

**Decree No. (725) of 2024 of the Chairman of the Egyptian Drug Authority
Regarding the Conditions and Procedures for Licensing Medical products store
and the Health Requirements to Be implemented**

The Chairman of the Egyptian Drug Authority,

Having reviewed:

- The Law on the Practice of the Pharmacy Profession issued by Law No. (127) of 1955 and - Law No. (127) of 1955 concerning the Practice of the Pharmacy Profession and its amendments;
- The Law establishing the Egyptian Drug Authority promulgated by Law No. (151) of 2019 and its Executive Regulations;
- Presidential Decree No. (7) of 2024 concerning the formation of the Board of Directors of the Egyptian Drug Authority;
- The minutes of the meeting of the Authority's Board of Directors held in its session No. (1) dated 20/7/2020;
- Ministerial Decree No. (25) of 2009 regarding the licensing of distribution companies and medical products store to carry out their activities, as amended by Decree No. (110) of 2010;
- Ministerial Decree No. (380) of 2009 concerning the reorganization of health requirements for pharmaceutical institutions, as amended by Decree No. (198) of 2011;
- Ministerial Decree No. (29) of 2016 regarding tracking the supply and distribution chain of pharmaceutical products within the Arab Republic of Egypt;
- Decree No. (271) of 2021 of the Chairman of the Egyptian Drug Authority regarding the conditions required for licensing accessory store related with pharmaceutical institutions;
- Decree No. (499) of 2021 of the Chairman of the Egyptian Drug Authority regarding obligat- ing factories, companies, distributors, importers, and warehouses of all types and sources of medical devices operating in the Egyptian market to use the international barcode for goods;
- Decree No. (505) of 2021 of the Chairman of the Egyptian Drug Authority regarding the reg- istration and updating of company registration in the Register of Third-party Manufacturing Companies;
- Decree No. (120) of 2022 of the Chairman of the Egyptian Drug Authority regarding the reg- ulatory guidline for the post-marketing surveillance plan based on a risk assessment system for biological products;
- Decree No. (121) of 2022 of the Chairman of the Egyptian Drug Authority regarding the adoption of the World Health Organization (WHO) guidelines on Good Distribution and Stor- age Practices;
- Decree No. (146) of 2022 of the Chairman of the Egyptian Drug Authority regarding the rules of the rapid alert, recall, and ban system for medical and biological products;
- Decree No. (781) of 2022 of the Chairman of the Egyptian Drug Authority regarding the regulatory guidline for the risk-based post-marketing surveillance plan for medical and bio- logical products;

- Decree No. (783) of 2022 of the Chairman of the Egyptian Drug Authority regarding the collection and analysis of samples of human, veterinary, herbal medical products, disinfectants, cosmetics, pesticides, raw materials, and extracts of medicinal plants and similar items, in accordance with scientific references and updates;
- Decree No. (265) of 2024 of the Chairman of the Egyptian Drug Authority regarding the procedures for examining and following up on corrective action plans submitted by warehouses, medical products stores, and pharmacies;
- What was presented by the Head of the Central Administration for Operations;
- And in the interest of proper workflow;

Resolved as Follows:

(Article 1)

The health requirements and the Good Storage and Distribution Practices (GSDP) attached to this Decree shall apply with respect to the licensing of medical products stores.

(Article 2)

Without prejudice to the general health requirements prescribed for pharmaceutical institutions, medical products store shall be licensed to carry out their activities in accordance with the procedures and conditions set out in detail in the regulatory guideline issued in implementation of the provisions of this decree. It shall not be permissible to lease the premises, or any part thereof, to third parties.

(Article 3)

Trading in, storing, or wholesaling drugs is prohibited except through Medical products stores licensed by the Egyptian Drug Authority. It is also prohibited to store any dietary supplements in medical products store except after obtaining the Authority's approval in accordance with the form prepared for such purpose and under the conditions and procedures determined by the Authority.

(Article 4)

Medical products store shall, upon obtaining or selling drugs, comply with the following:

1. Pharmaceutical products shall be obtained from factories licensed by the Egyptian Drug Authority, or from importers of products registered in the Egyptian Drug Authority's records, or from Medical products stores holding a Good Distribution and Storage Practices certificate. The storage of any drugs or products not contracted for distribution is prohibited.
2. Products shall be purchased or sold only pursuant to invoices recorded in the inbound and outbound registers, with their data entered into the computerized system, including the details of the seller, the buyer, and the product, subject of the sales invoice, all in the manner set out in the regulatory guideline issued in implementation of this Decree, provided that sales documents are maintained for five years.
3. Products shall not be sold to the public, and shall only be sold or distributed within the geographical scope for which the medical products store is licensed.
4. Facilities or discounts are granted only after obtaining the approval of the Egyptian Drug Authority as to the type and percentage of the discount and the products to which it applies. Discounts shall be limited to over-the-counter products as specified in the decrees issued by the Egyptian Drug Authority.
5. Each drug medical products store shall submit a statement of unavailable products within a period not exceeding one month from the date of their unavailability.

(Article 5)

Medical products store shall be subject to periodic and surprise inspections by the Egyptian Drug Authority. In the event that the Medical products store is found to have committed any violation of the provisions of Law No. (127) of 1955 concerning the Practice of the Pharmacy Profession, or any other related laws or decrees, or violated the provisions of this Decree, or dealt in products that are unregistered with the Egyptian Drug Authority, adulterated, counterfeit, smuggled, expired, not contracted for distribution, or without invoices, the Medical products store shall be administratively closed. Drugs shall be seized by the Egyptian Drug Authority's inspectors; and expired, counterfeit, or adulterated products shall be destroyed after taking the prescribed criminal procedures.

The Head of the Central Administration for Operations may also, where violations related to the fair distribution of products in the market are established, oblige the Medical products store to deal with certain pharmaceutical institutions exclusively for a period not exceeding six months, with a re-evaluation of the Medical products store's status in accordance with the submitted corrective action plan.

(Article 6)

For the purpose of ensuring pharmaceutical security in the Egyptian market, the Head of the Central Administration for Operations may suspend the supply of any products between Medical products stores and restrict their circulation to pharmacies only, based on a technical report from the competent administration, for a period not exceeding 6 months. Such period may be extended upon the approval of the Chairman of the Egyptian Drug Authority, based on the technical memorandum submitted by the Central Administration for Operations.

(Article 7)

The validity of the medical products store license is five years starting from the date of issuance of the license. A request for renewal shall be submitted during the last six months of the last year of the license term, in accordance with the health requirements attached to this Decree, with the exception of the area requirement. Medical products store shall be administratively closed if the license is not renewed by the end of the license validity.

Medical products store whose licenses has issued for more than 5 years shall submit a request for renewal no later than 1/1/2036; otherwise, they shall be administratively closed.

(Article 8)

The Head of the Central Administration for Operations shall issue the regulatory guideline for the health requirements applicable to medical products store subject to the Egyptian Drug Authority's jurisdiction, as well as the procedures for their licensing and inspection, within ten working days from the date of publication of this Decree. The guideline shall include the consolidated executive mechanisms for all rules and procedures for implementing and applying this Decree, clearly setting out all specific health requirements, procedures, timelines, and documents required for licensing and commencement of activity. The issuer of the regulatory guideline shall update it whenever required by operational needs and in accordance with newly issued laws and regulatory rules.

(Article 9)

This Decree shall be published in the Official Gazette (Al-Waqa'i' Al-Masriya) and shall be enforced starting as of the day after its publication. Any provisions contrary thereto shall be repealed.

Dr. Ali Al-Ghamrawi

Chairman of the Egyptian Drug Authority

Issued on: 12/12/2024

Requirements to Be Met by Medical products store

Attached to the Decree No. (725) of 2024 of the Chairman of the Egyptian Drug Authority

1. Compliance with the Good Storage and Distribution Practices (GSDP) set out in the regulatory guideline issued by the Egyptian Drug Authority and published on the Egyptian Drug Authority's official website, as well as all regulatory guidelines in accordance with the World Health Organization code and other international organizations, including any updates thereto.
2. The Medical products store area shall not be less than (500) square meters)storage space(. The required storage area may be divided over two internally connected floors, having a separate entrance, and the Medical products store shall be independent from any other activity.
3. The net height between the Medical products store floor and the ceiling shall not be less than 2.6 meters. The Medical products store entrance must be independent and shall not be connected to any private residence, workshop operated for another industry, or any openings that lead to or are connected with any of the above.
4. The institution shall be constructed of modern, non-combustible building materials in compliance with Egyptian standard specifications. The total area shall be calculated without deducting any internal building or walls from the overall area.
5. A fixed sign shall be placed on the Medical products store facade displaying the Medical products store name in Arabic, in accordance with the name stated in the issued license.
6. The Medical products store shall be provided with a cold room or refrigerators equipped with a thermometer for storing medicines that require temperatures lower than room temperature, with temperature readings recorded on a regular basis.
7. Availability of a licensed electricity meter and a recent electricity consumption receipt, or a certificate issued by the competent electricity company in the absence of a meter, confirming the permanent and continuous supply of electricity to the store until a permanent meter is installed for the store to be licensed.
8. Where the establishment of a toilet is requested, it shall be located in a separate area and shall not open directly onto drug storage areas. A corridor with a door shall be provided in front of the toilet. The toilet shall have a window opening onto a street or an air shaft, and a ventilating fan may be used. Toilet walls shall be tiled with ceramic. The toilet shall drain into a dedicated inspection chamber connected to the public sewage system, and an independent and separate supply of potable public water shall be provided.
9. The drainage shall discharge into a grease trap connected to the public sewage system or the building drainage, and the toilet shall discharge into the Medical products store's dedicated inspection chamber connected to the public sewage system or the building drainage. The grease trap and inspection chamber shall be located outside the Medical products store in accordance with the layout approved by the Egyptian Drug Authority.
10. No tanks, inspection chambers, or grease traps shall be permitted beneath the floor of the store, nor shall drainage lines, siphons, or toilet bases be permitted within it. Drainage lines may pass beneath the store floor only in exceptional cases approved by the Egyptian Drug Authority, provided that all necessary safety measures are taken. Medical products stores may be exempted from the requirements relating to water supply and drainage methods on the condition that no toilets are present within them.

11. The floor level of the store shall be at the same level as the adjacent ground. Exceptionally, adequate precautions may be taken to prevent water infiltration into the Medical products store, including the installation of a drainage network, provided that safe entry to and exit from the Medical products store are not compromised. In all cases, the Medical products store shall not be licensed in a basement, nor in store licensed for residential, administrative, or garage use.

12. Walls shall be covered with materials that are easy to clean to prevent bacterial growth. Floors shall be smooth, with sealed joints, easy to clean, and made of non-combustible materials. Drugs shall be placed on metal racks or racks made of non-combustible, bacteria-resistant materials at a height of (45) cm above the floor. No items shall be placed beneath these racks. Stored drugs shall be kept at least (20) cm away from walls and (60) cm away from the ceiling.

13. Without prejudice to obtaining the approvals of the competent Civil Protection Department prior to license issuance, an adequate number of serviceable fire extinguishers or a fire suppression system shall be provided, and all Medical products store windows shall be fitted with tightly woven wire mesh.

14. The Medical products store shall be equipped with a computerized system containing all data related to the drugs handled, including sales and purchase invoices, as well as supplier and customer data, in accordance with the regulatory guideline issued in this regard.

15. The Medical products store shall have a responsible manager who is a licensed pharmacist, and an adequate number of qualified staff shall be available.

16. Compliance with the technical specifications for vehicles used to transport products and supplies related to the Medical products store, in accordance with the applicable laws and regulatory guidelines issued in this respect.

17. Pharmaceutical waste shall be disposed of safely and properly in a manner that does not pose a risk to the environment or threaten public health.

18. The original license, a copy of the approved layout, and the professional practice license of the responsible manager shall be kept at the medical products store at all times for presentation upon request.