Decree of the Chairman of the Authority No. (379) of 2026

The Chairman of the Egyptian Drug Authority,

Having reviewed:

- Law No. 127 of 1955 on the Practice of Pharmacy;

- Law No. 151 of 2019 on the Establishment of the Egyptian Drug Authority;

- Presidential Decree No.18 of 2026 forming the Board of Directors of the Egyptian Drug Authority;

- The Decree of the Chairman of the Egyptian Drug Authority No. 343 of 2021 regarding the rules for registering biological products;

- The submission of Head of the Central Administration for Biological and Innovative products and Clinical studies

- And in the interest of work;

Decides

(Article One)

The following text replaces Article four of the Chairman's Decree No. 343 of 2021:
In emergency situations, a product may be marketed with an exemption from certain marketing authorization requirements, based on a comprehensive technical report for each case reviewed by the Emergency Committee, which will then issue its opinion and submit it for approval by the Chairman of the Authority.
In that case, it is required that samples of the product shall be withdrawn and analyzed by the Central Administration for Biological and Innovative Products and Clinical Studies, and that the applicant shall submit the marketing authorization file upon completion.

(Article Two)

This decree shall be published in the Egyptian Official Gazette and shall come into effect from the day following the date of its publication.

Dr.Ali El-Ghamrawy
Chairman of the Egyptian Drug Authority

Issued on: 30/6/2026

•Published in the Egyptian Gazette, Issue No. (379), issued on 4 August 2026