies of the possible alternatives provided by manufacturers across the EU.

EBA provided a set of propositions to tackle these issues, including a prolongation of transition period and a guidance from the EBA on which components require evaluation or validation. It was also proposed to develop a common approach for the validation and evaluation processed across the EU. On this matter, EBA is finalizing a position paper on

the international coordination and adoption of joint validation procedures that is thought to help Member States to meet the deadlines. The EBA opened the discussion with a question with regards to the appropriate communication with the Member States and their blood establishments. The DG SANTE representatives expressed their agreement with the necessity to grant manufacturers the possibility to extend the period of DEHP blood usage and asked the EBA to provide the position paper to the SANTE as well as NCAs with opportunity to comment.

3. Projects

3.1. New SoHO Joint Action GAPP (2)

The SoHO team presented new Joint action following the already completed GAPP Joint Action bringing the focus to authorization of new Blood, Tissue, and Cells preparations. The project aims to test and refine the GAPP methodology of new developments in different BTC sectors and produce practical tools for the professional and authority use. Planned pilot cases will document the applicability in all Member States, different levels of risk, cross-country applications and assessments as well as address the links with other legal frameworks. The participants were encouraged to contact their health ministries that would appoint an appropriate organization and get involved in this new action.

3.2. EU4HEALTH project "EGALITE"

This project aims to address the imbalances of access to the SoHO, dependence on 3rd countries and the lack of harmonization of practices and mutual recognition among the EU Member States. The project is coordinated by "Banc de Sang I Teixits" and it partners with 15 beneficiaries from 10 Member States, 10 external organizations, professional medical societies in EU as well as EDQM. The project consists of 8 work packages addressing different issues including an accreditation programme, a BTC database and the development of contingency plans.

4. Vigilance

4.1. RAB alerts - General overview

DG SANTE gave an informative presentation on the trends of reported rapid alerts related to the SoHO. CAs were informed about new option on the reporting platform, where the alerts that do not require the follow up with CA's might be closed directly.

4.2. SARE web reporting

The new web-reporting was presented, possible through SANTE Data Collection Platform replacing PDF format reporting.

4.3. ECDC update on communicable diseases

ECDC started the presentation with the assessment of the situation regarding the arrival of people displaced from Ukraine to the EU/EEA, mentioning the vaccine coverage of communicable diseases including HIV and hepatitis B. Next, the issue of increased severe acute hepatitis of unknown aetiology in children in the UK was raised. ECDC stated that they will continue investigate and monitor the progression of the disease. Then ECDC have an informative overview of the new Ebola virus disease outbreak in the Democratic Republic of Congo as well as incidence rates of chikungunya virus disease, dengue and West Nile virus in the world, as of May 2022. The presentation was finalized with presentation of most recent available COVID-19 epidemiological data.

DG SANTE mentioned the recent Member State help to the Ukraine with provision of blood bags. Polish and German CA`s shared their experience with centralized help to the Ukrainian blood establishments.

4.4. Vigilance Expert Subgroup update

The update of the 2018-2020 area of work and their status in 2021 was presented. VES introduced new donor adverse reaction severity grading tool that is assessing the seriousness of the reaction. The experience with the tool has shown differences in the interpretation of the grades, thus the VES proposed NCA`s to participate in a new pilot. The core objective of which is to conduct voluntary evaluation of separate data on the Grade 3 and higher serious adverse reactions for one`s year`s data. The pilot is thought to bring more harmonization to the SARE reporting.

5. International Organisations

5.1. EDQM presentation on the Blood Supply Contingency and Emergency Plan (B-SCEP) project

EDQM introduced the activities that are being conducted with regards to the blood sector. Namely, the 21st Edition of the Blood Guide is being prepared and the deadline for the comments is the 3rd of June 2022. The guide is expected to be published in Q1 of 2023. EDQM reminded the NCAs of the Plasma Supply Management Symposium that includes relevant resources such as recommendations for the stakeholders on plasma collection, sustainable PDMPs availability and donor vigilance.

The B-SCEP project has concluded and produces 3 deliverables. The set of general as well as more specific recommendations were produced on the establishment, implementation, and maintenance of a B-SCEP. EDQM produced a Model Preparedness Plan which includes a B-SCEP template that aids in structuring the key elements of the blood systems and provides a risk assessment tool. The participants were invited to familiarize themselves with the deliverables available on the EDQM webpage.

5.2. ECDC presentation of the Network for the Microbial Safety of Substances of Human Origin (SoHONet)

ECDC familiarized the attendees with the on-going work regarding the ECDC`S document on COVID-19, specifically donor selection, that is expected to be available for the public later this year.

On the matter of the new ECDC SoHO expert network (SoHONet), in March 2022 ECDC made a call for Member States to nominate members of this network that are working in the field and dealing with the aspects of biovigilance, donor assessment, donor selection or quality assurance. ECDC stressed that the nomination should be conducted through national public health authorities. The work of the network is planned to begin already in summer of 2022.

5.3 EMA extended mandate on shortages

After the 2 February 2023, Regulation (EU) 2022/123, the EMA mandate is expected to be extended to reinforce its role in monitoring and mitigating shortages of critical medical devices in the context of a public health emergency. To ensure the mitigation, the EMA will establish a new steering group - Executive Steering Group on Shortages and Safety of Medicines. Its responsibilities include the provision of recommendations on measures to tackle the potential shortages and decide on the need for urgent and coordinated action regarding the quality, safety, and efficacy of medicinal products.

5.4 WHO update

Point postponed.

6. AOB

6.1 Joint Research Centre work (literature review) on blood donor behaviour

JRC presented planned research activities on the behaviours of the blood donors. The plan consists of 3 stages: the literature review, feasibility study for randomized controlled trail in two or three EU Member States and a RCT itself. The main objective of the study is to understand the behavioural factors that guide blood donors and how they can be targeted with policy interventions.

6.2. Update on convalescent COVID-19 plasma

DG SANTE, SoHO team gave a brief overview of the recently published research on the topic and an update of the EU CCP Platform. SoHO has closed the Emergency support instrument for funding of blood establishments that has resulted in increased convalescent plasma collection and capacities of NGOs` and public blood collection services.

6.3. Information on upcoming procurements under EU4Health

SoHO team presented upcoming procurements within the EU4Health. A call for tenders for organizing "Training and networking of Substances of Human Origin (SoHO) Competent Authorities 'staff for oversight" was published on 10th of May 2022. The training programmes are aimed at oversight tasks in particular, inspections, vigilance and BTC preparation processes assessment.

Then, management of SoHO in hospitals procurement was presented. The key objective of this procurement relies on extending the role of central hospital departments and facilitating exchanges between key associations of these departments and medical professionals' associations that support the supply and use SoHO therapies. Development of recommendations and guidance for hospitals on the organizational management of SoHO in hospitals as well as mapping of currently engaged EU hospitals are the mains tasks to be undertaken by this project.

Another action under EU4Health is dedicated to the development of an IT platform "SoHO-X" in support of the revised BTC legislation. The platform will cover aspects of safety and quality, oversight, innovation, and supply. The platform is aiming to make data usage efficient for all stakeholders using it.

6.4 Report on the conference "The supply of plasma derived medicinal products in the future of Europe"

Italian CAs provided a short overview on the event on the supply of PDMP that took place on 28 and 29 April 2022 in Rome. The issues of dependencies of European PDMP market on 3rd countries, demands and future perspectives and strategies for the future of Europe were discussed. The Italian colleagues expect that the revision of the BTC legislation, SUPPLY project and cooperation with European bodies will provide additional tools working for the strengthening the supply and obtaining more equity and safety across the EU.

7. Final Remarks

DG SANTE thanked all participants attending the meeting and specified that this would be the last virtual meeting with CAs.