Resolution by EDA's President

No. 415/2025

EDA's President:

Having reviewed:

- Law no. 127 of the year 1955 on Practicing Pharmacy enacted subject to Law;

- Law on the establishment of EDA enacted subject to Law no. 151 of the year 2019, and executive regulations thereof;

- Presidential Decree No. 4 of the year 2025 Constituting the Egyptian Drug Authority;

- EDA Head decision no. 430 of the year 2021 on regulatory procedures for registering local and imported medical supplies bearing international quality certificates;

- EDA Head decision no. 505 of the year 2021;

- EDA Head decision no. 153 of the year 2025 regulating the registration of laboratory and diagnostic reagents;

- EDA BOD minutes of meeting in its session no. 1 dated 20/07/2020;

- The content presented by the Head of Central Administration of Operations and Head of Central Administration of Medical Supplies;

(Article 1)

This Decision shall apply to companies engaged in third-party manufacturing (Toll Manufacturing) of medical supplies. The Guidebook issued pursuant hereto shall define the scope of application, the medical supplies covered, and any exceptions granted.

"Companies" for the purpose of application of this Decision means companies that locally manufacture its medical supplies at EDA-licensed third party (EDA-licensed factories of medical supplies) by way of toll manufacturing.

(Article 2)

The terms and conditions contained within the Guidebook issued by the Central Administration of Operations on registering and updating companies in EDA Register of Toll Manufacturing Companies shall hereby be enforced.

(Article 3)

Medical supplies manufactured in accordance with the provisions of this Decision shall be stored in the company's licensed warehouse that fulfills all current health requirements enforced. The area of such warehouse shall not be less than 100 m2. A single warehouse may be shared by multiple companies to store the medical supplies referred thereto, all in accordance with the terms and conditions and procedures mentioned within the Guidebook issued thereon.

(Article 4)

Companies shall specify the facilities hosting their production activities and provide the relevant supporting documents. No production facility may be changed, nor a new facility added, without the prior approval of the EDA's Central Administration for Operations.

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(Article 5)

The registration of companies in the Register of Toll Manufacturing Companies shall be valid for a period of five (5) calendar years starting from the date of registration. An application for renewal shall be submitted during the last three (3) months of the final year of the registration's validity.

(Article 6)

Registration in the Register of Toll Manufacturing Companies may be suspended for a period not exceeding six months as per the conditions listed within the Guidebook.

(Article 7)

The company's registration cancelled from the Register of Toll Manufacturing Companies in the following cases:

1- Failure to notify the Central Administration for Operations of any change or amendment made to the commercial register within eighteen (18) months from the date of such change or amendment, as the case may be. The notice is a requirement for the following data:

- Company name;

- Licensee;

- Company activity.

2- The company obtains an EDA license to manufacture medical supplies in its own facilities.

3- The company fails to legalize its position within the six-month period stipulated within the previous article, without justifiable reason accepted by the authority concerned, as per the Guidebook.

4- The registration was not renewed upon its expiration, as per the procedures stipulated within the Guidebook.

(Article 8)

EDA shall have the authority to supervise Toll Manufacturing companies to ensure the enforcement of the provisions of this Decision. It shall also have the power to conduct technical inspections of such companies, their warehouses, records, and books to verify compliance with the provisions set forth in the applicable laws and decisions, in accordance with the rules prescribed in the Law on Practicing Pharmacy, the Law on the Establishment of the EDA, and their respective Executive Regulations. The company submitting the products registration license notice shall bear full liability for the medical supplies throughout their entire lifecycle.

(Article 9)

The Head of the Central Administration for Operations shall, within fifteen (15) working days from the date of entry into force of this Decision, issue a Guidebook for the implementation of its provisions. The Guidebook shall set out the executive mechanisms for all rules and procedures related to the application of this Decision, and shall also specify all relevant health requirements, procedures, timelines, and documents required for licensing and commencement of activities. The Guidebook shall be updated by its issuer whenever necessary and in accordance with any newly enacted regulatory rules or laws.

(Article 10)

This decree shall be published within the Egyptian Gazette, and shall be enforced as of the day following the publication. Any provisions to the contrary are hereby repealed.

Dr.Ali Al-Ghamrawi

Chairman of the Egyptian Drug Authority

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