Decree of the Chairman of the Egyptian Drug Authority No. (475) of 2025

Concerning the Establishment and Operation of the Unified National Electronic Pharmaceutical Track-and-Trace System

The Chairman of the Egyptian Drug Authority,

Having reviewed:

- Law No. (127) of 1955 Regulating the Practice of the Pharmacy Profession, and its amendments;

- Law No. (3) of 2005 on the Protection of Competition and the Prevention of Monopolistic Practices, and its amendments and Executive Regulations;

- Law No. (151) of 2019 concerning the Establishment of the Egyptian Drug Authority, and its Executive Regulations;

- Presidential Decree No. (4) of 2025 concerning the Formation of the Board of Directors of the Egyptian Drug Authority;

- The minutes of the meetings of the Authority's Board of Directors convened in Session No. (1) dated 20/7/2020, Session No. (14) dated 5/11/2024, and Session No. (15) dated 2/6/2025;

- Ministerial Decree No. (29) of 2016 concerning the tracking of the supply and distribution chain of pharmaceutical products within the Arab Republic of Egypt;

- Decree No. (499) of 2021 issued by the Chairman of the Egyptian Drug Authority concerning the mandatory use of the international barcode for goods by manufacturers, companies, distributors, importers, and warehouses of medical supplies of all types and sources operating in the Egyptian market;

- Decree No. (161) of 2025 issued by the Chairman of the Egyptian Drug Authority amending both Ministerial Decree No. (29) of 2016 and Decree No. (499) of 2021 issued by the Chairman of the Egyptian Drug Authority concerning the use of a unified coding system for goods and services based on unique identification numbers;

- Based on the memorandum submitted by both the Head of the Central Administration of inspection on pharmaceutical institutions and the Head of the Central Administration of Pharmaceutical Policies and Market Access;

- In the public interest and to ensure the safety, quality, and efficacy of human medicinal and biological products in the market, and to safeguard public health and achieve pharmaceutical security in Egypt;

(Article One)

- A Unified National Electronic Pharmaceutical Track-and-Trace System shall be established for human medicinal and biological products under the Authority's jurisdiction, to be applied across all stages of distribution of such products.

(Article Two)

-For the purposes of implementing the provisions of this Decree and its accompanying Regulatory Guideline, the following terms shall have the meanings assigned to each:

•**Law**: The Law establishing the Egyptian Drug Authority promulgated by Law No. (151) of 2019.

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•**Executive Regulations**: The Executive Regulations of the Law establishing the Egyptian Drug Authority issued by Prime Ministerial Decree No. (777) of 2020.

•**Authority**: The Egyptian Drug Authority

•**Products**: Human medicinal and biological products under the Authority's jurisdiction, whether locally manufactured or imported.

•**Manufacturer – Company – Warehouse – Pharmacy – Marketing Authorization Holder in Egypt**: Any legal entity established under the applicable laws of the Arab Republic of Egypt, operating as part of the supply chain, provided that it is registered in the Authority's electronic registry.

•**Circulation: Any operation or combination of operations including production, distribution,** possession, placing on the market, offering for sale, storage, use, handling, packaging, transportation, delivery, importation, or exportation of human medicinal and biological products under the Authority's jurisdiction.

•**The Unified National Electronic Pharmaceutical Track-and-Trace System**: a secure electronic program for the tracking and tracing ("Track & Trace") of all human medicinal and biological products. The system is based on registering and tracking all individual packs from the point of production or importation, through storage and distribution operations, until dispensing to the patient, exportation, or destruction, as the case may be.

(Article Three)

-Manufacturers, importing companies, distribution companies, and warehouses operating in the Egyptian pharmaceutical market shall enter locally manufactured or imported medicinal products, each under its respective responsibility, into the electronic track-and-trace system. Each product pack shall be assigned a unique identification number issued by the track-and-trace system, including the minimum data specified in the Regulatory Guideline of this Decree.

(Article Four)

-Manufacturers, importing companies, distribution companies, warehouses, and pharmacies operating in the Egyptian pharmaceutical market and registered in the Authority's electronic registry shall, each within the scope of its activities, provide the necessary technical infrastructure, including printing devices, electronic data-reading systems, software, and related applications, and shall ensure their linkage to the Unified National Electronic Pharmaceutical Track-and-Trace System, in accordance with the details set out in the Regulatory Guideline.

(Article Five)

-The provisions of this Decree shall apply to all imported finished human medicinal products as of 1/2/2026, and to locally packaged, repackaged, or manufactured products as of 1/8/2026. Batches produced or imported prior to these dates, as applicable, may remain in circulation in the market until their expiry date.

-A phased implementation approach shall be applied to products subject to this Decree according to dosage form and/or therapeutic groups, as set out in the Regulatory Guideline governing the mechanisms and procedures for implementing this Decree.

-It shall be prohibited to circulate any products manufactured or imported after the aforementioned dates unless they are registered in the track-and-trace system,

(Article Six)

-The Central Administration of inspection on pharmaceutical institutions shall seize and document medicinal products manufactured or imported after the dates specified in Article (Five) hereof in violation of the provisions of this Decree and the Regulatory Guideline.

-The Head of the Central Administration of inspection on pharmaceutical institutions may, upon a technical memorandum from the competent department, issue a Decision for the destruction of the violating products or approve a corrective action plan for their re-introduction into circulation after rectifying the causes of violation, provided that the prescribed service fees for monitoring the implementation of the corrective plan are paid.

(Article Seven)

T-In cases of emergency circumstances, any product may be circulated with an exemption from the requirement of registration on the Unified National Electronic Pharmaceutical Track-and-Trace System or from printing a unique identification number on the outer packaging. Such exemption shall be based on a detailed technical memorandum supported by scientific evidence or market studies prepared by the Central Administration of inspection on pharmaceutical institutions or the Central Administration of Pharmaceutical Policies and Market Access, each within its competence, and in accordance with the controls set out in the Regulatory Guideline, subject to approval by the Head of the Authority.

(Article Eight)

-The Head of the Central Administration of inspection on pharmaceutical institutions and the Head of the Central Administration of Pharmaceutical Policies and Market Access shall issue the Regulatory Guideline governing the rules, mechanisms, and procedures for activating the Unified National Electronic Pharmaceutical Track-and-Trace System within one month from the date of publication of this Decree, provided that it includes the compiled implementation mechanisms encompassing all rules, procedures, requirements, approvals, and controls necessary for the implementation and enforcement of the provisions of this Decree. It shall also include the phased implementation stages referred to in Article Five.

-The issuing authority shall update the Regulatory Guideline whenever required by operational needs, in accordance with any relevant legislative and regulatory developments.

(Article Nine)

-This Decree shall be published in the Egyptian Gazette and shall enter into force as of the day following the date of its publication, and all provisions contrary thereto shall be repealed.

Chairman of the Egyptian Drug Authority

Dr. Ali El Ghamrawy

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