Decree of the Egyptian Drug Authority President No. (786) of 2022

regarding the suspension or cancellation of the procedures for registering human pharmaceutical products or

the marketing authorization license based on the assessment of safety and efficacy

President of 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),(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 president of the Authority No. (146) of 2022 regarding the rules of the rapid alert system, withdrawal and recalling of the medical and biological products;

- The decree of the president 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 Chairperson of the Central Administration of Pharmaceutical Products and the Chairperson of the Central Administration for Pharmaceutical Care; and

-Having considered the interest of work;

has decided

(Article One)

This decree shall be implemented with respect to suspension or canceling of the procedures for registering human pharmaceutical products or the marketing authorization license based on the assessment of safety and efficacy.

(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.

-Human_ pharmaceutical product: Any preparation or product containing any substance or group of substances prescribed for the purpose of treatment, prevention or diagnosis of a human ailment, prescribed as having another medical effect, or prescribed for restoring, correcting, or modifying physiological functions through producing a pharmacological, immunological or metabolic effect to the public health, in accordance with the applicable references and standards, as well as any product(s) or material(s) that may be developed based on the developments of science and/or international standards and references.

-The company – applicant of registration application – the marketing license holder in Egypt: The legal entity established in accordance with the applicablelaws, provided that it shall be registered in the electronic register of recording the companies designated for that in the Egyptian Drug Authority. This entity shall havethe right to take all the necessary procedures to register the product, starting fromsubmitting the registration application until obtaining the marketing authorization license as per the articles and items stipulated by the law and the applicable organizing decrees.

-The marketing license holder for the product in the country of origin: The foreign legal entity that owns the product or the rights to market it abroad or the entity in whose name the Certificate of the Pharmaceutical Product is issued in the country of origin.

-Risk-Benefit Balance for pharmaceutical products: The assessment of the positive therapeutic effects of the pharmaceutical product compared to the risks Risk-Benefit Balance assessment shall be maintained continuously during the validity period of marketing the pharmaceutical product in order to promote and protect public health and ensure the safety of patients through effective reduction of risks after granting a marketing authorization.

(Article Three)

The President of the Authority shall have the right to suspend or cancel the registration procedures or the marketing authorization license of any human pharmaceutical product whose marketing is proven to cause harm to the public health, on the basis of a technical memorandum supported by scientific evidences and studies for each case individually.

(Article Four)

The Chairperson of the Central Administration of Pharmaceutical Products, in cooperation with the Chairperson of the Central Administration for Pharmaceutical Care, shall issue the regulatory guide of this decree.

(Article Five)

Stakeholders may appeal against the decisions issued by the competent departments of the Authority regarding the suspension or cancellation of the procedures for registering human pharmaceutical products or the marketing license in accordance with the provisions and procedures stipulated in the law and the executive regulation.

(Article Six)

This decree shall come into effect from the date of its issuance and any other provision(s) that may contradict this decree shall be null and void.

President of

Egyptian Drug Authority

Prof /Tamer Mohamed Essam