

Decree of the President of Egyptian Drug Authority No. (781) of 2022 Concerning the Regulatory Guideline of Plan of Control the Risky Side Effects of the Medical and Biological Products after Marketing

President of 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;
- Decree of the President of Egyptian Drug Authority No. (120) of 2022, Concerning the Regulatory Guideline of the Control Plan for Post-Marketing which is based on the System of Evaluating the Risky Side Effects of the Biological Products;
- Minutes of the Authority's Board of Directors' meeting held in its session on 20/7/2020;
- Material presented by the Chairperson of the Central Administration of Operations; and
- Having considered the interest of work;

Has decided

(Article One)

The provisions of the above-mentioned decree No (120) of 2022 shall apply to the medical products.

(Article Two)

The Chairperson of the Central Administration of Operations shall issue an updated version of the Regulatory Guideline of the control plane the risky side effects after marketing, which version shall include the rules applicable to both of medical and biological products within five days as from the date of approval of this decree.

(Article Three)

This decree shall come into effect from the date of its issuance and any other provisions that may contradict this DECREE shall be null and void.

President of the Egyptian Drug Authority

Prof. Tamer Mohamed Essam