



# 3 – SANTE activities on COVID-19

Health & Food Safety  
Directorate General

Ad-hoc COVID-19 blood CA meeting  
Webinar, 1 April 2020



## Cross-Border transport of SoHO

COM clarified that Substances of Human Origin (SoHO) are considered to be essential goods/services for which free circulation within the EU is crucial.

In particular for transport of following SoHO it is essential to facilitate border passage.

- Organs for transplantation
- Bone marrow or cord blood for transplantation
- Blood for transfusion
- Plasma for transfusion
- Plasma for manufacturing medicinal products

COM Guidelines for border management measures to protect health and ensure availability of goods and essential services (16/3 2020)  
(Annex 3) Template of Certificate for International Transport Workers (possible use for courriers)



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels  
SANTE.DDG1.B.4/

**NOTE FOR THE ATTENTION OF NATIONAL COMPETENT AUTHORITIES**

**Subject: COVID-19 and Substances of Human Origin**  
**Cross-Border shipments of SoHO as essential goods and services**

The European Commission has clarified that Substances of Human Origin (SoHO) are considered to be essential goods/services for which **free circulation within the EU** is crucial<sup>1</sup>.

In particular shipments of following SoHO are critical or essential<sup>2</sup>:

- Organs for transplantation
- Bone marrow or cord blood for transplantation (haematopoetic stem cells)
- Blood for transfusion
- Plasma for transfusion
- Plasma for manufacturing medicinal products

The template attached to the communication might be useful for drivers of vans/cars who do not have a certificate of professional competence (or at least a certificate recognised at EU level).

Internal borders:

- Essential good/service
- Template for drivers/courriers

External borders:

- Simplified custom declaration
- « human organs and other human or animal tissue or human blood suitable for permanent grafting, implantation or transfusion, in case of emergency and in order to ensure their timely delivery and use”

Ad-hoc contact points  
HSC and organs



## Other points

**ECDC report on SoHO and COVID-19** - risk assessment and preparedness measures for a safe supply of different SoHO (for NCA's, BE/TEs, transplant centers) (see Agenda)

**Convalescent plasma** – guidelines on collection and use for BEs, authorisation approach, need for data collection (see Agenda)

**Blood supply levels** – good/high levels reported (EBA)


**Rapid Alert Systems:** possible use for shortages (not epidemiological)

**Plasma collection levels** (for PDMP) – reported reductions DE, AT, HU, CR (PPTA organisational/staff concerns and donor mobility) - U.S. unclear

**Inspections** BE/TEs - on hold – need for risk-based rescheduling?



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## Blood, tissues, cells and organs

🏠 All topics

Overview

Blood

Tissues and cells

Organs

Projects

### Overview

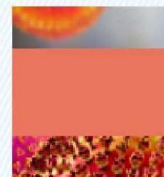
#### Latest developments in the framework of COVID-19 outbreak in the EU

- The European Commission has clarified that Substances of Human Origin (SoHO) are considered to be essential goods/services 📄 for which **free circulation within the EU** is crucial
- The ECDC has published a guidance document on COVID-19 and SoHO 📄

Blood, tissues, cells and organs are used in a variety of medical therapies. Treatments based on these substances of human origin (SoHO) save lives (e.g. blood transfusion in case of trauma), improve the quality of life (e.g. kidney transplants), and even help create life (gametes and in vitro fertilisation).

Despite their benefits, the use of SoHO presents risks, in particular the transmission of diseases. The European Commission helps address these risks through its mandate to set *high standards of quality and safety* of SoHO, in accordance with Art. 168(4)(a) of the

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Why is this



## Research funding and COVID-19

Managed by DG RTD (regular contacts with SANTE)

Dedicated COVID-19 call (Feb 2020)

- Projects selected, starting soon
- 1 project ATAC on plasma-based COVID therapies
  - SE/Karolinska, Takeda
  - Plasma derived Ig, no transfusion

Innovative Medicines Initiative (closes 7/4)

- Public/private set-up required
- Takeda, as main Plasma company, will not participate

Possible new call – being explored for plasma transfusion



**Info / Contact**

**[https://ec.europa.eu/health/blood\\_tissues\\_organ/overview\\_en](https://ec.europa.eu/health/blood_tissues_organ/overview_en)**

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**European Commission  
DG Health and Food Safety  
Unit B4 - SoHO team**