EDA Chairman Decree No. (572) of 2022 Issuing the Rules for Registration of Complementary Medical Preparations

Chairman of Egyptian Drug Authority,

After reviewing:

- Act No. (127) of 1955 concerning the practice of the pharmacy profession;
- Act No. (10) of 1966 concerning the control of food and regulation of its circulation, and its amendments;
- The Law of the National Food Safety Authority issued by Law No. 1 of 2017, and its executive regulations;
- The Law of the Egyptian Drug Authority issued by Law No. (151) of 2019 and its executive regulations;
- Presidential Decree No. (18) of 2020 forming the Board of Directors of the Authority;
- What was presented by the Vice Chairman of the Egyptian Drug Authority;
- And in the interest of work;

(Article One)

This decision shall apply with regard to the registration of complementary medical preparations.

(Article Two)

Complementary medical preparations are defined as preparations containing one or more active substances that have a complementary medical effect and are used for the purpose of assisting in treatment, prevention, restoration, correction, or modification of physiological functions.

(Article Three)

Complementary medical preparations shall be registered exclusively with the Egyptian Drug Authority. The validity period of the registration notification for locally produced complementary medical preparations shall be ten years. Imported complementary medical preparations may be registered—according to technical considerations and local market requirements assessed and monitored by the Authority—and their registration notification shall be valid for three years as a transitional stage until they are re-registered as local complementary medical preparations.

(Article Four)

The circulation of complementary medical preparations registered with the Egyptian Drug Authority shall be permitted only within licensed pharmaceutical establishments.

(Article Five)

The registration notification of a complementary medical preparation shall be canceled if the product is not continuously available in the markets for a period of eighteen months, by a decision of the Chairman of the Authority based on a substantiated technical report from the Central Administration of Pharmaceutical Preparations.

(Article Six)

Unregistered preparations with the Egyptian Drug Authority that have the nature of complementary medical preparations previously registered with any other governmental body shall be granted a grace period of six months from the date of enforcement of this decision to regularize their status and apply for registration with the Egyptian Drug Authority in accordance with the applicable rules. It shall be prohibited to produce them in factories and production lines licensed by the Egyptian Drug Authority, as well as to circulate them in pharmaceutical establishments after the expiry of that grace period.

(Article Seven)

The Vice Chairman of the Egyptian Drug Authority shall issue, upon submission from the heads of the relevant central administrations, a regulatory guide on the mechanisms and procedures for implementing this decision within five working days from the date of its enforcement.

(Article Eight)

This decision shall be published in the Egyptian Gazette and shall come into force on the day following its publication. All provisions contrary to it shall be repealed.

Chairman of

Egyptian Drug Authority

Prof. Dr. /Tamer Mohamed Essam