

EDA Issues Decree for Contract Manufacturing of Medical Supplies

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Introduction

On the 3rd of September 2025, the Chairman of the Egyptian Drug Authority (the “**EDA**”) issued a decree No. 415 of the year 2025 (the “**Decree**”) regarding the registration process for companies manufacturing medical supplies with third parties under a toll manufacturing arrangement (the “**Companies**”).

This Decree was published in the Official Gazette and came into effect on the 4th of September 2025. The Head of the Central Administration of Operations of the EDA (the “**CAO**”) shall issue the regulatory guidelines that would implement the provisions of the Decree within five working days of its publication.

We shall delve into the key highlights of the Decree as follows:

Scope of Application

As per the regulatory guidelines’ framework, the provisions of this Decree apply to the Companies. The latter are responsible for manufacturing local medical supplies in factories licensed by the EDA “Toll Manufacturing”.

Registration Requirements

The Decree provides requirements regarding the registration process of the Companies. It determines the validity period of the Companies’ registration in the EDA, its suspension as well as the terms for its cancellation.

Furthermore, it has stated other obligations on the Companies regarding the storage of medical supplies manufactured in light of this Decree, for instance, it shall be stored in a warehouse not less than 100 square meters, and the necessity to determine the factories responsible for the manufacturing process. Any amendment of the aforementioned shall be prohibited without the approval of the CAO.

In light of the above, the EDA has the authority to monitor and regulate the Companies to ensure the right implementation of the Decree, and to conduct technical inspection of its warehouses and its registers.

Market Reaction

The Decree aims to support investments and local pharmaceutical industry as it will provide an increase in local manufactured products and their supply to the market.