

**Decree of the Chairman of the Egyptian Drug Authority No. (804) of 2025  
Concerning the Issuance of the Regulatory Guideline Governing the Rules and  
Procedures for the Establishment and Operation of the Unified National Elec-  
tronic Pharmaceutical Track-and-Trace System for Human and Biological Me-  
dicinal Products**

**The Chairman of the Egyptian Drug Authority,**

Having reviewed:

- Law No. (127) of 1955 Regulating the Practice of the Pharmacy Profession, and its amend-ments;
- 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 concern- ing 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;
- Decree No. (475) of 2025 issued by the Chairman of the Egyptian Drug Authority concerning the establishment and operation of the Unified National Electronic Pharmaceutical Track- and-Trace System;
- And 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;

**(Has decided )**

**(Article One)**

- The provisions of the Regulatory Guideline attached to this Decree and stipulated in Article (Eight) of Decree No. (475) of 2025 issued by the Chairman of the Egyptian Drug Authority concerning the establishment and operation of the Unified National Electronic Pharmaceutical Track-and-Trace System shall apply with respect to the rules and procedures governing the establishment and operation of the system for human and biological medicinal products:

The provisions of the Regulatory Guideline attached to this Decree shall apply to all entities operating in the Egyptian pharmaceutical market, whether manufacturers, importers, marketing authorization holders, or logistics service providers. It shall also apply to all pharmaceutical establishments stipulated in Article (10) of the Law Regulating the Practice of the Pharmacy Profession referred to above.

The entities referred to in this Article shall implement the provisions of the Guideline, each within the scope of its respective activities.

**(Article Two)**

All competent departments shall implement this Decree and give effect thereto, each within its respective competence.

**(Article Three)**

This Decree and the accompanying Regulatory Guideline shall be published in the Egyptian Gazette and shall enter into force as of the day following the date of its publication.

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

**Issued on: 1/12/2025**