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

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

3 June 2020, 14:00-18:00 Central European Time

BY TELECONFERENCE

Summary Minutes

This extra-ordinary meeting of the Competent Authorities for blood and blood components (CAs) on COVID-19 took place on 3 June 2020. The previous CA meeting had taken place on 1 April 2020.

PARTICIPATION

CAs from 27 Member States (MS) attended the meeting, as well as Norway, Iceland and Liechtenstein. The meeting was also attended by representatives from the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the World Health Organization (WHO), the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA). Representatives from the European Blood Alliance (EBA) also attended.

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

1 WELCOME, INTRODUCTORY REMARKS, ADOPTION OF THE PREVIOUS MINUTES AND OF THE AGENDA

Sylvain Giraud welcomed the participants and the authorities to the second extraordinary Covid-19 Meeting of the Blood competent authorities. The chair briefly updated the participants on the recent adoption of the EU4Health programme. This programme aims to increase capacity on preparedness crisis, as well, as to provide available and affordable medicines and medical devices. Overall, the main goal is to improve healthcare access by strengthening the health systems not only with greater investments but also with a bigger focus on health promotion and diseases prevention. This meeting mainly focused on the initiatives being now developed with COVID-19 convalescent plasma (CCP) and the evaluation of its safety and effectiveness. Besides, it is also essential to assess the

maintenance of an adequate supply of blood and blood components with increasing demands.

The agenda of the meeting was adopted without changes. The participants were invited to state any conflicts of interest. None were declared.

2 UPDATE ON THE COVID-19 PANDEMIC – ECDC

ECDC updated the participants about the current situation on SARS-CoV-2 virus in Europe and worldwide, showing the most recent distribution of COVID-19 cases and deaths. In response to the pandemic, ECDC has published several risk assessments about the viral safety of SoHo and risk mitigation measures concerning the sustainability and sufficiency of national blood supply. No reports of COVID-19 transmissions through SoHo have been reported so far, although the risk should not be excluded. During March and April, decreases in the collection and blood distribution were registered, which has led to donation loss in several EU Member states. With regards to seropositivity, all EU/EEA members have shown low levels which indicates that a possible population immunity would not achieve levels to ensure indirect protection for the next winter season. ECDC will give further updates concerning the countries that will be considered out of the sustained transmission phase.

3 COMMISSION UPDATE ON COVID-19 ACTIVITIES IN OTHER SOHO FIELDS – DG SANTÉ

DG SANTE introduced its current activities in other SoHo fields by sharing the outcomes of the tissues and cells competent authorities meeting and organs competent authorities meeting, both focused on Covid-19 related issues. Organ donations and transplantation have been considerably impacted by the pandemic as well as tissue and cell transplants. NCA have suggested issuing a Common EU-statement on Organ Donation and Transplantation and the COVID-19 Crisis, which aims to raise awareness also at a political level. DG SANTE agreed to coordinate the process and the consensus statements of the NCA will be published during this month.

4 IMPACT OF THE PANDEMIC ON BLOOD OVERSIGHT FUNCTIONS

4.0 Update on discussions with Member State competent authorities at the Tissues and Cells CA meeting 19 May (**DG Santé**)

DG SANTE debriefed the participants on the conclusions of the Tissues and Cells CA meeting focused on Covid-19 issues. The impact of the pandemic on inspection and authorization activities is still very visible. Inspections were suspended in some MS since mid-march, while in others they have been postponed or only resumed under emergency or essential circumstances. Possible regulatory flexibility and temporary changes to regulation have been considered, for instance through extending GMP certificates and suspending inspections. Mitigation measures have been also taken concerning the development of an inventory of SoHo sector, in line with the ECDC guidance. For the upcoming months, most MS are moving towards restarting inspections either remotely or even on-site.

4.1 General discussion on the implications for oversight in the blood sector.

Some national competent authorities shared the current state on their inspection activities. Several MS have had their on-site inspections suspended since the beginning of the pandemic, however, some activities are already starting in countries like AT, GB, EE, HR, and SI. Desk-based or remote inspections were the choice for some countries during the lockdown measures, for example in AT, BE, HR, and FI. EMA is currently developing a procedure for distant assessment inspections.

5 MAINTAINING THE SUPPLY OF BLOOD AND BLOOD COMPONENTS NOW AND GOING FORWARD

5.0 Plasma for fractionation – **EMA** and **DG Sante**

EMA presented the results of the PMFs holders' survey, where no shortages at this moment have been identified. Disruptions in the supply were reported, however, all PMFs have contingency plans to be put in place if the availability of plasma-derived medicines is not ensured. EMA recommended further regulatory flexibility in terms of inspections and revision of the donor eligibility criteria. A follow-up survey will be made to evaluate if the measures applied to facilitate plasma collection are having a positive impact on plasma supply.

EMA, EC, and NCA agreed to put in place a series of measures to mitigate the impact of disruptions caused by COVID-19. With respect to regulatory flexibility on GMP inspections, the supervisory authorities will issue SONIs depending on if EEA or third country sites have been previously inspected or not. If not, the supervisory authorities can make an off-site distant assessment or on-site inspection depending on the inspections performed on the parent company of the manufactures. EMA remarked that when the period of the public health crisis has passed, pre-approval or routine inspections of plasma centres can resume their normal activity instead of desk-based inspections. EMA also expressed that new clinical trials with immunoglobulins are starting and therefore there is a need to ensure a sufficient amount of plasma.

DG SANTE informed the participants about the latest discussions with the International Plasma and Fractionation Association (IPFA) and the Plasma Protein Therapeutics Association (PPTA). PPTA showed concerns about the 30% decrease in plasma collection in their affiliated centers, both in EU MS and in the USA. National requirements imposed by some countries of the need to have a medical doctor present during the donation has brought some complications since now most of the doctors are involved in the pandemic response. They pointed out that all this is likely to lead to shortages of plasma-derived medicinal products in 6 months, from autumn 2020 and onwards.

5.1 Blood components for transfusion – **EBA**

EBA provided an overview of the blood supply situation since the start of this pandemic. Although in Mid-march, there was a decrease in blood donation, at the end of May the demand was close to the forecast demand, after all the blood establishments and national health authorities put measures in place to ensure the continuity of blood supply. These measures aimed to ensure the availability, quality, and safety of blood products and were applied to the donation centres, donors, and staff. However, the demand can increase as

soon as the surgeries fully restart again. Concerning the Covid-19 convalescent plasma, measures were also put in place to collect more plasma. EBA is now supporting an open database developed by the European Commission on CCP.

DG SANTE shared the concerns by patient groups who chronically depend on regular transfusions and plasma-derived medicinal products and how they are asking for public calls for donation of blood and plasma.

5.2 Increasing plasma supply – a strategy for achieving EU sufficiency (**EDQM**)

Europe is highly dependent on the USA on plasma-derived medicinal products. Following this, there is a need to increase plasma availability for fractionation in Europe in order to move to more strategic independence from the USA.

The Plasma Supply Symposium organised by EDQM in January 2019 has issued several recommendations about the plasma supply management. In regards to MS and National Competent Authorities, it was recommended to enforce donor vigilance, monitoring of the use of plasma-derived medicinal products, and the development of contingency plans. CA should increase awareness within the donor community regarding plasma donation as they are many whole blood donors who are not aware of plasma needs. Nevertheless, adequate funding should also be provided to blood establishments not only for blood collection but for plasma as well.

5.3 Blood Supply Contingency and Emergency Plan **(B-SCEP) (EDQM)**

EDQM presented a new project co-funded by the EC and CoE. The Blood Supply Contingency and Emergency Plan (B-SCEP Project) aims to ensure the continuity of blood components supply. This group will give recommendations on how to find a common framework and harmonization in addressing different risk scenarios, always aligned with the EU legislation and CoE's standards.

6 COVID-19 CONVALESCENT PLASMA

6.0 Update of CCP guidance document (**DG Santé**)

DG SANTE presented the updated version of the CCP guidance document, with the proposed changes from BEs, CAs, and ECDC. In this proposal, the CA specifically requested the need to mention emergency/compassionate use when it applies. For the authorization aspects, ECDC requested that the authorizations should specify the intended use, whether it is for transfusion or fractionation. Concerning the donor eligibility criteria, some changes were made to be in alignment with the ECDC revised guidance for blood donation. EE showed concerns regarding the fact that ECDC allows donors to donate 28 days after recovery without the requirement of re-testing. In their Covid-19 CPP clinical trials, they reported having found positive tests after the time frame assigned to full recovery. For the testing of donated CCP, the neutralizing antibody titers were changed, and CE marked or in-house tests that have been approved at the national level should be used. CAs were encouraged to send further ideas and suggestions to the Commission as a follow-up to the meeting.

6.1 Progress on the EU CCP database project (**DG Santé**)

DG SANTE shared the progress made on the EU CCP database project. This project aims to consolidate EU evidence on the safety and effectiveness of this therapy. The structures of the EU CPP platform were explained as well as data processing principals under the GDPR. The findings generated by these data should be used in the form of an open-access database to have aggregated data available for research.

DG DIGIT presented a user interface platform of the database to the participants, with some data from the information already submitted.

6.2 Overview of results globally from CCP transfusion

Italy as the first country to start CCP collection and transfusion in the EU provided the participants with an overview of the results obtained so far. There are still uncertainties about the CCP effectiveness and safety of convalescent plasma therapy for Covid-19 patients. Nevertheless, it was reported that in the first patients treated with CCP no signs of toxicity or adverse reactions have been notified. Some concerns were noted on how the titres are measured because there is no scientific evidence of a defined titre at the moment. Low titre CCP around 1:80 seems to have good efficacy. The operational protocols for the donation of COVID-19 CCP in Italy were shared, as well as donor eligibility criteria.

DG SANTE expressed that there is a significant volume of units collected on CCP, although the transfusion volumes are still quite limited in the majority of countries. This reconfirms the value of cooperating between the Member States and bringing the data together.

6.3 Proposal of EU support through Horizon 2020 to a research project on CCP (**DG SANTE and EBA**).

EBA presented the Support-E Project, a project proposal on CPP supported by EU Horizon 2020 programme. This project aims to seek a coordinated approach across the EU Member States, where the EU can provide guidance for assessing the value of Covid-19 CCP. The objective is also to support the high quality clinical evaluation of CCP and to reach a consensus on its efficacy across EU MS. It is expected that the blood establishments that are currently involved with CCP supply for monitored use or clinical trials share their data in the database. Furthermore, recommendations from this project will be given on how to promote best practices about the current and possible subsequent crisis.

7 WORLD BLOOD DONOR DAY DURING THE PANDEMIC – 14 JUNE

7.0 Global message **(WHO)**

WHO presented the World Blood Donor Day (WBDD), an annual global event to raise awareness about the need for regular blood donations. With the pandemic outbreak of the coronavirus disease, the donation rate is low to meet the demands for blood transfusion. WHO calls upon international organizations and national competent authorities to collaborate in promoting and supporting the WWBD.

7.1 EU support (**DG Santé**)

DG SANTE thanked the WHO representative for his presentation and shared the EU support on the WWBD. This year the commissioner's message will highlight the importance of blood donations, especially during the COVID-19 pandemic crisis. The commissioner will also raise awareness about the need for plasma donations as there is a risk of a shortage of plasma derivatives.

8 ANY OTHER BUSINESS

No additional points were raised.

9 FINAL REMARKS

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