

**Decree of the President of the Authority No. (425) of 2022 on Approving
the Policy and Rules Regulating the Batches of Biological Products Release**

President of Egyptian Drug Authority,

Having perused

- The Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- The Law on Establishing the Egyptian Drug Authority Promulgated by the Law No. (151) of 2019, and its executive regulations;
- The material presented by the chairperson of the Central Administration for Biological and Innovative Products and Clinical Studies;
- Having considered the interest of work;

Decided

(Article One)

The policy and rules regulating the releasing the batches issued by Egyptian Drug Authority shall apply on releasing of the batches of biological products.

(Article Two)

The Chairperson of the Central Administration for Biological and Innovative Products and Clinical Studies shall issue the regulatory guideline of the rules regulating the release of batches of biological products within five days from the date of publishing of this decision.

(Article Three)

This DECREE shall be published in Al-Waqa'i' Al-Misriyya and shall enter into force as of the day following its publication therein. Any other Decrees that may contradict this DECREE shall be null and void.

President

Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Written on 18/7/2022

