Decree of the Chairman of the Egyptian Drug Authority No. (780) of 2022

Chairman of the Egyptian Drug Authority,

Having **perused**

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

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

- Minutes of the Authority's Board of Directors meeting held in its session on 20/07/2020;

- Ministerial decrees Nos.: (113 of 2004), (191 of 2005), (296 of 2009), (575 of 2012), (645 of 2012), (342 of 2014), (425 of 2015), (820 of 2016), (600 of 2018) and (645 of 2018) regarding the rules and procedures of granting marketing approval to pharmaceutical products, reorganizing and amending some provisions of the rules and procedures of the registration of human pharmaceutical products;

- The decree of the chairman of the Authority No. (150) of 2022 regarding reorganization of the rules and procedures of the reregistration of human pharmaceutical products;

- Material presented by the Head of the Central Administration of Pharmaceutical Products and the Head of the Central Administration of Drug Control; and

- Having considered the interest of work;

has decided

(Article One)

This decree shall be implemented with respect to application of the principle of reliance on reference health authorities in the registration and laboratory testing of imported medical products for human use that have been granted a Certificate of Pharmaceutical Product from one of the reference countries approved by the Technical Committee for Drug Control.

(Article Two)

For the purposes of the provisions of this decree, the following terms shall have the meanings set out for each term hereunder:

•**The law:** Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019.

•**The executive regulation**: The executive regulation of the Law on Establishing the Egyptian Drug Authority promulgated by the Prime Minister's Decree No. (777) of 2020.

•**The Authority**: The Egyptian Drug Authority.

•**Reliance**: Relying on decisions of the reference health authorities in registration and analysis procedures.

•**Reference Countries**: The group of countries for which the Technical Committee for Drug Control has issued a decision declaring those countries as such.

•**The owner of marketing license of the product in the origin country- the owner of the product license in a country for the imported human medical products**: The legal entity that own the

product or its marketing rights abroad or the entity which the product certificate in the origin country is issued in its name.

•**Marketing the medical products**: Is a process or more of the processes of producing, distribution, possession, submitting, presenting for sale, storing, use, reservation, packaging, transporting, delivering, importing or exporting the medical and biological products subjected to the law provisions.

(Article Three)

The Head of the Central Administration for Pharmaceutical Products shall issue the guideline of the rules for applying reliance on reference health authorities for the procedures of registering imported products that that have been granted a Certificate of Pharmaceutical Product from one of the reference countries approved by the Technical Committee for Drug Control. Correspondingly, the Head of the Central Administration of Drug Control shall issue the guideline of the rules for applying reliance on reference health authorities in analyzing imported products that have been granted a Certificate of Pharmaceutical Product from one of the reference countries approved by the Technical Committee for Drug Control, within five days from the date on which this decree comes into force.

(Article Four)

This decree shall come into effect from the date of its issuance. All relevant administrations shall implement it in accordance with their respective jurisdictions.

Chairman of Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Written on 6/12/2022