Decree of the Chairman of the Authority No. 845 of 2025

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. (4) of 2025 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;

-Decree of the Chairman of the Authority No. (324) of 2024;

-The presentation made by the Head of the Central Administration of Pharmaceutical Institutions Licensing and the Head of the Central Administration for Pharmaceutical Facility Inspection;

-And in the public interest;

Decided

(Article One)

The texts of Articles (Three, Five, Eight, and Nine) of the aforementioned Decree of the Chairman of the Authority No. (324) of 2024 shall be replaced with the following texts:

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 Pharmaceutical Institutions Licensing for a period of one year.

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 for Pharmaceutical Institutions Licensing.

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 for Pharmaceutical Facility Inspection. 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 Eight:

The Chairman of the Egyptian Drug Authority shall issue a decree to form a committee to examine and issue licenses for locations and facilities for the integrated management of Medical product and devices waste. The said committee may seek the assistance of experts in various specialties as it sees fit to complete its 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 Pharmaceutical Institutions Licensing shall issue the regulatory guide regarding the mechanisms and procedures for licensing locations and facilities for the integrated management of medical product and devices waste. Furthermore, the Head of the Central Administration for Pharmaceutical Facility Inspection shall issue the regulatory guide regarding the mechanisms and procedures for 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 Two)

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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