EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Meeting of the Competent Authorities for Blood and Blood Components

25 April 2023 14.00-18.30 (CET)

Minutes

PARTICIPATION

The meeting was attended by Competent Authorities from 23 Member States, Norway, Montenegro, and Turkey. The European Directorate for the Quality of Medicines (EDQM), the European Centre for Disease Prevention and Control (ECDC), the European Health and Digital Executive Agency (HaDEA), the European Medicines Agency (EMA) and the European Blood Alliance (EBA), also attended as observers. The NTT Data staff (contractor for the analysis and governance of the EU SoHO platform, NTT Data is part of Nippon Telegraph and Telephone Corporation) only attended for the interactive session of the meeting.

1. WELCOME, INTRODUCTORY REMARKS AND ADOPTION OF THE AGENDA

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 DG SANTE, Head of Team SoHO (D2). Meeting attendees were informed on the agenda, including the interactive session on the mock-ups of the EU SoHO Platform and other AOB points, namely, a short presentation by EDQM on the newest version of the blood guide, a presentation regarding the overview of recent initiatives related to crisis-preparedness, and the classification of CCP nasal spray. Speakers were asked to respect their allocated time for presentation, to allow for discussion.

No participant reported any conflict of interest.

2. REGULATORY MATTERS: POINTS FOR INFORMATION

2.1. SoHO regulation

DG SANTE, SoHO team presented the current process and timeline of the upcoming adoption of BTC legislation. The legislation is negotiated parallel in the European Council and European Parliament and can therefore not be discussed in substance during this meeting. The next steps of the political process were shared with the participants, regarding the final text trialogues

where the 2 institutions come together with the European Commission and agree on a final version of the text.

2.2. Other Member State legislative updates

Turkey briefly mentioned the national developments in the blood service/set-up/legislation

3. SoHO-X – INTERACTIVE PART

3.1. EU SoHO Platform: state of play

DG SANTE, SoHO team gave a short introduction on the EU SoHO platform set-up, more specifically, 'the Wheel' which describes of the platform business requirements is done using in circular text boxes connected to the central one representing the EU SoHO platform and more information on working session that will start.

3.2. Registration of entities – workflow

DG SANTE, SoHO team presented the concept of entities as laid out in the proposal for the new SoHO Regulation It was explained that every SoHO entity must register, and their obligations depend on the type of activity they do. The registry must be kept up to date. The concept of 'critical entity' was explained in relation to emergency plans and reporting supply alerts.

3.3. Digital module for registration: INTERACTIVE SESSION

A short introduction was provided on the overall EU SoHO platform set-up and an introduction into the working session. During the interactive sessions, NCAs gave feedback on the test mock-ups of the module for registration of entities and possible further authorization, within the future EU SoHO platform. Collected feedback was provided to NTT the contract to consider when designing a first draft of the platform.

4. SUPPLY OF BLOOD AND PLASMA

4.1. Pharmaceutical initiatives - SPOC, working group HM**A**/EMA (EMA)

Klaus Kruttwig from EMA's Medicine Shortages Single Point of Contact (SPOC) office briefed the NCA's on the March meeting of EMA/Head of Medicine Agencies (HMA) on shortages of medicines. The meeting focused on the need for financial support from the EC to Member States and coordinated plans for increasing plasma collection. Other topics included the need for harmonization in donor eligibility criteria, closer collaboration between stakeholders, and increased awareness of donating whole blood or plasma.

4.2. SUPPLY project on Plasma Derived Medicinal Products (ISS/Sanquin)

EBA presented the work of the SUPPLY project (EU4Health) as project coordinator. The main project outcome is a set of recommendations and guidance for Blood establishments, competent authorities, medical societies, and other professional stakeholders to support them in being able to increase plasma collection in the EU by the public health sector and achieve optimal availability of plasma medicines for patients both in a general situation as well as in times of

crises. The project will allow to build a bridge between pharma and SoHO initiatives, to get a comprehensive picture from donation to use of manufactured medicinal product.

Further findings will be exchanged between SPOC/HMA and SUPPLY/SoHO work.

4.3. Behavioural determinants and interventions for blood donation (Joint Research Centre (JRC), European Commission)

Colleagues from JRC presented their draft report titled "Blood Donation in the EU: Exploring Behavioural Insights for Innovative Interventions".

The report consists of a literature review of behavioural insights for blood donation, and of the blood donation panorama of the EU Member States. The report provides insights on factors that drive blood donation, identify barriers to blood donation and explore best practices for increasing donation rates. The next step is the finalization of the report and its publication as a JRC Science for Policy Report. The next possible step is for JRC to conduct a field experiment in some Member States to test the effect of certain interventions on donation behaviour. SANTE will therefore bring JRC in touch with the EU-27 blood competent authorities.

5. SUPPLY OF BLOOD BAGS

5.1. Introduction (SANTE)

The SoHO team updated participants on recent legislative developments (MDR and REACH amendments to deadlines), affecting the authorisation of DEHP-free blood bags and mitigating the risk of blood bag supply interruptions.

5.2. Validation blood components prepared in DEHP-free blood bag set INTERACTIVE PART

Thomas Klei (Sanquin), on behalf of the European Blood Alliance, presented their proposals for the validation of the wide range of blood components that will be prepared with these new devices. Authorities expressed interest in working together to streamline the approval of these validations. A sub-group will come together in an ad-hoc working group to achieve this.

From the interactive part (discussion) - The participants agreed that an ad-hoc working group should be established to develop recommendations on the approval of non-DEHP blood bag sets, with the aim of streamlining and accelerating that process, as the devices become available. FR, IT, SE and CY indicated their interest to participate. Participants were invited to send any further nominations for this working group to the SANTE secretariat. SANTE.

6. AOB

6.1. Classification advice on nasal spray of COVID Convalescent Plasma (EMA/HMA)

The EU-Innovation Network Borderline and Classification Group (EU-IN BLCG) discussed the case of convalescent plasma (CCP) being used as prophylaxis against viral transmission when applied as a nasal spray. CCP is a therapy that uses plasma from people who have recovered from an infection and includes COVID-19 antibodies. The process involves selecting donors, processing the plasma, and filling up vials with a spray pump. The main point of discussion was whether CCP should be classified as a medicinal or blood product. The applicant is in contact with a Belgian agency, that circulated a survey to Member States to gain

more insight into the classification. Some pharma authorities had considered this in a survey to be a medicinal product, while others were open to classification under the new SoHO regulation. Participants of this blood NCA meeting underlined the extensive experience within blood NCA's in ensuring safety and quality, and in verifying efficacy, during the COVID crisis. They did not see any legal criteria to classify this as a medicinal product, nor any added value in terms of safety or quality. EU-IN will verify whether the survey from the Belgian pharma CA can be extended to collect responses from the blood NCAs.

The meeting/presentation allowed to promote discussion between CA regarding medicine across the EU, support harmonized product classification, and promote innovation. This open exchange with EU-IN BLCG was very much appreciated by participants.

6.2. New EDQM Guide on Safety and Quality of Blood

A presentation was made by EDQM on its drafting work on the guidelines.

6.3. ECDC – set-up SoHO-NET blood meeting

ECDC presented work on drafting guidance and recommendations.,

Participants had some questions on the coherence between EDQM and ECDC guidelines, and on how to ensure they have a say in the development of future guidelines (for ECDC, but also for EDQM). SANTE explained that with ECDC and EDQM it prepares for how the future collaboration would take shape, and that it will keep the NCAs posted on this. A dedicated communication on this is being prepared between SANTE, ECDC and EDQM and will soon be disseminated.

6.4. Meetings between SANTE and expert bodies

SANTE presented an overview of different regular exchanges with EU expert bodies. These include regular exchanges with EDQM and ECDC on the form of a possible future role of these two agencies in the SoHO regulation. Also, there are regular exchanges with these bodies and EMA regarding plasma-related topics and other SoHO-related topics.

6.5. Emergency supply and supply resilience

The SoHO team presented an introductory overview on 'Emergency supply and supply resilience' and create awareness on initiatives relevant for supply of critical SoHO. Several points were discussed, including the supply chain for critical SoHO, the Critical Entities Resilience (CER) Directive, the overall framework for emergency preparedness and SoHO, and the interlink between military and civilian preparedness for SoHOs. The Directive 2022/2557 or the Critical Entities Resilience Directive (CER) was also introduced, that entered into force at the beginning of this year. This directive concerns the health sector and specifically identifies entities manufacturing basic pharmaceutical products and pharmaceutical preparations.

In general Member States considered that the new SoHO regulation would be more effective and tailored to ensure this resilience in the SoHO sector (compared to the CER directive). The CER directive does indeed allow for sector-specific legislation to prevail, but this is to be explored/confirmed with HOME, as there is a possible time-gap between dates of entry into force. In the margin of the meeting, we explored possible roles for ECDC and EDQM in future

emergency planning. Further interest was reported from Member States (blood services) in stockpiling fresh frozen plasma for military and civil emergencies, following D2's report on recent discussions with the NATO Joint Health Group.

FINAL REMARKS

The next virtual meeting is planned on 24 May and will be a joint meeting of the competent authorities for blood, tissues & cells, and organs.

DG SANTE thanked all participants attending the meeting.