Decree of the Chairman of the Egyptian Drug Authority
No. (265) of the Year 2024

The Chairman of the Egyptian Drug Authority,

After reviewing:

- Law No. 48 of 1941 on the Suppression of Fraud and Deception;

- Law No. 163 of 1950 on Compulsory Pricing and Profit Determination;

- Law No. 127 of 1955 on the Practice of the Pharmacy Profession;

- Law No. 113 of 1962 on the Reorganization of the Importation, Manufacture, and Trade of Medicines, Medical Supplies, and Medical Chemicals;

- The Consumer Protection Law issued by Law No. 181 of 2018, and its Executive Regulations;

- The Egyptian Drug Authority Law issued by Law No. 151 of 2019, and its Executive Regulations;

- Presidential Decree No. 7 of 2024 regarding the formation of the Board of Directors of the Authority;

- The minutes of the EDA Board of Directors meeting held in its session No. 1 on July 20, 2020;

- Ministerial Decree No. 25 of 2009 regarding licensing procedures for distribution companies and drug stores to initiate their activity, amended by Decree No. 110 of 2010;

- Ministerial Decree No. 499 of 2012 regarding the pricing of human pharmaceutical products;

- Decree of the Egyptian Drug Authority No. 121 of 2022 regarding the adoption of the World Health Organization (WHO) Guidelines for Good Distribution and Storage Practices;

- Decree No. 1 of 2010 regarding licensing procedures for public pharmacies, amended by Decree No. 1 of 2015;

- The presentation submitted by the Head of the Central Administration for Operations;

- And in the public interest;

(Article One)

Without prejudice to the Authority's power of administrative closure of the pharmaceutical establishment, fees for the services attached to this decree shall be collected in return for services of reviewing and monitoring the implementation of the corrective action plan (CAPA) submitted by stores, warehouses, and pharmacies to eliminate the causes of violations recorded in the inspection report, which are provided by the Central Administration for Operations.

(Article Two)

The Head of the Central Administration for Operations shall issue the procedural guide for the mechanisms and procedures of reviewing and monitoring the corrective action plan submitted by stores, warehouses, and pharmacies, within five working days from the date of entry into force of the provisions of this decree. This guide shall include the collective executive mechanisms for all rules and procedures to implement and apply this decree, clearly detailing the dates for submitting the corrective plan and the maximum grace periods for its implementation. The issuer of the regulatory guide shall also ensure it is updated whenever the workflow requires, in accordance with newly introduced laws, regulatory rules, and relevant scientific developments.

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(Article Three)

The prescribed service fees shall be deposited into the account of the Accounting Unit of the Egyptian Drug Authority.

(Article Four)

This decree shall be published in Al-Waqa'i' Al-Misriyya, and any provisions violating it are hereby repealed.

Chairman of the Egyptian Drug Authority

Dr. Ali El Ghamrawy

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Fees for Services of Reviewing and Monitoring the Implementation of the Corrective Action Plan Submitted by Stores, Warehouses, and Pharmacies

To eliminate the causes of violations recorded in the inspection report, provided by the Central Administration for Operations

No.	Provided Service	Service Fee (in Egyptian Pounds – EGP)
1	Violation of Good Storage and Distribution Practices (GSP/GDP) – minor and major, excluding critical violations	5,000
2	Violation of the engineering layout drawing approved by the Egyptian Drug Authority	5,000
3	Absence of a pharmacist at the pharmaceutical establishment for three times within a single year	3,000
4	Changing the name of the pharmaceutical establishment from the name issued in the license	10,000
5	Acquisition of products in violation of the decrees issued by the Authority	1,000 per product
6	Failure to implement an integrated electronic system in the store/warehouse that allows tracking the circulation of items	20,000
7	Failure to document trading/circulation transactions between pharmaceutical establishments via distribution contracts	500 per store/warehouse
8	Failure to fully record specific invoice data demonstrating sale or purchase	5,000 per product
9	Selling outside the distribution scope of the store/warehouse specified on the license of the pharmaceutical establishment	5,000 per product
10	Violation of the profit margins prescribed for the distributor and the pharmacist	10,000 per product

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