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B4 – Medical products: quality, safety, innovation

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

### **Covid-19 meeting of the Competent Authorities for Tissues and Cells 19 May 2020**

**BY TELECONFERENCE**

#### **Summary Minutes**

The meeting of the tissues and cells national competent authorities (NCAs) took place on 19 May 2020. The previous meeting had taken place on 22 and 23 October 2019.

Competent authorities from all EU-27 Member States (MS) participated in the meeting. All candidate and applicant countries, except Albania and Montenegro, attended the meeting. In addition, the representatives of the European Centre for Disease Prevention and Control (ECDC), the World Health Organisation (WHO), the Council of Europe (EDQM) were present as observers and the Consumer, Health and Food Executive Agency (CHAFEA) was also represented. Representatives of stakeholder associations (EBMT, WMDA, EEBA) attended for specific agenda topics, as detailed below.

The representatives of the European Commission/DG SANTE unit B4 chaired the meeting. The meeting was organised by teleconference due to Covid-19 travel limitations in place.

The meeting focused on Covid-19 issues relevant for the tissues and cells field in particular, the impact of COVID-19 on donation programmes, testing protocols, inspection and authorisation issues.

#### **1. WELCOME**

The chair welcomed the participants and noted that due to Covid-19 pandemic the initially planned meeting of 9-10 June 2020 was replaced with this virtual one.

Introducing the meeting, the chair acknowledged that due to COVID-19 pandemic there are great challenges faced by the Tissues and Cells competent authorities but also by professionals and stakeholders active in the field. Given the circumstances and the urgency to address issues accumulating in the tissues and cells field, DG SANTE considered it important to convene this meeting to facilitate an exchange between the Tissues and Cells competent authorities, the observers and the representatives from stakeholder associations.

The SoHO team member informed the meeting of the usual house rules.

#### **2. ADOPTION OF THE AGENDA**

The participants adopted the agenda without major modification.

The Summary Minutes of the previous meeting had been approved by email and published on the DG SANTE website.

DG SANTE invited the participants to declare any conflicts of interest. None were declared.

### **3. ECDC COVID-19 UPDATE**

ECDC updated the participants on the current situation regarding the SARS-CoV-2 pandemic in the EU and worldwide, showing the most recent distribution of COVID-19 cases and deaths. In response to the pandemic, ECDC has published several risk assessments on the topic and two specific documents on the safety of SoHo and the risk mitigation measures recommended. No reports of COVID-19 transmissions through SoHo have been reported so far, although the risk should not be excluded.

According to ECDC, EU/EEA countries should continue precautionary actions to mitigate the potential risks to the viral safety of SoHO and to manage the sufficiency of the national SoHO supply. Measures should be proportionate to the evolution of the pandemic and consistent with governmental and public health advice. Furthermore, as some countries are introducing gradual easing of measures to contain the spread of the virus, it is crucial that SoHO establishments remain vigilant and maintain precautionary measures.

ECDC has already provided guidance for transplant and transfusion services on how to ensure sustained and safe supply of different SoHO. NCAs have welcomed their support.

### **4. SUMMARY OF COMMISSION ACTIVITIES ON COVID-19**

DG SANTE introduced its current activities in other SoHO fields, focusing on recent initiatives related to the COVID-19 pandemic in the blood and organs fields, namely the development of a Covid-19 convalescent plasma guidance and data base as well as a planned common statement proposed by the Organs NCAs on Organ donation and transplantation during the pandemic.

#### *Convalescent plasma guidance and data base*

The blood NCAs agreed on common guidance to authorize and monitor collection and utilisation of Covid-19 convalescent plasma. DG SANTE involved professionals to facilitate building of a database to register collection and transfusion data. The authorisation process build on the joint action GAPP which involves national competent authorities for blood and tissues and cells.

#### *NCA common statement for organ donation and transplantation*

Organ donations and transplantation have been considerably impacted by the pandemic as well as tissue and cell transplants. The organ NCA proposed issuing a Common EU-statement on Organ Donation and Transplantation and the COVID-19 Crisis, which aims to raise awareness and identify actions needed, at the policy making level. DG SANTE agreed to coordinate the process and the consensus statement and to publish it in due course.

### **5. IMPACT OF THE PANDEMIC ON T&C OVERSIGHT FUNCTIONS**

#### **5.1.Update on discussions with Member State competent authorities (DG Sante)**

DG SANTE briefly introduced the discussion on the impact of the pandemic on inspection and authorisation activities. The participants reiterated that the impact is significant. In particular, inspections were suspended in some MS in mid-March 2020, while in others they were postponed or conducted only in emergency or essential circumstances. For the upcoming months, most MS are moving towards restarting inspections either remotely and some on-site.

## **5.2. Inspections and authorisations – NCA experiences**

The representatives of the tissues and cells NCA from Italy, the Netherlands, Ireland and Denmark presented activities related to oversight functions at the national level emphasising the current situation in their countries and focusing on the impact on inspection / authorisation activities.

It was noted that the Covid-19 pandemic had a severe impact on inspection scheduling, a number of inspections were suspended or changed to remote methods. It was discussed whether on-site inspection could be effectively replaced by remote inspections. Desk-based inspections combined with various approaches to interaction with TE personnel were described, including teleconferencing and secure file sharing.

It was suggested that the inspection expert subgroup (IES) established under the CASoHO Expert Group might look into these issues and possibly develop recommendations on how to ensure oversight during a pandemic.

## **6. SURVEILLANCE AND VIGILANCE**

### **6.1.SARE DATA 2019 exercise**

DG SANTE reported that having received comments and corrections from the NCA on the data from the 2019 SARE exercise, EDQM will prepare a draft report. The authorities will be invited to comment before the report is published. For the 2020 SARE exercise, the launch will be delayed to June for tissues and cells. The blood SARE exercise will be launched in May, as scheduled.

### **6.2.Other issues from MS?**

No issues were raised.

## **7. FEEDBACK FROM THE EDQM COVID-19 WEBINAR**

EDQM summarised the topics discussed during a webinar on Tissue donation from deceased donors during the Covid-19 pandemic. The webinar, held on 28 April 2020, focused on sharing experiences between tissue establishments in different countries and discussing the risk of transmission through tissues from deceased donors as well as testing practices. The representative highlighted challenges to tissue establishments during the pandemic: all tissue establishments experienced a reduction of deceased donation activity since March 2020. It was further elaborated that transmission of respiratory viruses by transplantation of human tissues has not yet been described and that currently there is no evidence that SARS-CoV-2 can be transmitted through the transplantation of tissues. According to some participants in the webinar, the financial impact of the pandemic may result in difficulties for the long term sustainability of activities in tissue establishments.

## **8. T&C SUPPLY ISSUES**

Tissue and cell donation and transplantation have been significantly impacted by the Covid-19 pandemic, in particular hematopoietic stem cells (HPC) and corneas. Insights were provided by invited experts from the professional associations EBMT, WMDA and EEBA.

The representatives summarised their specific concerns for HSC and for ocular transplants (corneas) in the context of Covid-19 pandemic. The experts focused their presentation on the impact of the pandemic on HPC donation and transplantation in the EU and on how the impact can be mitigated moving forward. Actions that could be taken at the EU level to support the field were described. The participants had an interesting exchange on risk and possible mitigation strategies.

## **9. ANY OTHER BUSINESS**

WHO announced that a COVID-19 specific webinar on blood supplies with experts from around the world had been organised by WHO for May 27, 2020. Those interested were invited to join the webinar.

DG SANTE thanked all the attendees for their active participation during the meeting and reminded participants that all presentations and associated documents would remain accessible in the CIRCABC platform.