

Law of Pharmaceutical Establishments

and Preparations

Royal Decree No. M/31

Dated 1/6/1425H – 18/7/2004

The following terms and phrases, wherever mentioned in this Law, shall have the meanings expressed next to them, unless otherwise required by context:

Ministry: Ministry of Health.

Minister: Minister of Health.

Profession: Profession of pharmacy.

Pharmacist: A person holding a bachelor's degree in Pharmaceutical Sciences or Doctor of Pharmacy (PharmD) degree from a Saudi Pharmacy College or equivalent.

Pharmacy Technician: A person holding a Pharmacy Technician diploma from a Saudi health institute or college or equivalent.

Licensed Pharmacist: A pharmacist licensed to practice the profession in the Kingdom.

Pharmaceutical Preparation (Medication): A pharmaceutically manufactured product containing one substance or more, and used externally or internally in treatment or prevention of human or animal diseases.

Herbal Preparations: Plants and herbs that have medical claims and are pharmaceutically prepared.

Pharmaceutical Establishment: A pharmacy or an establishment selling herbal preparations; a factory of pharmaceutical preparations; a store of pharmaceutical and herbal preparations; the scientific office of the pharmaceutical company; or a center of medicinal consultation and pharmaceutical preparations analysis.

Pharmacy: A pharmaceutical establishment where pharmaceutical products are prepared and dispensed.

Pharmaceutical and Herbal Preparations Sale Store: A pharmaceutical establishment licensed to import, distribute or wholesale pharmaceutical and herbal preparations.

Scientific Office: A pharmaceutical establishment that provides scientific, technical and marketing information on pharmaceutical preparations throughout the Kingdom.

Herbal Preparations Selling Establishment: A pharmaceutical establishment where herbal

products are prepared and dispensed.

Medicinal Consultation and Pharmaceutical Preparations Analysis Center: A pharmaceutical establishment that provides medicinal consultations, carry out analysis of pharmaceutical and herbal preparations, conduct bioavailability and bioequivalence studies, control quality of medicines and determine drug levels in biological fluids.

Regulations: The Implementing Regulations of this Law.

Article 2

A pharmaceutical establishment may not operate except after obtaining the required license from the Ministry in the name of owner.

Article 3

Ownership of a pharmacy, an establishment for sale of herbal preparations or a center for medicinal consultation and pharmaceutical preparations analysis shall be restricted to Saudis. Granting a license shall be subject to the following conditions:

- a- The owner, or one of the partners, must be a pharmacist holding a practice license. Existing establishments shall be exempted, except in cases of death, sale or assignment. The Minister may deem the nationality condition sufficient in remote areas specified by the Regulations.
- b- The manager of the pharmacy, establishment or center must be a full-time Saudi pharmacist holding a practice license. The Minister may grant exemption from the nationality condition in the absence of a sufficient number of Saudi pharmacists.
- c- The pharmacy, establishment or center shall satisfy the conditions and specifications set forth in the Regulations.

Article 4

Granting a license for a wholesale pharmaceutical and herbal preparations sale store shall be subject to the following:

- a- The license applicant shall be a Saudi national; in the case of an individual, he must be at least 21 years of age.
- b- The applicant must not have been convicted of a crime impugning honor or integrity unless rehabilitated.
- c- The manager shall be a full-time Saudi pharmacist or pharmacy technician holding a practice license.
- d- The sale store shall satisfy the conditions and specifications set forth in the Regulations.

Article 5

Licensing for a pharmaceutical and herbal preparations factory shall be subject to the following:

- a- Obtaining a manufacturing license issued by the competent authority.
- b- The technical manager of the factory shall be a full-time Saudi pharmacist holding a practice license.
- c- The factory shall satisfy the conditions and specifications set forth in the Regulations.

Article 6

A company or a pharmaceutical preparation manufacturing establishment with a factory registered in the Kingdom shall have a scientific office. Granting the license for the scientific office shall be subject to the following:

- a- The office manager shall be a full-time Saudi pharmacist holding a practice license.
- b- The office shall satisfy the conditions and specifications set forth in the Regulations.

Article 7

The term of a pharmaceutical establishment license shall be five renewable years.

Article 8

An applicant for a pharmaceutical establishment license or renewal thereof shall pay the prescribed fees as follows:

Pharmaceutical establishment License or Renewal Fee

Pharmaceutical and herbal preparations sale store 3,000 riyals

Pharmacy 1,000 riyals

Medical herbs sale store 1,000 riyals

Medicinal consultation and pharmaceutical preparations analysis center 1,000 riyals

Scientific office 1,000 riyals

Article 9

Licensing for a hospital dispensary shall be included in the hospital license.

Article 10

A pharmaceutical establishment may not employ unlicensed pharmacists or pharmacy technicians.

Article 11

Only a full-time licensed Saudi pharmacist holding a practice license may work in the field of advertising and introducing pharmaceutical and herbal preparations. The Minister may grant exemption from the nationality condition in the absence of an adequate number of Saudi pharmacists.

Article 12

Medicines shall be priced based on factory price or price of export to the Kingdom in the currency of the country of origin or any other currency designated by the Ministry. The Ministry shall periodically review prices of medicines.

Article 13

A profit margin shall be added to prices of medicines for a wholesale pharmaceutical preparations sale store and pharmacy as follows:

Factory or Export Price	Sale Store Profit Margin (Based on Factory or Export Price)	Pharmacy Profit Margin (Based on Pharmaceutical Sale Store Price)
50 riyals or less	15%	20%
More than 50 riyals and not exceeding 200 riyals	10%	15%
More than 200 riyals	10%	10%

Article 14

A pharmaceutical establishment must sell registered pharmaceutical preparations in packages specified by the Ministry. Such preparations may not be offered for sale prior to pricing by the competent authority.

Article 15

Samples of pharmaceutical and herbal preparations intended for promotion may not be offered for sale.

Article 16

Pharmaceutical preparations may not be sold retail except in pharmacies. As an exception, the Minister shall issue a list of pharmaceutical preparations that may be sold retail in outlets other than pharmacies.

Article 17

Herbal preparations, to be determined by a Minister's decision, may not be sold except in pharmacies or herbal preparations sale establishments.

Article 18

Pharmaceutical establishments may not possess any amount of pharmaceutical and herbal preparations without having documents establishing purchase origin and quantities.

Article 19

Pharmaceutical and herbal preparations may not be circulated prior to registration with the Ministry.

Article 20

Committees for registration of factories of pharmaceutical preparations and products shall be formed by a Minister's decision. The Regulations shall determine registration conditions and manner of formation of said committees as well as their work procedures. Remuneration of committee members shall be determined by a Council of Ministers' resolution upon recommendation by the Minister.

Article 21

A pharmaceutical and herbal preparations factory shall be registered for a renewable five-year term for a fee of five thousand riyals paid upon registration or renewal.

Article 22

A pharmaceutical or herbal preparation shall be registered for a renewable five-year term for a fee of one thousand riyals for any concentrates, pharmaceutical formula or package paid upon registration or renewal.

Article 23

Pharmaceutical preparations factories registered in the Kingdom and their representative sale store shall make available registered pharmaceutical and herbal preparations thereof regardless of price or consumption rate.

Article 24

Pharmacies shall make available pharmaceutical preparations registered in the Kingdom. The Ministry shall issue a list of pharmaceutical preparations that must be made available in pharmacies.

Article 25

Unregistered pharmaceutical preparations may not be exported without the Ministry's approval.

Article 26

The Ministry may, if necessary, approve the import of unrestricted pharmaceutical and herbal preparations prior to registration.

Article 27

The Minister may issue a decision to revoke the registration of a pharmaceutical and herbal preparations factory or any pharmaceutical or herbal preparation or halt circulation thereof, based on a recommendation by the competent registration committee. The Ministry may approve re-export or destruction of said preparation.

Article 28

The Ministry may approve entry of unrestricted pharmaceutical and herbal preparations in limited quantities for personal use, pursuant to a medical report.

Article 29

Taking into consideration the exception stipulated in Article 16, pharmaceutical and herbal preparations sale stores may sell pharmaceutical and herbal preparations only to licensed medical establishments and pharmacies.

Article 30

Pharmaceutical and herbal preparations sale stores may import registered pharmaceutical and herbal preparations if not made available by the factory, based on the Ministry's approval.

Article 31

A pharmaceutical preparations factory may not commence manufacturing pharmaceutical and herbal preparations in commercial quantities prior to registration.

Article 32

A pharmaceutical preparations factory may not be used for any purpose other than manufacturing pharmaceutical and herbal preparations the factory is licensed for.

Article 33

A pharmaceutical preparations factory shall follow guidelines of Good Manufacturing Practice (GMP) for pharmaceutical and herbal preparations.

Article 34

A pharmaceutical establishment shall be liquidated according to procedures set forth in the Regulations.

Article 35

The Ministry may inspect pharmaceutical establishments to ensure compliance with provisions of this Law, its Regulations and decisions issued by the Ministry in accordance therewith. Ministry inspectors shall have the right to record and report violations.

Article 36

Advertising pharmaceutical and herbal preparations in the media shall be subject to controls set forth in the Regulations.

Article 37

Committees formed under the Law of Private Health Institutions issued by Royal Decree No. M/40 dated 3/11/1423H shall consider violations of the provisions of this Law. Said committees may, without prejudice to any severer penalty prescribed by another law, impose one or more of the following penalties:

- 1- Warning
- 2- A fine not exceeding one hundred thousand riyals
- 3- Closure of the establishment for a period not exceeding sixty days.
- 4- Revocation of the establishment license.

Committee decisions shall be approved by the Minister and may be appealed before the Board of Grievances within sixty days from the notification date. The final decision imposing the penalty may be published at the expense of the violator in three local newspapers, one of which is issued in the area where the pharmaceutical establishment is located.

Article 38

~~The Minister shall issue the Implementing Regulations of this Law within ninety days from date~~ of publication in the Official Gazette. Said Regulations shall become effective upon entry into force of this Law.

Article 39

This Law shall repeal the Articles relating to trading in medicines and pharmaceutical preparations set forth in the Law of Pharmacy Practice and Trading in Medicines and Medical Preparations issued by Royal Decree No. (M/18) dated 18/3/1398H.

Article 40

Subject to the exception provided for in Paragraph (a) of Article 3 of this Law, all pharmaceutical establishments shall adjust their status according to the Provisions of this Law within one year from its effective date.

Article 41

This Law shall be published in the Official Gazette, and shall enter into force one hundred and twenty days from its publication date.