Decree of the Chairman of the Egyptian Drug Authority No. (184) of 2023

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 dated on 20/7/2020;

- 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 for granting marketing approval to pharmaceutical products, reorganization and amendment of some provisions of the rules and procedures of the registration of human pharmaceuticals products.

- Decree of the chairman of Egyptian Drug Authority No. (343) of 2021 regarding the Rules of registration of biological products.

- The decree of the chairman of the Authority No. (150) of 2022 regarding Reorganizing the Rules and Procedures of Re-registration of Human Pharmaceutical Products.

- Decree of the chairman of Egyptian Drug Authority No. (780) of 2022 regarding reliance on reference health authorities in the registration, evaluation and analysis of imported products with a certificate of registration and circulation from one of the reference countries approved by the Technical Committee for Drug control.

- Material presented by the Head of the Central Administration of Pharmaceutical care; and

-Having considered the interest of work;

(Article 1)

This decree shall be implemented with respect to the application of the principle of reliance on reference regulatory health authorities approved by the Technical Committee for Drug control regarding pharmacovigilance decisions, reports and information for pharmaceutical and biological products registered or submitted for registration in the Egyptian Drug Authority.

(Article 2)

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 of establishing the Egyptian Drug Authority promulgated by Law No. (151) 0f 2019.

The Executive Regulation: The executive regulation of the law on establishing the Egyptian Drug Authority promulgated by Prime Minister's Decree No. (777) of 2020.

The Authority: The Egyptian Drug Authority.

Reliance: Relying on information, reports and decisions of the reference health authorities related to the pharmacovigilance.

Reference Health Authorities: It is the group of countries for which a decision was issued by the Technical Committee for Drug Control.

Marketing the Pharmaceutical products: Is a process or more of the processes of production, distribution, possession, offering for sale, storage, use, preservation, packaging, transport, delivery, import or export of the pharmaceutical and biological products subjected to the law provisions.

(Article 3)

The Head of the Central Administration of Pharmaceutical care shall issue the guideline for applying reliance on reference regulatory health authorities approved by the Technical Committee for Drug control regarding pharmacovigilance decisions, reports and information for pharmaceutical and biological products registered or submitted for registration in the Egyptian Drug Authority, within five days from the date on which this decree comes into force.

(Article 4)

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

President of the Egyptian Drug Authority

Prof. Tamer Mohamed Essam

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