Decree of the Chairman of the Egyptian Drug Authority No. (3) of 2022 Concerning the Regulatory Guidelines for the Importation or Dispatch of Blood Plasma and the Exportation of Finished Plasma Derivatives

The Chairman of the Egyptian Drug Authority,

Having reviewed:

- Law No. (127) of 1955 Regulating the Practice of the Pharmacy Profession, and its amendments;

- Law No. (151) of 2019 concerning the Establishment of the Egyptian Drug Authority, and its Executive Regulations issued by Prime Ministerial Decree No. (777) of 2020;

- Law No. (8) of 2021 Regulating Blood Operations and the Collection of Plasma for the Manufacture and Exportation of Plasma Derivatives, and its Executive Regulations issued by Prime Ministerial Decree No. (2603) of 2021;

- Chairman's Decree No. (605) of 2021 concerning the Regulatory Guidelines for the Requirements to be Fulfilled by Separate Warehouses for Plasma, its Derivatives and Supplies, the Procedures for Licensing Blood Plasma Collection Centers, and the Procedures for Obtaining a Technical Operating License for Blood Derivatives Factories;

- The minutes of the Authority's Board of Directors meeting convened on 20/7/2020;

- The minutes of the coordination meetings held with the Egyptian Authority for Unified Procurement, the latest of which was convened on 14/11/2021;

- The memorandum submitted by the Head of the Central Administration of Pharmaceutical Policies and Market Access at the Egyptian Drug Authority;

- And for the interest of work;

(Article One)

This Decree shall apply to the importation or dispatch of blood plasma and the exportation of finished plasma derivatives. For the purposes of implementing its provisions, the following terms and expressions shall have the meanings assigned thereto respectively:

- **Law**: The Law Regulating Blood Operations and the Collection of Plasma for the Manufacture and Exportation of its Derivatives promulgated by Law No. (8) of 2021.
- **Plasma**: One of the blood derivatives, including therapeutic plasma and plasma collected for manufacturing purposes.
- **Plasma Derivatives**: Biological products derived from plasma components, including, but not limited to, albumin, clotting factors, and other plasma derivatives.
- **Intermediate Plasma Derivatives**: One of the plasma derivatives that is partially separated and subjected to further manufacturing steps for the purpose of producing bulk compounds and finished pharmaceutical products.
- **Finished Plasma Derivatives**: Biological products derived from plasma components in their complete pharmaceutical dosage form (finished products).
- **Dispatch of Plasma**: The sending of blood plasma for the purpose of manufacturing it outside the Arab Republic of Egypt and re-importing it in the form of plasma derivatives.
- **Conditional Release**: A release under custody by the Egyptian Drug Authority permitting the entry of shipments pending final release in accordance with the rules regulating the same as prescribed by the Egyptian Drug Authority

(Article Two)

This Decree shall apply to the importation or dispatch of blood plasma and the exportation of finished plasma derivatives submitted as of the effective date of this Decree.

(Article Three)

The importation or dispatch of blood plasma, or the exportation of finished plasma derivatives, may not be undertaken except through a specialized Egyptian company whose principal purpose is the collection, dispatch, manufacture, and importation of plasma or its derivatives for pharmaceutical manufacturing purposes.

(Article Four)

Import approvals or dispatch approvals for blood plasma, as well as export approvals for finished plasma derivatives, shall be granted in order to fulfill the requirements for localizing the manufacture of plasma derivatives within the framework of the national project for self-sufficiency in plasma derivatives, including:

- **Provision of medicinal products manufactured from plasma derivatives;**
- **Working towards the transfer of manufacturing technology related to blood plasma and plasma derivatives;**
- **Achieving self-sufficiency in finished plasma derivatives.**

(Article Five)

The Head of Central Administration of Pharmaceutical Policies and Market Access shall issue the regulatory guidelines governing the importation or dispatch of blood plasma and the exportation of finished plasma derivatives within five days from the date of approval of this Decree.

(Article Six)

his Decree shall enter into force as of the date of its issuance and shall repeal all provisions contrary to its provisions.

Chairman of the Egyptian Drug Authority

Prof. Dr. Tamer Mohamed Essam

Issued on: 5/1/2022