

Decree-Law No. (20) for the year 2015
Amending certain provisions of Decree Law No. 18 of 1997
With regard to the organization of the pharmacy profession and
pharmaceutical centres

We are Salman bin Hamad Al Khalifa, Acting King of the Kingdom of Bahrain.

After reviewing the Constitution, and in particular Article (87) thereof,

And the Decree-Law No. (2) for the year 1987 regarding the practice of non-doctors and pharmacists for allied health professions,

And Decree-Law No. (18) of 1997 regarding the organization of the pharmacy profession and pharmaceutical centres,

And the Code of Criminal Procedure promulgated by Legislative Decree No. 46 of 2002, as amended,

Law No. (81) for the year 2006 approving the unified system of industrial organization of the GCC countries,

Law No. 15 of 2007 on narcotic drugs and psychotropic substances,

Law No (38) for the year 2009 establishing the National Health Regulatory Authority

Based on the proposal of the Prime Minister,
and after the Council of Ministers' agreement,

We have drawn up the following law:

Article 1

The title of pharmacists in article (1) and in the provisions of articles 14, 21, 27, 28, 33, 1, 45, 46 and 55, the fourth chapter title, and the articles number: (57 first paragraph), (58), (83), (86 first paragraph), (91 third paragraph), (93) and (107) of Decree Law No. (18) 1997 concerning the organization of the pharmacy profession and pharmaceutical centres, the following texts:

Article (1) Definition of pharmacy profession:

Producing, installing, preparing, retailing or possessing for the purpose of sale any medicine, drug or medicinal plant authorized to be sold in pharmacies or a drug used by external or internal or by injection to prevent, treat or have a physiological effect on the body or are described to have these advantages.

Article (14)

A pharmaceutical centre may not be established without the prior authorization of the Authority. The application for licensing shall be submitted to the authority in accordance with the conditions and procedures determined by a decision of the Board of Directors.

Article (21)

The pharmaceutical centre may not be used for any purpose other than the purpose for which it is licensed, nor shall it have direct or indirect contact with a private residence in the manner in which it makes it part of it.

Article (27)

The license to open a public pharmacy may only be granted to Bahraini nationals and Bahraini companies, provided that the owner of the pharmacy or any of its partners is not subject to a felony or an offense against honour or trust unless he has been rehabilitated in both cases or pardoned of the concerned authorities.

In any case, the pharmacy administration must be entrusted to a legal pharmacist notified by the owner of the pharmacy, and the pharmacy director may not manage more than one pharmacy at the same time. He must be available in the pharmacy at all times were it is open to the public to operate the pharmaceutical procedures in it.

Article (28)

No natural or legal person or a partner in a company may be licensed to open more than five pharmacies.

The number referred to in paragraph 1 of this Article may be exceeded by one pharmacy in any area of more than five square kilometres without an existing pharmacy, in accordance with the regulations and procedures determined by a decision of the Board of Directors.

Article 33

1- The owner of the pharmacy shall immediately notify the Authority, as soon as the pharmacy director quit the job through a registered letter. The owner of the pharmacy must appoint a new director within a period not exceeding thirty days from the date of departure and should notify the authority through registered mail with the letter of the acceptance of the new director to manage the pharmacy.

Article (45)

Without prejudice to the laws governing industrial activities and factories, it is prohibited for any natural or legal person to establish a factory for drugs and pharmaceuticals products without providing the approval of the Authority to meet the specifications and standards determined by the Authority.

In all cases, it is prohibited to operate any drug and pharmaceutical products factory without obtaining an operating certificate from the Authority.

The procedures for submitting the application for approval and the certificate referred to in this Article shall be determined by a decision of the Board of Directors, the rules of granting them, the particulars recorded therein, the duration of their validity and the fees prescribed therein.

Article (46)

It shall apply to the notification of the decision rejecting the application for approval and the certificate referred to in Article (45) of this Law, and the appeal against it and the appeal against the same provisions stipulated in Article (20) of the same law.

Article (55 final paragraph):

A decision of the Board of Directors shall be issued specifying the models of these records and the registration requirements therein and any requirements to ensure their safety and to prevent tampering and manipulating with their data and information.

The fourth chapter:

Import, Export, Marketing and Research of Drugs and Pharmaceutical Products.

Article (57):

With the exception of pharmaceutical facilities, drugs and pharmaceutical products - even free medical samples - may not be imported except through the pharmacy centres and subject to obtaining a license from the Authority, in accordance with the conditions and procedures determined by a decision of the Board of Directors.

Article (58):

It is prohibited to import drugs and pharmaceutical products for personal use, whether in the form of parcels or others, unless the conditions specified by a decision of the Board of Directors are met.

Article (83)

The pharmacist may not replace the medicine or pharmaceutical product prescribed in the prescription with another drug. In addition, the pharmacist may, with the consent of the patient, dispense a drug similar to that prescribed in the prescription if the drug contains the same active ingredient and the same concentration in the prescribed medicine, as long as the physician did not document otherwise

Article (86):

The maximum permissible profit in the trade of drugs and pharmaceutical products shall be determined by a decision of the Board of Directors. Profit in each substance or pharmaceutical product shall be calculated on the basis of its cost as indicated in the official invoices

Article (91) paragraph 3:

The employees referred to in the first paragraph of this article shall be granted the status of judicial control officers by a decision of the Minister of Justice in agreement with the Board of Directors, in respect of the crimes provided for in this law which fall within their jurisdiction and shall be related to their functions. and all criminal investigation records shall be referred to the public prosecutor From the CEO.

Article (93):

(A) A term of not less than three months' imprisonment and a fine not exceeding ten thousand Dinars or one of these two penalties shall be imposed, and the shop where the violation was committed and the material and equipment confiscated in any of the following acts:

- (1) Establish or operate a pharmaceutical centre without a license, or establish or operate a drug and pharmaceutical product factory without obtaining the certificate referred to in Article (45) of this law in force.
- 2) Provide incorrect data or resort to illegal methods that unlawfully result in obtaining a license to establish a pharmacy centre or a place to store medicines outside the pharmacy or obtain the certificate referred to in Article (45) of this law.

3) Store medicines or pharmaceutical products outside a pharmacy in an unauthorized location.

In all cases, the Authority must administratively close the premises where the violation occurred until the criminal proceedings are settled.

(B) Any person who contravenes the provisions of Article (53) of this law shall be punished by imprisonment for a period of not less than three months and a fine not exceeding ten thousand dinars or one of these two penalties. The court may close the shop where the violation occurred and confiscate the materials and equipment.

The Authority shall administratively close the premises where the violation occurred until the criminal proceedings are settled.

Article (107):

The provisions of this Law shall not prejudice any of the provisions of Law No. (15) of 2007 on narcotics and psychotropic substances.

Article 2

The definitions of "Authority", "Board of Directors", "Chief Executive Officer" and "Pharmaceutical Establishment" shall be added to Article (1) of Decree-Law No. (18) of 1997 regarding the organization of the pharmacy profession and pharmacy centres. (4 bis), (36 bis), (96 bis), (99 bis) and (107 bis), the following texts shall be added:

Article (1)

The Authority: The National Health Regulatory Authority

Board of Directors: NHRA Board of Directors.

Chief Executive Officer: NHRA Chief Executive Officer.

Pharmaceutical establishment: An entity licensed to engage in the import, export or marketing of medicines or to carry out pharmaceutical research and studies.

Article (23 Second Paragraph):

Keeping or storing medicines in a place separate independent from the pharmaceutical centre is not permitted unless authorised by the authority and after the payment of the prescribed fee, in accordance with the procedures set out in this law regarding the licensing of the pharmacy centres. A decision of the Board of Directors shall be issued on the conditions that must be met in those places. and the regulations to be considered during the transfer of medicines and pharmaceutical products from and to these places.

Article (26) Item 4:

4- If it is proved that the pharmacy centre is operated or managed by another person who is not licensed or one of its employees.

Article (40 bis):

The pharmacist may, after obtaining a license from the Authority and paying the fee prescribed for this license, conduct simple laboratory tests for individuals, by the legal pharmacists working in them. A decision shall be issued by the Board of Directors to determine the types of laboratory tests, licensing procedures and categories.

Article (63 bis):

It is permissible to authorize the pharmaceutical establishments to carry out the activities of importing, exporting and marketing medicines, conducting research and pharmacological studies in accordance with the conditions and fees determined by the decision on of the Board of Directors. The license shall determine the licensed activity of the pharmaceutical establishment and its duration shall be one year extendable to similar periods.

Article (96 bis):

Without prejudice to the criminal liability of a natural person, a legal person shall be liable to a fine not exceeding twenty thousand dinars if any of the offenses established under the provisions of this law have been committed in his

name or for his account or for his benefit. And was the result of the approval or concealment or gross negligence of a board member, Director or other official authorized by such legal person.

Article (99 bis):

Without prejudice to criminal or civil liability, and taking into account the provisions of Articles (98) and (99) of this Law, the Committee shall have the following penalties for the pharmacy centres that prove their violation of the provisions of this law:

- 1) Warning.
- 2) Close the pharmacy for a period not exceeding one year.
- 3) Cancellation of the license of the pharmacy permanently and the deletion of its name from the Authority's registry.
- 4) The owner of the pharmacy or any of its partners, if it was company, is denied access to new licenses to open pharmacies for a period not exceeding five years from the date of the decision of deprivation.

Article (107 bis):

The provisions of this Law shall not prejudice the rights established for the benefit of any natural or juridical person in accordance with the bilateral or international agreements in force in the Kingdom of Bahrain.

Article 3

The pharmacies shall comply with their provisions in accordance with the provisions of this law within six months of the date on which the provisions of this law shall apply.

Article 4

The definition of ministry and minister in Article (1) of Decree-Law No. (18) for the year 1997 concerning the organization of the pharmacy profession and pharmaceutical centres shall be repealed as well as Articles (17), (29), (30), (31) and 32 second paragraph) and (34) of the same law.

Article 5

The word "the Authority" shall replace the word "the Ministry", and the sentence "the Board of Directors" shall replace the word minister. and "the concerned section of authority" shall replace the sentence "the Department of Pharmacy in the Ministry", "the Department of Pharmacy and Drug Control"; "The Pharmacy and Drug Control Committee of the Ministry", and replace "owners of the pharmacy" with the words "pharmacy owner". and the words "Criminal" by "Penal" and the words " Undersecretary of the Ministry of Health " the word " CEO ", wherever they appear in Decree-Law No. (18) of 1997 concerning a profession Pharmacy and Pharmaceutical Centres.

Article 6

The Prime Minister and the Ministers, each in his own capacity, shall implement the provisions of this Law and shall come into force one month after the date of its publication in the Official Gazette.

Acting King of the Kingdom of Bahrain

Salman bin Hamad Al Khalifa

Prime Minister

Khalifa bin Salman Al Khalifa

Issued at Riffa Palace:

Date: 1 Dhul Qadah 1436 e

Corresponding to: 16 August 2015