

Egyptian Drug Authority

Decree No. 271 of 2021

Regarding The Requirements that shall be met in The Accessory Stores Related to Pharmaceutical Institutions

Chairman of the Egyptian Drug Authority,

After perusal the following:

- The Pharmacy profession practice Law No. 127 of 1995 and its amendments;
- The Egyptian Drug Authority Law No. 151 of 2019 and its executive regulations;
- Ministerial Decree No. 11 of 1955 regarding the requirements that shall be met in accessory stores;
- What was presented by the head of the Central administration of operations;
- And For the work interest;

Decided

(Article 1)

The accessory stores prepared for storing medical products for the need of pharmaceutical institutions shall meet the following requirements:

- 1- The accessory store shall be constructed of modern non-combustible building materials that comply with the Egyptian standard conditions. The net height of the ceiling shall not be less than 2.6 meters.
- 2- The accessory store space shall be on one or two levels. It shall have one door and one upper ceiling. The connection between them shall be done by an internal ladder. The presence of attic shall not be included in the calculation of the accessory store area.
- 3- The ground level of the accessory store shall not be less than the level of the street or the land adjacent there to, as the case may be. The ground level can be lower than the adjacent ground with the condition of taking adequate precautions to prevent water from leaking into the storage place, including the availability of a drainage network. It is not permissible to open accessory store in the basement or garage or in an apartment licensed as a residential or administrative activity.
- 4- The floor shall be made of non-combustible materials, tight interspacing and easy to clean
- 5- Cover the walls with easy-to-clean materials to prevent bacterial growth
- 6- The storage place shall meet the requirements of good storage practices (GSDP) as follows:
 - a. Maintaining the temperature and humidity according to the specifications of medicines and pharmaceutical products. The temperature shall not exceed 30 degrees Celsius and the humidity shall not exceed (65%), with the installation of thermometers and hygrometers in a visible place in the storage place to measure them. The pharmacist shall record the readings on a regular basis. In the event that there are products to be stored at special temperatures, a refrigerator or a cold room must be available, and the temperatures shall be measured by means of external calibrated thermometers

b. Allocate a separate place for storing expired pharmaceutical products away from valid pharmaceutical products, until these products are destroyed or returned to the producing company under approved documents, and coordination with the competent health authorities, and a sign shall be placed on this place with a clear statement, "Expired medical products that must not be used."

c. Placing a narrow wire mesh on the windows of the accessory store.

d. Storing medical products on metal stands, or made of materials that are not combustible and prevent bacterial growth – fixed at a height of 45 cm from the ground. It is strictly prohibited to put anything below these stands. Stored products shall be at least 20 cm away from the wall and at least 60 cm from the ceiling.

7-A licensed electricity meter must be available in the accessory store, and in case that it is not available, the license applicant must have a certificate from the competent electricity authority that the accessory store is provided with continuous and independent electric current until the electricity meter is available

8-It is prohibited to have a water supply and a bathroom inside the accessory store belonging to any of the pharmaceutical institutions.

9-It is allowed to have a water supply inside the accessory store belonging to the factories licensed and subjected to the supervision and inspection of the Egyptian Drug Authority. In the event of water supply available, it shall be equipped with an independent water supply meter, and the drainage system shall be independent.

10-It is prohibited to use the accessory store for housing, and also it is prohibited to put sleeping tools inside it.

11-Fire extinguishers or a fire-extinguishing system shall be available inside the accessory store.

12-In the case of licensing accessory store belonging to the licensed factories subjected to the supervision and inspection of the Egyptian Drug Authority, it shall be outside the limits of the factory fence. Air curtains shall be installed at all entrances and exits and shall be operated automatically with opening.

13-A fixed banner shall be placed on the door of accessory store belonging to any of the pharmaceutical institutions, written on it in clear Arabic script, "accessory store belonging to the pharmaceutical institution with the name shown in the license of the pharmacy institution, and a statement that the trading shall not be made through it.

14-It is prohibited to keep in the institution any materials or tools other than the materials and tools necessary for the work for which the accessory store is licensed.

15-The area of accessory store belonging to medical products store shall not be less than 25 square meters (twenty-five square meters), and not to exceed the space of the medical products store stated in the applicable regulatory decrees.

16-The area of accessory store belonging to the community pharmacy, the private pharmacy, the warehouse, or the shop for trading in medical plants shall not be less than 25 m (twenty-five square meters). The area shall not be more than twice the area of the original pharmaceutical institution to which it belongs.

(Article 2)

The competent health authority shall apply the following licensing controls:

1-Conducting the first licensing inspection on the place to be licensed within thirty days from the date of receiving the licensing application by the competent health authority. If the health requirements are not fulfilled, the license applicant shall be granted a first period of eight months to fulfill the health requirements, Then the licensing inspection shall be repeated at the end of the granted period. If the inspection proves that the health requirements are not met, the license applicant shall be granted a second period of four months, which is half the first period, to complete it. If it is subsequently proven that the health requirement are not fulfilled, the licensing application shall be rejected.

- 2-Ensure that the storage area matches the latest layout approved by the competent health authority.
- 3-The accessory store license data shall be registered on the original license of the pharmaceutical institution. The license data of the pharmaceutical institution shall also be recorded on the license of its accessory store.
- 4-The community pharmacy, the private pharmacy, the medical products store, the warehouse, or the shop for trading in medical plants shall have only one accessory store. Accessory store of the community pharmacy, medical products store, warehouse, or the shop for trading in medicinal plants shall be within the same district of the original pharmaceutical institution. As for the private pharmacy, its accessory store shall be within the licensed institution in which the private pharmacy is located. It is prohibited to license accessory store belonging to medical products stores in villages.
- 5-The pharmaceutical institution shall have the right to license accessory store in case it needs additional storage space.
- 6-The accessory store shall be dedicated only to storing medical products for the needs of the pharmaceutical institution to which it belongs (community pharmacy, private pharmacy, medical products store, warehouse, or shop for trading in medical plants). It is strictly prohibited to distribute medical products from it, store medical products for another pharmaceutical institution, or sell to the public. In case of violation of the previous rule, the owner of the pharmaceutical institution to which the accessory store belongs and the responsible manager shall be notified. In case of repetition, the accessory store shall be closed administratively for a period of one month, and in case of continuous violation, the license shall be permanently cancelled.
- 7-It is prohibited to rent any part of accessory store that belongs to community pharmacy, private pharmacy, medical products store, warehouse, or the shop of trading in medical plants. It may also not be used for anything other than its licensed purpose.
- 8-In the event of cancellation of the license of the main pharmaceutical institution, the license of the accessory store is cancelled as consequence.
- 9-In case of licensing an accessory store. The original license of the pharmaceutical institutions must be valid and it must be proven that the institution is currently active.
- 10-The managing pharmacist of the pharmaceutical institution (community pharmacy, private pharmacy, medical products store, warehouse, or the shop of trading in medical plants) is responsible for the accessory store that belongs to the institution.
- 11-The accessory store shall be licensed as a commercial activity and not connected with a private residence or a shop for another industry or has outlets connected to any of that. It is also necessary to address the competent district office to indicate the place to be licensed is a commercial store not a residential apartment, a garage, basement, or an administrative place and whether it belongs to state property or is located in a random un organized region and whether a decision has been issued to remove the building or not. In case of licensing accessory store belonging to a medical products store, the district office shall be addressed to ensure that the place is located in a city not in a village,
- 12-The original license of the accessory store, the layout approved by the competent health authority, a photocopy of the license of the original pharmaceutical institution to which the accessory store belongs and a photocopy of the license to practice the profession of the manager in charge of the original pharmaceutical institution shall always be kept in the accessory store for submission upon request.

13-The competent pharmacy administration shall send the licensing file of the accessory store belonging to a medical products store to the Egyptian drug Authority after fulfilling the health requirements and documents as stated in Annex No. (1), for review and taking decision, and the license shall be issued after payment of the service consideration.

(Article 3)

Owners of accessory store belonging to the pharmaceutical institutions existing at the time of publication of this decree shall reconcile the accessory store in terms of the health requirements of within a maximum period of one Gregorian year starting from the date of application of the decree.

(Article 4)

All decisions that contradict with this decree shall be cancelled.

(Article 5)

This decision shall be published in the Egyptian gazette, and shall be effective by the day following the date of its publication.

Head of the Egyptian Drug Authority

Prof /Tamer Mohamed Essam

Written on 25/5/2021

Annex No (1)

Documents required to be submitted to license accessory store belonging to a pharmaceutical institution:

- 1- an application signed by the owner of the original pharmaceutical institution to license an accessory store shall be directed to the competent pharmacy administration in the case of licensing accessory store belonging to a medical products store, a community pharmacy, a private pharmacy, or a shop that trades in medical plants, or the application shall be directed to the Egyptian Drug Authority in the case of licensing accessory store belonging to warehouse or factories licensed and subjected to the supervision of the Egyptian Drug Authority.
- 2- A layout of three copies of the accessory store to be licensed.
- 3- The receipt of payment of the examination fee of three Egyptian pounds.
- 4- An undertaking signed by the owner of the original pharmaceutical institution, stating that no selling of pharmaceutical products to public or any other pharmaceutical institution from the accessory store belonging to community pharmacy, private pharmacy, medical products store, warehouse, or shop for trading in medical plants, and stating that no storing of any pharmaceutical products belonging to another institution in it.

Documents to be completed during the accessory store licensing procedures and before issuing the license:

- 1- A copy of the contract of possession of the accessory store (rental contract, or ownership contract), and it shall be valid and authenticated (real estate declaration or court judgment) (bring the original for perusing).
- 2- The competent district to which the place to be licensed as a accessory store belongs, shall be addressed (in the case of a community pharmacy, private pharmacies, medical products store, warehouse, or shop for trading in medicinal plants). To ensure that the place to be licensed in terms of is a place with commercial activity and not a residential apartment, basement or garage, and to state whether it is located in a random unplanned region or not, and whether a demolition or removal decision has been issued for the building or not
 . Also, in case of licensing an accessory store belonging to a medical products store, the competent district shall state that the address of the place to be licensed is located in a city and not in a village.
 In case of licensing the accessory store in area belonging to the New Urban Communities Authority, it shall be addressed to give their an opinion on the current activity of the place under licensing, and approve the issuance of accessory store.
- 3- An original document from the electricity company stating that there is an independent electricity meter inside the place to be licensed as accessory store only. This document shall clearly state the meter number and the place address,
 or bring an original document from the electricity company stating that the electricity has been connected in the place permanently and independently until the meter is installed, with an explanation of the reason for not installing the meter from the electricity company. This document is required in case of a community pharmacy, a private pharmacy, a medical products store, a warehouse, or a shop for trading in medical plants).