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**Legislative Decree No. (20) of 2015 amending some provisions of Decree Law No. (18) of 1997 regarding the Regulation of the Pharmacy Profession and Pharmaceutical Centers**

We, Salman Bin Hamad Al Khalifa, Acting King of the Kingdom of Bahrain,

Having reviewed the Constitution, especially Article (87) thereof;

Legislative Decree No.(2) of 1987 regarding the Practice of Non-Physicians and Pharmacists of Allied Medical Professions;

Legislative Decree No.(18) of 1997 regarding the Regulation of the Pharmacy Profession and Pharmaceutical Centers;

Criminal Procedures Law promulgated by Legislative Decree No.(46) of 2002, as amended;

Law No. (81) of 2006 approving the Unified law (Statute) of the Industrial organization for The Gulf Cooperation Council.

Law No. (15) of 2007 regarding Narcotic Drugs and Psychotropic Substances;

Law No. (38) of 2009 establishing the National Health Regulatory Authority,

And upon the submission of the Prime Minister,

And after the approval of the Council of Ministers;

**Hereby Decree the following Law:**

**Article One**

The definition of " Pharmacy Profession " contained in article (1), and the texts of articles: (14), (21), (27), (28), (33, paragraph 1), (45 ), (46), and (55 last paragraph), the title of the fourth chapter, and the article numbers: (57 first paragraph), (58), (83), (86 first paragraph), (91 third paragraph), (93) and (107) of Legislative Decree No (18) of 1997 regarding the regulation of the pharmacy profession and pharmaceutical centres, The following texts:

**Article (1) Definition of Pharmacy Profession:**

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 center 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 center 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 offence against honour or trust unless he has been rehabilitated in both cases or pardoned by the concerned authorities.

In any case, the pharmacy administration must be entrusted to a legal pharmacist, who the owner should notify the authority of, and the pharmacy director may not manage more than one pharmacy at the same time

A legal pharmacist must be available in the pharmacy at all times when 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 one of this Article may be exceeded by one pharmacy in any area of more than five square kilometers without an existing pharmacy, in accordance with the regulations and procedures determined by a decision of the Board of Directors.

**Article (33 paragraph 1):**

1- The owner of the pharmacy shall immediately notify the Authority, -as soon as the pharmacy director quit this 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 letter attached to it the letter of the acceptance of the new director to manage the pharmacy.

**Article (45):**

Without prejudice to the laws governing the 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, in addition to the rules of granting them, the information 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, the grievance against it and the appeal against the same provisions stipulated in Article (20) of the same law.

**Article (55 last 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.

**Chapter Four:**

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

**Article (57 first paragraph):**

With the exception of pharmaceutical facilities, drugs and pharmaceutical products - even free medical samples - may not be imported except through the pharmaceutical centers 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. An exception to that, 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 in the prescription.

**Article (86 first paragraph):**

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 provided that the permissible profit rate decreases as the cost price increases and increases as the cost price decreases.

**Article (91 third paragraph):**

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 by a decision from the Chief Executive Officer.

**Article (93):**

a) A penalty of at least three months' imprisonment and a fine not exceeding ten thousand dinars or either of these two penalties, and the closure of the shop in which the offence occurred and the confiscation of all the materials and equipment it contains, each of the following:

1) Established or operated a pharmaceutical centre without a license, or established or operated a drug and pharmaceutical product factory without obtaining the certificate in force referred to in Article (45) of this law.

2) Provided incorrect data or resorted to illegal methods that unlawfully result in obtaining a license to establish a pharmacy centre or a place to store medicines outside the pharmaceutical center or obtained the certificate referred to in Article (45) of this law.

3) Stored 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 violates 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 regarding Narcotic Drugs and Psychotropic Substances.

**Article Two**

The definitions of "Authority", "Board of Directors", "Chief Executive Officer" and "Pharmaceutical Establishment" shall be added to Article (1) of Legislative Decree No. (18) of 1997 regarding the organization of the pharmacy profession and pharmaceutical centers. A second paragraph shall be added to Article (23) and a new clause under the number (4) to Article (26), and new articles shall be added with the numbers (40 bis), (63 bis), (96 bis), (99 bis) and (107 bis), the texts of which shall be as follows:

**Article (1):**

**Authority:** The National Health Regulatory Authority.

Board of Directors: The Authority’s Board of Directors.

**Chief Executive Officer:** The Chief Executive Officer of the Authority.

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 Paragraph Two):**

Medicinal products and pharmaceutical products may only be kept or stored in a place separate from the pharmaceutical centre after having obtained a licence to this effect from the Authority - after payment of the prescribed fee - in accordance with the procedures determined in this law concerning the authorization of pharmaceutical centres. A decision is issued by the Board of Directors concerning the requirements that must be met at these locations and the controls that must be taken into account when transporting medicines and pharmaceutical products to and from these locations.

**Article (26 clause 4):**

4- If it is established that the pharmaceutical centre is operated or managed by an unlicensed person or one of his employees.

**Article (40 bis):**

The pharmacy may, after obtaining a licence from the Authority and paying the fee determined for that licence, carry out simple laboratory tests for individuals, by the statutory pharmacists working there, and a decision shall be taken by the Board of Directors specifying the types of laboratory tests, the controls, authorisation procedures and the categories of fees prescribed.

**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 a decision of the Board of Directors. The license shall determine the licensed activity of the pharmaceutical establishment and its duration shall be one year expendable 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 offences 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 the criminal or civil liability, and taking into account the provisions of Articles (98) and (99) of this Law, the Committee shall place the following penalties for the pharmaceutical centers that prove their violation of the provisions of this law:

1) Warning.

2) Closure of 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 deprivation decision.

**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 conventions in force in the Kingdom of Bahrain.

**Article Three**

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

**Article Four**

The definition of “Ministry” and “Minister” in Article (1) of Legislative Decree No. (18) for 1997 regarding the organization of the pharmacy profession and pharmaceutical centers shall be repealed as well as Articles (17), (29), (30), (31) and (32, second paragraph) and (34) of the same law.

**Article Five**

The word "Authority" shall be replace with the word "Ministry", and the phrase "Board of Directors" with the word "Minister", and "Concerned body of the Authority" shall be replaced with the phrases "Department of Pharmacy in the Ministry", "Department of Pharmacy and Drug Control in the Ministry", "Department of Pharmacy and Drug Control" and "Pharmacy and Drug Control Committee of the Ministry", and replace the phrase "Owner of the pharmacy" with the phrase "Pharmacy Owner", and the phrase "Kingdom of Bahrain" by "State of Bahrain", and replace the phrase "Owner of the pharmacies" with the phrase "Pharmacies Owners", the words "Criminal" by "Penal" and the phrase " Undersecretary of the Ministry of Health " replaces the word "Chief Executive", wherever they appear in Legislative Decree No. (18) of 1997 concerning the Pharmacy profession and Pharmaceutical Centers.

**Article Six**

The Prime Minister and the ministers - each within his jurisdiction- shall implement the provisions of this Law and shall come into force one month from 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:

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