

Minister of Health Decree

No. 380 of 2009

Reorganizing The Health Requirements For Pharmaceutical Institutions

Minister of Health:

After perusal the following

- Law No. 127 of 1955 regarding the pharmacy profession practice
- Law No. 453 of 1954 on Commercial and Industrial Workshop.
- The ministerial decree dated 9.05.1955 regarding imposing public health requirements for pharmaceutical institutions.
- The ministerial decree dated 03.04.1956 regarding health requirements for pharmaceutical institutions.
- Ministerial Decrees No. 265 of 1981 and 539 of 2007.
- Upon what was presented by the Minister Assistant for Pharmaceutical Affairs

Decided

(Article 1)

The attached health requirements regarding the licensing of pharmaceutical institutions shall be applied, and the ministerial decree dated 02.04.1956 shall be invalid.

(Article 2)

This decision shall be published in the Egyptian Official Gazette, and shall be applied from the day following the date of its publication.

Minister of Health

Issued on: 13/9/2009

This decision was published on the Egyptian Gazette; Issue No. 224 on 29.09.2009.

Health Requirements for Pharmaceutical Institutions

according to

Ministerial Decree No. (380) of 2009

To establish and issue a license of a pharmaceutical institution, the following requirements must be fulfilled:

- 1- The institution shall be constructed of modern non-combustible building materials that comply with the Egyptian standard conditions, the height of the ceiling shall not be less than 2.6 in any part of the institution.
- 2-The ground of the institution shall be at the same level as the ground adjacent thereto. The ground level can be lower than the ground adjacent to it but with a condition of taking adequate precautions to prevent water leakage inside the pharmaceutical institution, including the availability of a water drainage network, It is required not to hinder the patient's entry and exit to the pharmaceutical institution. In all cases it is not permissible to open a pharmaceutical institution in the basement.
- 3- The walls shall be covered with easy-to-clean materials to prevent bacterial growth.
- 4- That the pharmaceutical institution shall have a supply of public pure water, from which water shall be taken directly by a tap installed inside the institution at the top of the tub with a filter.
- 5- Good storage practice (GSP) shall be provided for the pharmaceutical products, in terms of:
 - a.Maintaining the temperature and humidity stated by the specifications of medicines and pharmaceutical products, installing thermometer and hygrometer in a visible place at the institution ,and recording the readings at fixed intervals during working hours, taking into account that the temperature shall not exceed 30 degrees Celsius and the pharmacist shall record the reading on a regular basis.
 - b.The necessity of having a refrigerator with a freezer equipped with a thermometer to store the products that need temperatures lower than room temperature, and recording the readings on a regular basis.
 - c. Allocating a safe and secured place for drugs that affect the psychological state and narcotic drugs.
 - d. Allocate a separate place for storing expired medical products away from the rest of the valid medical products in use, until these products are destroyed or returned to the producing company according to approved documents with coordination with the competent health authority, Provided that a sign shall be placed on this place with a clear phrase (Expired medicines must not be used).
 - e. Dispose of pharmaceutical waste in a safe and sound manner that shall not pose a threat to the environment or to the health of the community.
- 6-Allocate a suitable place in the pharmacy to counsel privately with the patient about the information related to their medication and ensure that the patient becomes aware of the appropriate way to use and store medication , its possible side effects and the appropriate and safe way to dispose the left medication after therapy program.

7-Providing access to the international information network and the use of a special program on the computer to keep records, medical prescriptions, and all data related to the pharmaceutical institution, as any information shall be invoke upon requesting it, as well as keeping the invoices and documents indicating the incoming and outgoing medicines for a period of at least five years.

8- The presence of a permanent source of electricity in the institution.

9- Placing a fixed banner on the door of the pharmaceutical institution indicating the name of the institution and the name of its owner.

10- Discharge of waste into public sewers according to the layout approved by the competent health authority. If there are no public sewers at a distance of 30 meters, the drain shall be in a separate tank built in a space belonging to the owner and outside the buildings according to the approved layout.

Sewer or tank openings shall be covered with tight iron covers and ventilated with a four-inch pipe higher by at least two meters than adjacent and opposite surfaces. Its upper opening shall be covered with a narrow wire mesh for preventing entry of insects.

The tankers shall have special entrances so that sweeping them does not cause any harm to the passage in any room of the pharmaceutical institution. The tankers shall also be at least two meters away from the walls, unless the tank is closed and isolated, in this case it is permissible to waive the requirement of distance from the walls.

And if the public sewers approach and become 30 meters or less from the pharmaceutical institution, sewage pipes shall be connected to it and the existing tanks shall be demolished after being swept.

The tubs shall be drained on gully trap that drain to the public sewage system, and the gully traps and sewer holes shall be located in a space outside the pharmaceutical institution.

It is prohibited to find any reservoir, sewer hole or gully trap under the ground of the institution. It is also not permissible to find drain pipes, siphons, or toilet bowls inside them. Drainage pipes may be passed under the ground of the institution in emergency cases approved by the competent health authority, in this case, all safety measures shall be taken.

11- In the case of a request to construct a bathroom: The bathroom shall be located in a separate place and have a door that does not open to areas of dealing with the public or storing area of pharmaceutical products. It shall have a window that opens to a street or a skylight. An air extractor may be used, and the toilet shall be drained into a special sewer hole that drains into public sewage system.

12- It is prohibited to rent or use any part of the institution for a purpose other than the purpose for which it is licensed.

13- It is prohibited to find materials or tools other than the materials and tools necessary for the work for which the pharmaceutical institution is licensed.

14- It is prohibited to have animals or birds in the pharmaceutical institution.

15- It must be ensured that the pharmaceutical institution matches the latest layout approved by the competent authorities, and it is prohibited to make any modification in the institution without obtaining in advance a written approval from the competent health authority.

16- The area of a community, private, or governmental pharmacy, or shops for trading in medical plants and their extracts, shall not be less than 40 square meters. For medical products stores or warehouses, the area shall not be less than 500 square meters. The medical products stores area may be divided into two levels, provided that they shall have a separate door from any other activity. As for factories of pharmaceutical products, enough space shall be available to achieve the requirements of good manufacturing practice GMP according to the guidelines of the World Health Organization WHO.

17- The original copy of the license, a copy of the approved layout drawing, the book of the workers authorized to work in the institution, the license to practice the profession of the managing pharmacist, and the Egyptian pharmacopoeia shall be kept in the institution at all times to be submitted upon request.

18- Warehouses, medical products stores, and shops for trading in medical plants and their extracts may be exempted from the requirements for the water source and the method of sewage, if there are no toilets inside the place.

19- As for the health requirements of the factories of pharmaceutical products, Ministerial Decree No. (265) of 1981 regarding the health and technical requirements that shall be met in pharmaceutical factories and Ministerial decree No. (539) for the year 2007 regarding the adoption of the Egyptian guidelines of good manufacturing practice for pharmaceutical products shall be applied.