



**EUROPEAN COMMISSION**

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation

B4 – Medical products: quality, safety, innovation

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

### **COVID-19 meeting of the Organs Competent Authorities**

**30 April 2020**

**BY TELECONFERENCE**

### **Summary minutes**

This meeting of the Competent Authorities on Organ donation and transplantation took place on 30 April 2020. The previous meeting had taken place in September 2019.

Organs National Competent Authorities (NCA) from all EU Member States attended the meeting except for Slovenia. In addition, representatives of the NCA from Norway, the Republic of North Macedonia, Iceland and the United Kingdom were present. Representatives from the European Centre for Disease Control and Prevention (ECDC), the Council of Europe (EDQM), the World Health Organisation (WHO), Eurotransplant, Scandiatransplant and the European Society for Organ Transplantation (ESOT) also attended the meeting.

The meeting was organised and chaired by the representatives of the European Commission/DG SANTE unit B4 (Medical products: quality, safety, innovation).

#### **1. WELCOME, INTRODUCTORY REMARKS AND ADOPTION OF THE AGENDA**

The chair welcomed the participants. Introducing the meeting, the chair mentioned that due to the COVID-19 pandemic there are great challenges faced by the NCA, but also by professionals and stakeholders active in the field. Given the circumstances and the urgency to address issues accumulating in the organs field, DG SANTE considered it important to convene this meeting to facilitate an exchange between the Organs NCA on COVID-19 related issues, as well as to discuss possible initiatives to mitigate the impact of COVID-19 on the organs field.

The participants were asked to state any conflicts of interest. No conflicts of interest were declared. The agenda of the meeting was adopted without changes.

DG SANTE provided a short introduction to the impact of COVID-19 on the organs field, as well as to their recent activities related to COVID-19 in the field of Substances of Human Origin (SoHO). These activities included DG SANTE involvement in facilitating transport of SoHO within the EU through “green lanes”, a data collection exercise and guidance on treating COVID-19 patients with convalescent plasma, and a collaboration with ECDC in the formulation of guidance for the SoHO sector during the COVID-19 pandemic.

## **2. OVERVIEW OF THE COVID-19 PANDEMIC (ECDC)**

ECDC provided the participants with an overview of the risks posed to the SoHO field by the COVID-19 pandemic. Although there were no reported cases of transmission, ECDC suggested some precautionary measures on SoHO and COVID-19, which are specified in detail in the published guidance. In addition, it was noted that infection with COVID-19 through the primary route represents a high risk to immunosuppressed transplant patients. DG SANTE and the participants thanked ECDC for their dedicated work on this guidance.

## **3. IMPACT OF COVID-19 ON ORGAN DONATION AND TRANSPLANTATION**

Spain, Germany, Italy, France, Greece and the UK were invited to give short overview on the impact of the COVID-19 pandemic on organ donation and transplantation in their countries.

Overall, donation and transplantation activity significantly decreased across the EU during the pandemic and most living donation programmes had been suspended. NCA had implemented testing protocols for SARS-CoV-2 and advised prioritisation of urgent transplants of critically ill patients. Challenges that were mentioned by the NCA related to the movement of organs due to border control regimes and a decrease in the number of flights, as well as to the availability of medical staff and equipment. The participants emphasised the importance of uniform EU-wide data collection. They also highlighted the possible opportunities arising from the pandemic, such as a necessity to increase ICU capacities, remodel, and digitise procedures that will be useful in the long-term.

- Spain is one of the countries that is strongly affected by the pandemic. Donation and transplantation activity in Spain had been reduced from 7.2 to 1.2 donations per day and from 16 to 2.1 transplantations per day.
- In Germany, donation and transplantation activity was also significantly impacted, particularly by discontinuing most living donation programmes. Deceased donation programmes were continued with a careful selection of donors and recipients. Challenges with regard to the movement of transplant teams due to a decrease in the number of flights and closed borders were described.
- In Italy, the impact of the pandemic was particularly evident in the north of the Country. From February 28<sup>th</sup> to April 10<sup>th</sup>, the overall transplantation activity from deceased donors decreased by about 40%. The National Transplant Center (CNT) recommended SARS CoV 2 BAL testing for all deceased donors. Health Ministry classified donation and transplant activities as essential healthcare activities even during the pandemic. Most living transplantation programs were suspended, and the transplant centres with the highest activity in the country restarted their living donation programmes only in April. Recommendations to perform nasopharyngeal swab for COVID detection on all transplant recipients and living donors were set. Some national organ allocation programmes were also suspended, in order to limit transplant team transfers among regions. CNT issued some recommendations for COVID phase 2: keep the attention high on brain damaged patients; avoid down staging of hospital coordinating units; ensure healthcare therapy to waitlisted patients through devoted COVID free pathways; monitor the number of COVID-free beds, to assess procurement potential; define protocols for a homogenous approach for communication with donor families. Eventually, CNT also set up a surveillance program to monitor the number of COVID-positive transplanted or waitlisted patients, and measure their outcome.
- France reported that their transplantation activity had been reduced to 20-25% of the normal activity. Living donations were suspended and patients in urgent need of a transplant were prioritised. France presented a SARS-CoV-2 testing protocol for

living and deceased donors, but described challenges in the implementation of this protocol due to a low availability of tests. Other challenges were related to the availability of medical staff, whereas ICU capacities had so far been sufficient.

- Greece was comparably less affected by the COVID-19 pandemic. However, the country had implemented precautionary measures. Living donations had been postponed and transplantation activity was reduced by 85%. Redesign and reinforcement of the ICU system, which can be beneficial for transplant patients in the future, was being considered. Furthermore, there an opportunity to remodel and digitise procedures was highlighted.
- The UK had suspended elective surgery in many regions. The maximum age of deceased donors was reduced, donor testing for SARS-CoV-2 was implemented, and donors were selected on a case-by-case basis. The numbers of donations and transplantations had decreased significantly and particularly pancreas and renal transplants were suspended in most cases. Liver and heart units stayed open for urgent transplants.

DG SANTE thanked all the NCA who had shared their experiences with the participants.

#### **4. GOING BACK TO NORMALITY: PLANS OF NATIONAL COMPETENT AUTHORITIES, PROFESSIONALS (ONT)**

The Spanish National Organisation on Transplantation (ONT) gave a presentation on how donation and transplantation programmes could be reactivated in the context of the pandemic. ONT highlighted the need for an effective communication strategy with the general population, patients, donors and health professionals. Donation programmes should be reactivated gradually, and urgent and critically ill patients should be prioritised. The gradual reactivation was suggested to take place in COVID-19 free pathways and be accompanied by an improved ICU management and use of digital technology such as telemedicine. Moreover, ONT emphasised the importance of SARS-CoV-2 testing protocols and promoted a more local recovery of organs. ONT also highlighted a need for research and for support of national registries, audits and biovigilance in the field of donation and transplantation. The importance of a safe working environment, accurate training, and increased recognition for health professionals was emphasised.

The participants were provided with a short update on the EDITH project, which aims to set up EU-wide registries for the follow-up of kidney transplant recipients and living kidney donors. Collection of the EU-wide data is essential to highlight the benefits and cost-effectiveness of organ transplants. The participants were informed that the European Society of Organ Transplantation (ESOT) was the only candidate to ensure the sustainability of the EDITH project by hosting two kidney transplant registries that were developed in the project. ESOT and the EDITH project leader will continue internal discussions and present the follow up in the next Organ NCA meeting (date tbc).

#### **5. PREPAREDNESS PLANNING: BUILDING ORGANISATIONAL FLEXIBILITY TO SCALE TRANSPLANT PROGRAMMES (ESOT)**

ESOT gave a presentation on how to build the organisational flexibility necessary for the reactivation of transplant programmes. They highlighted the need to rethink how transplant programmes are organised. The importance of research, registries, transparency, telemedicine and collaboration was highlighted.

NCA representatives had an extensive discussion on possible measures that could be taken to support the re-initiation of activities in the organs field in the future. They suggested issuing a Common statement on Organ Donation and Transplantation and the COVID-19 Crisis, which would aim to raise awareness, highlight the importance of the organs sectors and the actions

necessary to remedy the situation. The participants requested that DG SANTE coordinate. DG SANTE agreed to coordinate the process and consult the full group for inputs on the draft statement prepared by a small drafting group before adoption of the statement by the full group.

NCA's enquired whether an IT platform could be provided that would allow them to share knowledge and experiences with each other. It was also noted that there is a need to become less dependent on third countries for the supply of equipment and medicines in the long-term.

DG SANTE thanked ESOT for their presentation and the NCA's for the discussion and agreed to start the preparation of the draft statement.

## **6. OTHER COVID-19-RELATED ISSUES THAT NCA'S AND OBSERVERS WISHED TO RAISE**

The participants received a short update on the situation in the Scandi transplant countries. The number of donors has decreased in all of these countries except Denmark. Most transplant programmes were still running, but there were some challenges in the exchange of organs across borders. Eurotransplant also reported that donations had decreased from ca. 6.5 donors to four donors per day among its member countries.

WHO invited the participants to take a look at their guidance on COVID-19 related matters available online<sup>1</sup>. WHO had not produced any specific guidance on organ donation or transplantation, but noted that guidance from other organisations on this topic are published on the website of the [Notify Library](#).

## **7. FINAL REMARKS**

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

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<sup>1</sup> <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance>