

Decree of the President of the Egyptian Drug Authority No. (38) of 2022

President of the Egyptian Drug Authority:

Having Considered:

- 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;
- Arab Republic of Egypt President's Decree No. (18) of 2020 concerning the Constitution of the Board of Directors of the Egyptian Drug Authority;
- Decree of the President of the Egyptian Drug Authority No. (342) of 2021 Concerning Issuing the Rules of Biological Products' Registration;
- Material presented by Head of the Central Administration of Biological and Innovative Products and Clinical Trials;
- Having considered the interest of work;

Has decided

(Article One)

The text of Article four of the aforementioned Decree of the President of the Egyptian Drug Authority No. (343) of 2021 shall be replaced by the following text:

- In emergency circumstances, a product may be distributed and excepted from some conditions required for registration based on an integrated technical report for each case by the Vice President of the Egyptian Drug Authority and approving this report by the President of the Authority.

In such a case, a sample of that product shall be withdrawn and analyzed by the Central Administration of Biological and Innovative Products and Clinical Trials and the applicant shall present the registration file upon fulfillment.

(Article Two)

This DECREE shall be published in the Egyptian Official Gazette and shall come into effect from the day following its publication therein.

President

of the Egyptian Drug Authority

Written on / / 2022

Prof./ Tamer Essam

