Decree of the President of the Authority No. (444) of 2023

President of the Egyptian Drug Authority,

Having perused:

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

- Law on Establishing the Egyptian Drug Authority Promulgated by Law No. (151) of 2019, and its Executive Regulation;

- Prime Minister's Decree No. (869) of 2010 on the Rules and Regulations of Control the Grants, Gifts and Donations provided by Foreign, National or International Entities amended by the Law No. (1818) of 2019;

- Decree of the President of the Authority No. (66) of 2020 on the Rules and Procedures for the Import and Customs Release of Medical Products;

- Material presented by the chairperson of the Central Administration of Pharmaceutical Policies and Market Access;

- Having considered the interest of work;

Has decided

(Article One)

The following rules shall be committed regarding the procedures for import and customs release of pharmaceutical products (medical, biological, veterinary, herbal, cosmetic, antiseptics and pesticides) and raw materials (active and inactive); as well as packaging materials and other relevant chemical and analysis requirements:

• The pharmaceutical products and their raw materials (active and inactive), packaging requirements and / or analysis requirements and relevant chemicals, shall be registered or under registration in the Egyptian Drug Authority in order to allow of importing of these products.

• The importation of the medical and biological products that are not registered in the Egyptian Drug Authority, shall be allowed to be imported in the event that they are requested by entities or individuals in the event of lack to similars products registered and circulated in the local market; or if the available quantities are not sufficient to cover the needs, based on a statement of the Department of Follow-up of the Availability and Continuity of Circulating of Products in the Egyptian Drug Authority; Provided that the import shall be from one of the reference countries. In the event of failure to provide similars registered and circulated in one of the reference countries by the entity, the importation from a non-reference country may be permitted, provided that the necessary requirements shall be fulfill to ensure the follow-up of their quality and safety.

• It shall be allowed to import medical and biological products received as grants and donations in accordance with the rules organizing the acceptance of the grants and donations, provided that the necessary technical requirements contained in the regulatory guideline, shall be fulfilled.

(Article Two)

The chairperson of the Central Administration of Drug Policies and Market Support shall issue the regulatory guideline on the mechanisms and procedures for import and customs release of pharmaceutical products, their raw materials and packaging requirements, within (15) fifteen working days from

the date of implementation of this decree, provided that the regulatory guideline shall include the executive mechanisms containing all the rules and procedures and it shall clarify all the requirements, approvals, technical studies and the attachments necessary to implement the provisions of this decree. Also, it shall be taking into account updating the source of the regulatory guideline whenever required by the work need in accordance with the new regulatory laws and rules and relevant scientific developments to ensure the quality and safety of all pharmaceutical products circulated in the Egyptian market.

(Article Three)

This DECREE shall be published in Al-Waqa'i' Al-Misriyya 'Egyptian Chronicles', the Supplement of the Official Gazette' and shall enter into force as of the day following its publication therein. Any other provisions that may contradict this DECREE shall be null and void.

President of the Egyptian Drug Authority

Prof. Tamer Mohamed Essam