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

Extra-ordinary COVID-19 meeting of the Competent Authorities for Blood and Blood Components

1 April 2020, by teleconference

Summary Minutes

This extra-ordinary meeting of the Competent Authorities for blood and blood components (CAs) on COVID-19 took place on 1 April 2020. The previous CA meeting had taken place on 18-19 February 2020.

PARTICIPATION

CAs from 19 Member States (MS)[1] attended the meeting. In addition, CAs from Norway, Montenegro and the United Kingdom were present. Furthermore, the meeting was attended by representatives from the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

The representatives of the European Commission/DG SANTE unit B4 chaired the meeting.

1. WELCOME AND INTRODUCTORY REMARKS

The chair welcomed the participants, explaining that the aim of the meeting was to provide an update on developments related to COVID-19 at Commission level and to seek a coordinated approach to the collection and supply of COVID-19 convalescent plasma (CCP). The agenda of the meeting was adopted without changes.

2. UPDATE ON THE COVID-19 PANDEMIC

ECDC provided the participants with general information on the SARS-CoV-2 virus and the disease COVID-19, caused by the virus including an update on the current situation in Europe and worldwide. The WHO had classified the outbreak as a pandemic on 11 March 2020 and there had been a sharp increase in the number of COVID-19 cases and deaths over the previous weeks. The countries that were most affected at the time in the EU were Italy, Spain, France and Germany.

3. COMMISSION UPDATE ON DG SANTE ACTIVITIES TO DATE

[1] It wasn't possible to verify all participants so the number of MS attending may have been higher.

3.1 Commission activities in relation to SoHO and COVID-19

DG SANTE introduced its current activities in relation to Substances of Human Origin (SoHO) and the COVID-19 pandemic. The Commission had clarified that SoHO are included in the category of essential substances, for which free circulation in the EU is crucial. The requirement to circulate without border delays applies particularly to organs, bone marrow and cord blood for transplantation, to blood and plasma for transfusion, as well as to plasma for manufacturing of medicinal products. Guidance on border management measures had been published on the Commission website.

DG SANTE reported a strong collaboration with ECDC in the formulation of a report on SoHO and COVID-19, which includes a risk assessment and preparedness measures for the safe supply of different SoHO.

With regard to research, the Commission DG for Research and Innovation (DG RTD) had launched a dedicated call for research proposals on COVID-19 treatment options. This call was closed in February 2020 and the selected projects were due to start soon. One project (ATAC) will address plasma-based therapies, however, it will focus on plasma-derived medicines and not on transfusion. DG RTD had also launched an Innovative Medicines Initiative (IMI) call directed at public-private partnerships for the development of COVID-19 treatments, and was in the process of exploring other options to enable funding for research on CCP therapies.

3.2 Discussions with EBA, authorities and FDA on convalescent plasma for COVID-19

DG SANTE informed the participants regarding a series of discussions related to CPP with the European Blood Alliance (EBA), ECDC, the Food and Drug Administration of the US (FDA) and the EU blood authorities that are active in the GAPP joint action on authorisation of SoHO preparation processes. Overall, there was a clear interest in developing programmes that would facilitate the investigation of the safety and efficacy of CCP transfusions. Many EBA members were about to start or had already started collecting CCP and several clinical trials have been approved. In the US, the FDA had authorised CCP for compassionate use of without mandating the collection of outcome data. EBA and the authorities also reported a significant demand from clinicians to provide CCP immediately, outside of clinical trials, for patients that are not responding well. It had been agreed in all these discussions that the transfusion CCP in the EU should be associated with the collection of a minimum set of outcome data. In this regard, it was agreed that there should be a common approach to the authorisation of donor selection and CCP supply.

4. AUTHORISATION OF CONVALESCENT PLASMA SUPPLY IN THE EU – A COMMON APPROACH TO PLASMA COLLECTION AND TO SHARING OF COLLECTION AND OUTCOME DATA

The discussion was opened by ECDC, who provided background information on the potential for CCP treatment for COVID-19 patients. Convalescent plasma therapy is a passive antibody therapy that involves the transfusion of plasma from recovered patients to diseased patients. It is mainly expected to function through viral neutralisation, but also through antibody-dependent cellular cytotoxicity and/or phagocytosis. ECDC had reviewed the potential risks and benefits of this treatment for COVID-19 and had concluded that the potential benefits outweighed the known and theoretical risks, considered to be very low. In the absence of any other proven therapeutic or prophylactic therapies, it was appropriate to begin with the

emergency use of convalescent plasma as soon as possible and to gather information on patient outcomes.

4.1 Presentation of a draft document

DG SANTE presented a draft document that proposed a coordinated approach to the collection of CCP across the EU. It was noted that the aim was to establish common high-level protocols for donation and the collection of outcome data on a large scale to demonstrate the safety and effectiveness of the treatment. The proposed document specified the criteria for blood establishments (BEs) to receive the authorisation to collect and distribute convalescent plasma, criteria for donor selection, details on how convalescent plasma should be collected and processed, criteria on who should be treated with convalescent plasma, and the outcome data that should be collected. In order to facilitate the collection of outcome data, the Commission DG for Informatics (DG DIGIT) had offered to develop and host a database where EU level donation and outcome data could be aggregated. The proposal was that data should be inserted directly by BEs and that the database would ideally include data from extended/compassionate use, as well as from established clinical trials. The findings generated by this data collection exercise would be made publicly accessible in the interest of transparency and open science.

4.2 Discussion with Member States

Overall, the authorities welcomed the initiative proposed by DG SANTE. Eight national representatives indicated that there is an interest in establishing CCP supply in their countries. Three noted that their BEs were ready to start collection imminently. Authorities asked several questions on the specifics of the document, which were answered by DG SANTE and ECDC. Some concerns were raised regarding whether it should be possible to collect whole blood and separate CCP if the technology for apheresis is not available and whether it is necessary to obtain a separate authorisation for the collection of CCP. It was noted that authorisations would have to be desk-based, since on-site inspections were currently not possible.

4.3 Next steps

It was agreed that DG SANTE would amend the document on to collection of CCP across the EU, in the light of the comments made and would send a revised draft to the participants for further review after the meeting. It was further agreed that the draft document could be shared for comment with the medical directors in blood establishments. Following the comments from authorities and having revised the document accordingly, DG SANTE would publish it as a consensus document

5. OTHER COVID-19 RELATED ISSUES

DG SANTE mentioned that they are in discussion with the European Medicines Agency (EMA) regarding plasma master file certification issues, given that third country inspections of plasma collection centres in the United States were suspended due to the crisis.

6. FINAL REMARKS

DG SANTE thanked all the attendees for their active participation in the discussion.