

EDA Issues Decree Regulating Laboratory and Diagnostic Reagents

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Introduction

In a significant move to enhance public health safeguards and regulatory clarity, the Egyptian Drug Authority (the “**EDA**”) issued Decree No. 153 of 2025 (the “**Decree**”), to regulate the registration, importation, and circulation of laboratory and diagnostic reagents.

Effective as of 3 April 2025, the Decree establishes clear procedures and timelines for obtaining marketing authorizations and import approvals for such products.

We outline the key highlights of the Decree as follows:

Scope of Application

The Decree applies to all applications submitted for marketing authorizations and import approvals related to laboratory and diagnostic reagents.

License Validity and Renewal

Products registered under the Decree's framework are granted marketing authorizations valid for five years, subject to renewal through the submission of a formal application within the final six months prior to expiry.

Mandatory Licensing Requirement

The Decree prohibits the circulation or importation of laboratory or diagnostic reagents unless a valid marketing authorization has been obtained from the Central Administration for Medical Supplies.

Implementation Guide

The head of the Central Administration for Medical Supplies shall be required to issue a comprehensive regulatory guide within 15 working days following the Decree's entry into force. This guide shall outline the procedural steps, documentation requirements, timelines, and compliance deadlines for manufacturers and importers.

Market Reaction

We expect that the Decree will be met positively by industry stakeholders as the EDA gears more towards regulatory clarity and quality control. However, manufacturers and importers may have some concerns regarding tight timelines for implementation with a growing need for greater clarity on the procedures, required documents, and timelines for licensing. The upcoming issuance of the implementation guide will be closely monitored to address these concerns.