The new Egyptian Unified Electronic System for Drug Traceability

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Introduction

On 28 July 2025, the Egyptian Drug Authority ("**EDA**") issued Decree No. 475 of 2025 (the "**Decree**") which was published on 11 August 2025. This Decree establishes and regulates a national unified electronic system for drug traceability (the "**System**"). The measure is part of Egypt's continuing efforts to ensure the safety, quality, and effectiveness of pharmaceutical and biological products circulating in the Egyptian market.

The traceability system

The Decree formally creates the National Unified Electronic Track & Trace System. This System applies to all human pharmaceutical and biological products that fall under the EDA's jurisdiction, whether locally manufactured or imported (the "**Products**"). Every package must receive a unique identification number, allowing it to be tracked from production or importation through distribution, storage, and dispensing to the patient, or until its export or destruction.

Obligations of stakeholders

The Decree imposes specific duties on factories, importing companies, distribution companies, warehouses, and pharmacies operating in the Egyptian pharmaceutical market and registered with the EDA. Such obligations include:

- Register the Products with the EDA with the System.
- Provide technical infrastructure, including printing devices, barcode scanners, and related software, and link the same with the System.

Implementation Timeline

The Decree introduces a phased implementation:

- From **1 February 2026**, the rules apply to all fully produced imported Products.
- From **1 August 2026**, the rules apply to all locally packaged or repackaged or produced Products.

Products already in the market before these dates may continue to circulate until their expiry or consumption, but any Products manufactured or imported after these deadlines must be included in the System.

Enforcement and Penalties

The Decree empowers the EDA's Central Administration for Inspection of Pharmaceutical Establishments to seize any Products not complying with the traceability requirements after the deadlines. Non-compliant Products may be destroyed or subject to corrective action plans, provided that the violating entity pays the required fees and implements approved remedies.

Exceptional Cases

In urgent or exceptional situations, the Decree allows for Products to be traded without being listed in the System. Such exceptions require a detailed technical report, supported by scientific or market studies, and must be approved by the EDA's chairman under the conditions set by the executive guidelines.

Executive Guide

The Decree requires the heads of the relevant central administrations to issue a regulatory guide within one month from the Decree's publication. This guide will provide detailed rules, procedures, and technical requirements for implementing the System. The guide will also outline the stages of gradual implementation and will be updated as necessary.

Conclusion

The Decree forms a major step towards improving drug safety and transparency in Egypt. By introducing a unified electronic track-and-trace system, the EDA aims to protect public health, combat counterfeit medicines, and enhance confidence in the Egyptian pharmaceutical market, reduce waste, protect brands and enhance inventory management. The phased deadlines give stakeholders time to adapt, but strict enforcement is expected once the system becomes mandatory.