



**MINISTRY OF HEALTH OF ROMANIA
GENERAL DIRECTORATE FOR MEDICAL ASSISTANCE AND PUBLIC
HEALTH**

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To:

SOHO - TEAM

INFORMATION - on Critical SoHO and Critical SoHO Entities

In the context of the implementation of **Regulation (EU) 2024/1938 of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application**, the Ministry of Health informs entities carrying out activities involving substances of human origin (SoHO) about how to access information concerning the **designation of critical SoHO and critical SoHO entities in Romania**.

Information on Critical SoHO

The list of SoHO designated as critical in Romania, as well as any subsequent updates, will be made publicly available through the official communication channels of the Ministry of Health and the competent authority for SoHO as follow:

- **Plasma components** – blood components belonging to the plasma components category.
- **Plasma components** – plasma products identified separately within the European classification of SoHO products.
- **Platelets** – blood components intended for transfusion and included in the category of critical SoHO.
- **Red cells** – blood components intended for transfusion and included in the category of critical SoHO.
- **Haematopoietic progenitor cells from bone marrow** (*Progenitor cells, haematopoietic, bone marrow*) – **E0000078**.
- **Haematopoietic progenitor cells from peripheral blood** (*Progenitor cells, haematopoietic, peripheral blood*) – **E0000080**.
- **Haematopoietic progenitor cells, unspecified** (*Progenitor cells, haematopoietic, unspecified*) – **E0000081**.
- **Corneal tissue** (*Ocular, corneal*) – **E0000053**.
- **Cardiovascular valves** (*Cardiovascular, valve*) – **E0000089**.

Information on Critical SoHO Entities

SoHO entities meeting the applicable conditions and playing an essential role in ensuring the availability of critical SoHO may be designated as **critical SoHO entities**, in accordance with Regulation (EU) 2024/1938.

The designation of an entity as a critical SoHO entity shall be established by a **formal decision of the competent authority**, which will be communicated to the entity concerned.

Information concerning designated critical SoHO entities, including formal designation decisions and any subsequent amendments, will be made available through the official channels established for this purpose.

Updates to the lists

The lists of critical SoHO and critical SoHO entities will be updated whenever necessary, including in the event of:

- the designation of new critical SoHO or critical SoHO entities;
- changes to the conditions underlying a designation;
- termination or modification of a designation;
- identification of new information relevant to the availability of critical SoHO;
- adoption of new decisions or instructions applicable to critical SoHO entities.

Updated versions of the lists will be published through the official communication channels of the Ministry of Health and the competent authority for SoHO.

Instructions for SoHO Entities

SoHO entities designated as critical will receive information and instructions concerning the obligations and measures applicable to their status as critical SoHO entities.

These may include, where applicable, requirements concerning:

- ensuring business continuity;
- emergency preparedness and management;
- maintaining the capacity to provide critical SoHO;
- notification of situations that may affect the availability or continuity of the supply of critical SoHO;
- implementation of measures established by the competent authority;
- provision of information necessary for monitoring the availability of critical SoHO.

Relevant instructions and documents will be published and updated through the official communication channels of the competent authorities.

Where can the information be found?

Information concerning critical SoHO, critical SoHO entities, formal designation decisions, updates to the lists and relevant instructions will be made available on the official SoHO webpages of the **Ministry of Health** and the **National Transplant Agency**, in accordance with the respective legal responsibilities of each institution.

SoHO entities are encouraged to regularly consult these webpages in order to access the latest available information and documents.

GENERAL DIRECTOR

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