Bureau of Experts at the Council of Ministers

Official Translation Department

Law of Pharmaceutical and Herbal Establishments and Preparations

Royal Decree No. M/108
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Translation of Saudi Laws

NOTES:

1. This translation is provided for guidance. The governing text is the Arabic text.
2. The translation of Saudi laws takes the following into consideration:
   - Words used in the singular form include the plural and vice versa.
   - Words used in the masculine form include the feminine.
   - Words used in the present tense include the present as well as the future.
   - The word “person” or “persons” and their related pronouns (he, his, him, they, their, them, and who) refer to a natural and legal person.

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Law of Pharmaceutical and Herbal Establishments and Preparations

Article 1

In this Law, the following words and phrases shall have the meanings assigned thereto, unless the context requires otherwise:

Law: Law of Pharmaceutical and Herbal Establishments and Preparations.

Authority: Saudi Food and Drug Authority.

Board: Board of Directors of the Authority.

CEO: Chief Executive Officer of the Authority.

Pharmacist: A person holding a bachelor's degree in pharmaceutical sciences or a doctor of pharmacy degree from a college of pharmacy in the Kingdom, or their equivalent.

Pharmacy Technician: A person holding a pharmacy technician degree from a health institute or college in the Kingdom, or its equivalent.

Pharmaceutical Preparation (**Medication**): A pharmaceutically manufactured product which contains one or more substances used externally or internally in the treatment or prevention of human diseases.

Herbal Preparation: Any plant or herb with therapeutic claims that is pharmaceutically prepared.

Counterfeit Pharmaceutical or Herbal Preparation: A preparation the content, identity, or source of which is intentionally altered with the intent to deceive, even if the ingredients remain the same, including preparations with trademarks and generic marks. A pharmaceutical or herbal preparation shall be deemed counterfeit if it is contaminated; contains contaminated, incorrect, inactive, or ineffective ingredients; does not contain active ingredients; or is packed in counterfeit packages.

Spoiled Pharmaceutical or Herbal Preparation: A preparation the properties of which have changed, rendering it unfit for use.

Pharmaceutical Establishment: Any pharmaceutical and herbal preparations factory or wholesale warehouse, scientific office, or medicinal consultation or pharmaceutical and herbal preparations analysis center.

Pharmacy: An establishment where pharmaceutical and herbal preparations are prepared and dispensed or sold.

Pharmaceutical and Herbal Preparations Wholesale Warehouse: A pharmaceutical establishment which imports, distributes, or sells pharmaceutical and herbal preparations wholesale.

Scientific Office: A pharmaceutical establishment which provides scientific, technical, and marketing information on pharmaceutical and herbal preparations in the Kingdom.

Herbal Preparations Outlet: An establishment where herbal preparations are prepared and sold.

Medicinal Consultation or Pharmaceutical and Herbal Preparations Analysis Center: A pharmaceutical establishment that provides medicinal consultations, analyzes pharmaceutical and herbal preparations, conducts bioavailability and bioequivalence studies, controls the quality of medicines, and determines drug levels in biological fluids

Regulations: Implementing Regulations of this Law.

Article 2

A pharmaceutical establishment shall not operate without obtaining the required license from the Authority in the name of its owner.

Article 3

A medicinal consultation or pharmaceutical and herbal preparations analysis center shall meet the following licensing conditions:

1. The director is a full-time pharmacist licensed to practice the profession.
2. The center complies with the conditions and specifications specified by the Regulations.

Article 4

A pharmaceutical and herbal preparations wholesale warehouse shall meet the following licensing conditions:

1. The director is a full-time pharmacist or pharmacy technician licensed to practice the profession.
2. The warehouse complies with the conditions and specifications specified by the Regulations.

Article 5

A pharmaceutical and herbal preparations factory shall meet the following licensing conditions:

1. An industrial license is obtained from the competent authority.
2. The technical director is a full-time Saudi pharmacist licensed to practice the profession.
3. The factory complies with the conditions and specifications specified by the Regulations.

Article 6

Each company or sole proprietorship manufacturing pharmaceutical or herbal preparations, which has a factory registered in the Kingdom, shall have a scientific office. A scientific office shall meet the following licensing conditions:

1. The director is a full-time Saudi pharmacist licensed to practice the profession.

2. The office complies with the conditions and specifications specified by the Regulations.

Article 7

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

Article 8

Pharmaceutical establishments shall, when applying for the issuance or renewal of a license, pay the fees as specified below:

Pharmaceutical Establishment	Fee
Pharmaceutical and herbal preparations factory	10,000 riyals
Pharmaceutical and herbal preparations wholesale warehouse	3,000 riyals
Medicinal consultation or pharmaceutical and herbal preparations analysis center	1,000 riyals
Scientific office	1,000 riyals

Article 9

A pharmaceutical establishment may not hire pharmacists, pharmacy technicians, or other health practitioners unless they are licensed to practice the profession.

Article 10

Only full-time Saudi pharmacists licensed to practice the profession may work in the advertisement and promotion of pharmaceutical and herbal preparations. The CEO may waive the nationality requirement in case of a shortage in the number of Saudi pharmacists.

Article 11

A pharmaceutical or herbal preparation shall be priced based on factory price or the price of export to the Kingdom in the currency of the country of origin or the currency determined by the Authority. The Authority shall review the prices of pharmaceutical and herbal preparations on a regular basis.

Article 12

A markup shall be added to the price of a pharmaceutical or herbal preparation for each pharmaceutical and herbal preparations wholesale warehouse, pharmacy, and herbal preparations outlet, as follows:

Factory or Export Price	Warehouse Markup (based on factory or export price)	Pharmacy or Herbal Preparations Outlet Markup (based on the sale price of the preparation determined for the warehouse)
50 riyals or less	15%	20%
More than 50 riyals and up to 200 riyals	10%	15%
More than 200 riyals	10%	10%

Article 13

Promotional samples of pharmaceutical and herbal preparations may not be sold.

Article 14

1. Retail pharmaceutical preparations may only be sold in pharmacies. As an exception, the CEO may decide the preparations that may be sold elsewhere.
2. Retail herbal preparations may only be sold in pharmacies and herbal preparations outlets. As an exception, the CEO may decide the preparations that may be sold elsewhere.

Article 15

1. It is prohibited for a pharmaceutical establishment to hold any quantity of pharmaceutical or herbal preparations without having documents establishing the origin of purchase and quantities thereof.
2. A pharmaceutical and herbal preparations factory shall replace any quantity of preparations sold to a pharmaceutical and herbal preparations wholesale warehouse if the expiration date is within one month. The same shall apply to the warehouse vis-à-vis the pharmacy.

Article 16

Any person who dispenses or sells a counterfeit, spoiled, expired, or unregistered pharmaceutical or herbal preparation shall, upon knowledge thereof, notify the Authority of the information related to the dispensed or sold preparation and its quantity as well as the name and address of the person to

whom the preparation was dispensed or sold. Such person shall also refund the buyer.

Article 17

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

Article 18

The registration term of a pharmaceutical or herbal preparation shall be five renewable years; a fee of one thousand riyals shall be collected, upon registration or renewal, for each concentration, pharmaceutical formula, or package.

Article 19

Registered pharmaceutical and herbal preparations may only be sold in accordance with the prices and packages determined by the Authority.

Article 20

Committees for the registration of pharmaceutical and herbal preparations factories and products shall be formed pursuant to a decision by the CEO. The Regulations shall determine the registration conditions as well as the manner of formation and work procedures of said committees. The remuneration of committee members shall be determined pursuant to a Board decision.

Article 21

Pharmaceutical and herbal preparations factories registered in the Kingdom and their representative wholesale warehouses shall make registered pharmaceutical and herbal preparations available however low their price or consumption is.

Article 22

Pharmaceutical and herbal preparations may not be exported without the Authority's approval.

Article 23

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

Article 24

The CEO may issue a decision to revoke the registration of any pharmaceutical and herbal preparations factory or any pharmaceutical or herbal preparation and halt its circulation upon a recommendation by the competent registration committee. The Authority may approve the re-exportation or destruction of said

preparation.

Article 25

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

Article 26

Subject to the exception referred to in Article 14 of this Law, pharmaceutical and herbal preparations wholesale warehouses shall not sell pharmaceutical and herbal preparations to other than licensed pharmacies, herbal preparations outlets, and medical establishments.

Article 27

Pharmaceutical and herbal preparations wholesale warehouses may import registered pharmaceutical and herbal preparations which are not made available by the producing factory, subject to the Authority's approval.

Article 28

A pharmaceutical and herbal preparations factory may not produce pharmaceutical and herbal preparations in commercial quantities unless they are registered.

Article 29

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

Article 30

A pharmaceutical and herbal preparations factory shall apply the guidelines of good manufacturing practice.

Article 31

Advertising for pharmaceutical and herbal preparations shall be subject to controls set by the Regulations.

Article 32

A pharmaceutical establishment shall be liquidated pursuant to the procedures set by the Regulations.

Article 33

The Authority shall, through inspectors appointed pursuant to a decision by the

CEO, inspect pharmaceutical establishments as well as pharmaceutical and herbal preparations to verify compliance with the provisions of this Law and the Regulations. Such inspectors shall, within the limits of the Regulations, have the following powers:

1. Seize pharmaceutical and herbal preparations in violation of the provisions of this Law.
2. Handle the seized items as follows:
   a) Take the seized items and any documents related thereto into custody, when necessary.
   b) Take samples for testing.
   c) Recommend the destruction of registered items proven to be spoiled, counterfeit, expired, or harmful to health.
   d) Recommend the destruction of unregistered seized items.

Said items shall be destroyed pursuant to a decision by the Authority and in accordance with accepted technical practices. Destruction shall be at the violator's expense and shall be undertaken by a committee, or more, formed for such purpose pursuant to a decision by the CEO.

Article 34

Any person who commits any of the following acts shall be deemed to have violated this Law:

1. Counterfeiting or attempting to counterfeit any pharmaceutical or herbal preparation.
2. Selling, dispensing, or possessing with the intent to trade, a counterfeit, spoiled, expired, or unregistered pharmaceutical or herbal preparation.
3. Manufacturing or formulating a pharmaceutical or herbal preparation in violation of the registration conditions, or in violation of any of the provisions of this Law and the Regulations.
4. Bringing or attempting to bring into the Kingdom an unregistered, counterfeit, spoiled, or expired pharmaceutical or herbal preparation.
5. Using false information to promote a pharmaceutical or herbal preparation, whether on the preparation or in advertising, or in violation of the registration conditions.
6. Transporting or storing a pharmaceutical or herbal preparation in violation of the transportation and storage conditions prescribed by the Authority.
7. Bringing or attempting to bring into the Kingdom, with the intent to deceive, the packages or wrappers of a pharmaceutical or herbal preparation.
8. Manufacturing, printing, possessing, selling, or displaying, with the intent to deceive, the packages or wrappers of a pharmaceutical or herbal preparation.
9. Committing any other violation of the provisions of this Law.

Article 35

1. Without prejudice to any harsher penalty provided for in any other law, a person who commits any of the acts set forth in Article 34 of this Law shall

be subject to one or more of the following penalties:

a) A fine not exceeding five million riyals.

b) Temporary closure of the pharmaceutical establishment for a period not exceeding 180 days.

c) Cancellation of the license.

The penalties stipulated in paragraphs (a) and (b) may be doubled if the violation is repeated.

2. If the violation involves committing any of the acts set forth in Article 34(1, 2, 4, 7, and 8) of this Law, the violator shall be subject to imprisonment for a period not exceeding 10 years or a fine not exceeding 10 million riyals, or to both penalties. Additionally, either of the penalties provided for in paragraphs (1)(b) or (1)(c) of this Article may be imposed.

Article 36

The Authority shall undertake the imposition of fines that are less than one hundred thousand riyals against violating scientific offices and medicinal consultation or pharmaceutical and herbal preparations analysis centers; the imposition of fines that are less than two hundred thousand riyals against violating pharmaceutical and herbal preparations wholesale warehouses; and the imposition of fines that are less than three hundred thousand riyals against violating pharmaceutical and herbal preparations factories, according to a table issued by the Board which includes a classification of the violations and their corresponding penalties. Said penalties shall be approved pursuant to a decision by the CEO or his designee. In all cases, the Authority may, when necessary, take any precautionary measures it deems appropriate.

Article 37

1. A committee, or more, shall be formed pursuant to a decision by the Board and shall comprise no less than three members, one of which, at least, shall be a legal advisor.
2. Without prejudice to the provisions of Article 36 of this Law, the committee, referred to in paragraph (1) of this Article, shall have the following powers:
   a) Reviewing violations of the provisions of this Law, excluding the violations provided for in Article 35(2), and imposing the penalties stipulated in Article 35(1) of this Law.
   b) Reviewing appeals filed with the Authority against penalty decisions issued in accordance with Article 36 of this Law.
3. The committee's work rules and procedures and the remuneration of its members shall be determined pursuant to a Board decision.
4. Committee decisions may be appealed before the Administrative Court within 60 days from the date of knowledge thereof. If the Administrative Court revokes the penalty decision issued by the committee, it shall review the violation and impose the penalty it deems appropriate from among the penalties stipulated in Article 35 of this Law.

Article 38

Violations governed by Article 35(2) of this Law shall be referred to the Public Prosecution for investigation and referral to the competent court in accordance with statutory procedures.

Article 39

The judgment or penalty decision, as the case may be, may provide for the publication of the text of the ruling at the expense of the violator in a local newspaper issued in his area of residence or in the nearest area if no newspaper is published in his area of residence, or in any other appropriate medium, depending on the type, gravity, and impact of the violation. Publication shall be made after the judgment becomes final or the decision becomes unappealable upon the lapse of the appeal period or upon being affirmed by the competent court.

Article 40

The Board shall issue the Regulations within 120 days from the date of publication of this Law in the Official Gazette. The Regulations shall become effective after this Law enters into force.

Article 41

This Law shall supersede the Law of Pharmaceutical Establishments and Preparations promulgated by Royal Decree No. M/31, dated 1/6/1425H, and shall repeal any provisions conflicting therewith

Article 42

This Law shall enter into force 120 days following the date of its publication in the Official Gazette.