

## Egyptian Drug Authority

### Egyptian Drug Authority Decree of the Chairman of the Egyptian Drug Authority No. (324) of 2024 Regarding the Licensing of Integrated Management Facilities for Medical Products and Devices Waste

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

After reviewing:

- The Law on the Practice of the Pharmacy Profession issued by Law No. (127) of 1955 and its amendments;
- The Environment Law issued by Law No. (4) of 1994, its Executive Regulations, and their amendments;
- The Egyptian Drug Authority Law issued by Law No. (151) of 2019 and its Executive Regulations;
- The Waste Management Regulation Law issued by Law No. (202) of 2020 and its Executive Regulations;
- The Clinical Medical Research Regulation Law issued by Law No. (214) of 2020 and its Executive Regulations;
- The Law Regulating Blood Operations and Plasma Collection for the Manufacture and Export of its Derivatives issued by Law No. (8) of 2021 and its Executive Regulations;
- Presidential Decree No. (7) of 2024 regarding the formation of the Board of Directors of the Egyptian Drug Authority;
- The minutes of the Authority's Board of Directors meeting held in session No. (1) on 20/07/2020;
- The presentation made by the Head of the Central Administration of Operations;
- And in the public interest;

#### **Decided**

#### **(Article One)**

The provisions of this decree shall apply regarding the licensing of integrated management facilities for Medical Products and Devices Waste. A facility licensed by the Authority for this purpose shall be considered a pharmaceutical establishment in accordance with the provisions of the aforementioned Law No. (151) of 2019 and its Executive Regulations.

#### **(Article Two)**

In the application of the provisions of this decree, the following terms and expressions shall have the meanings set out opposite each of them:

- The Law:** The Law establishing the Egyptian Drug Authority issued by Law No. (151) of 2019.
- The Executive Regulations:** The Executive Regulations of the Law establishing the Egyptian Drug Authority issued by Prime Minister Decree No. (777) of 2020.
- The Authority:** The Egyptian Drug Authority (EDA).
- Medical Preparations, Medical Supplies, and Biological Products:** All preparations and supplies subject to the Authority's supervision and the raw materials used in their production according to Law No. (151) of 2019.

- **Waste:** Damaged materials, objects, or movables abandoned by their holder, whether they can be recycled or must be disposed of.
- **Industrial Waste:** Waste resulting from industrial or manual activities or any similar activity, which does not contain hazardous waste.
- **Non-hazardous Waste:** Waste which, by its nature, does not possess hazardous characteristics, whether it is municipal, industrial, agricultural, or resulting from demolition and construction work or similar.
- **Hazardous Waste:** Waste containing organic or inorganic components or compounds harmful to human health or the environment due to its physical, chemical, or biological characteristics, or because it possesses hazardous properties such as being infectious, flammable, explosive, or toxic.
- **Hazardous Substances:** Substances with hazardous properties that harm human health or have an adverse effect on the environment, such as infectious, toxic, explosive, flammable, or ionizing radiation materials.
- **Pharmaceutical Waste:** Waste resulting from pharmaceutical facilities and institutions of all types licensed by and under the supervision of the Authority.
- **Handling of Hazardous Substances:** All operations leading to their collection or transport, including transboundary transport and the required procedures for their export, import, storage, recycling, treatment, recovery of useful components, or reuse.
- **License:** The document issued by the competent administration at the Authority for the handling of hazardous substances and waste as specified by Law No. (202) of 2020 and Law No. (4) of 1994 referred to above.
- **Licensee:** A pharmaceutical facility specialized in the integrated management of medical preparation and supply waste.
- **Integrated Waste Management:** The integration between different waste activities, including the reduction of waste generation, reuse, collection, storage, sorting, transport to designated sites or facilities, treatment, valuation, recycling, and final disposal in an environmentally safe manner.
- **Waste Management:** Managing any stage of integrated waste management.
- **Waste Storage:** The temporary deposition of waste inside a facility or site with specific technical specifications without performing any treatment operations.
- **Waste Handling:** Every operation that leads to the collection, transport, storage, treatment, or use of waste.
- **Final Disposal:** Every operation concerned with the safe disposal of waste in a facility or site licensed for the disposal of such waste.

#### (Article Three)

Pharmaceutical facilities and institutions licensed by the Egyptian Drug Authority may apply for a license to manage pharmaceutical waste within the licensed facility or institution, provided that the health requirements detailed in the regulatory guide for this decree are met in the locations designated for managing such waste. The license shall be issued by the Central Administration of Operations for a period of one year.

#### (Article Four)

A register shall be established at the Authority for recording integrated waste management companies for Medical product and devices waste. They shall be granted a license for Integrated Management of Medical Products and Devices Waste for a period of one year, provided the health requirements detailed in the regulatory guide for this decree are met. The facility designated for managing such waste shall be considered a pharmaceutical establishment.

**(Article Five)**

A new organizational division shall be established within the internal structure of the Egyptian Drug Authority under the name “Licensing Unit for Integrated Management of Medical Products and Devices Waste,” reporting to the General Administration of Licensing of Scientific Offices, Medical Product Stores, Warehouses, Stability and Bioequivalence Center at the Central Administration of Operations. It shall be responsible for licensing locations and facilities for the integrated management of Medical product and devices waste inside and outside pharmaceutical institutions and facilities. The said unit shall coordinate with the Waste Management Regulatory Agency to establish mechanisms and procedures for monitoring the handling of hazardous substances and waste and take the necessary measures in this regard.

A new organizational division shall also be established within the internal structure of the Egyptian Drug Authority under the name “Safe Inspection Management Unit for Pharmaceutical Preparation Waste,” reporting to the General Administration for Market Control at the Central Administration of Operations. It shall be responsible for the control and inspection of locations and facilities licensed by the Authority for the integrated management of pharmaceutical waste.

**(Article Six)**

the license for Integrated Management of Medical Products and Devices Waste shall be revoked in the event of a violation of the procedures and rules detailed in the regulatory guide issued in implementation of the provisions of this decree.

**(Article Seven)**

The Egyptian Drug Authority shall have the power to control integrated management locations and facilities for Medical Products and Devices Waste to verify the implementation of the provisions of this decree. It shall have the authority to conduct inspections of those locations and facilities, as well as registers and books, to verify the application of the provisions contained in the laws in force in this regard and the relevant decrees, according to the rules established in the Law on the Practice of the Pharmacy Profession, the Law establishing the Egyptian Drug Authority, their implementing decrees, and the valid regulatory guides.

**(Article Eight)**

The Head of the Central Administration of Operations shall form committees to examine and issue licenses for locations and facilities for Integrated Management of Medical Products and Devices Waste. The said committees may seek the assistance of experts in various specialties as they see fit to complete their work, whether from the Authority’s employees or other specialists in the field of waste disposal.

**(Article Nine)**

The Head of the Central Administration of Operations shall issue the regulatory guide regarding the mechanisms and procedures for licensing and inspecting locations and facilities for the integrated management of Medical product and devices waste within fifteen working days from the date of implementation of this decree. It shall include the consolidated executive mechanisms for all rules and procedures for implementing and applying this decree, clearly stating all requirements, approvals, technical studies, and attachments necessary for applying the provisions of this decree, after being approved by the relevant central administrations according to the technical rules approved and updated at the time of approval. The issuer of the regulatory guide shall update it whenever the needs of the work require so, in accordance with new laws, regulatory rules, and relevant scientific developments.

**(Article Ten)**

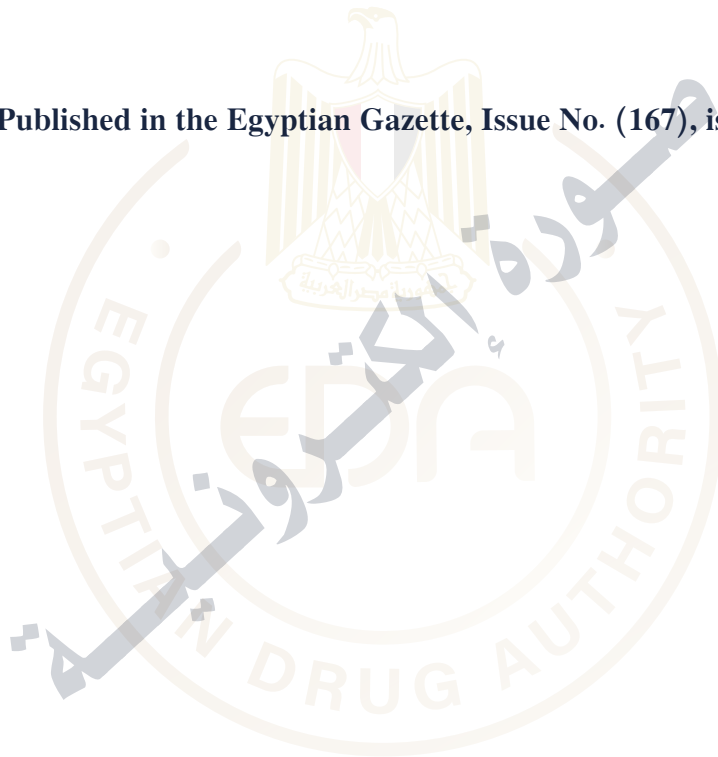
This decree shall be published in the Egyptian Gazette and shall be effective from the day following its publication. Any provisions contradicting it are hereby repealed.

**Dr. Ali Al-Ghamrawi**

**Chairman of the Egyptian Drug Authority**

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