Legislative Decree No (18) for 1997
With Respect to the Practice of Pharmacists and Pharmaceutical Centers

We, Isa bin Salman Al Khalifa Amir of the State of Bahrain

After full consideration of the Constitution,
Amiri Order No (4) for 1975,
Legislative Decree No (26) for 1975 on the regulation of pharmaceutics, pharmaceutical centers
and its amendments,
Legislative Decree No (4) for 1973 on the regulation of the circulation of narcotic substance and
its preparation and use and its amendments,
Legislative Decree No (19) for 1995 on the validation of qualifications,
Legislative Decree No (23) for 1986 on Private Hospitals,
Legislative Decree No (7) for 1989 On the Practice of Human Medicine and Dentistry
Upon submission of the Minister of Health
Upon seeking the advice of the Shura Council
And, with the approval of the Cabinet
Hereby decree the following law:

Article (1)

Unless otherwise indicated, the following words and terms shall have the meanings assigned
opposite each:
Country: State of Bahrain
Ministry: Ministry of Health
Minister: Minister of Health
Pharmacy Profession: the processing, mixing, preparation, retail or possession with the
intention of selling of any medicine or drug, the use of plants or any other substance
subcontractors or apparent or injecting to protect human or animal diseases or cure them or
have a physiological impact on the body.
Licensed Pharmacist: every pharmacist licensed to practice the profession of pharmacy in
accordance with the law.
Pharmacy Technician: All licensed pharmacy technician in accordance with this law.

Public Pharmacy: Pharmacy is designed to prepare prescriptions and sell medicine to the public (stand alone).
Private Pharmacy: The pharmacy of the medical facility or a pharmacy that is designated for specific group of people.
Pharmaceutical Centers: All type of public pharmacies, their branches and private pharmacies.
Pharmaceutical Manufacturing Factory: A facility where that is the preparation, formulation or production, processing or retail medicines intention of selling in bulk.

Chapter I
In the practice of the profession of Pharmacy and Pharmacy Technician

Article (2)
No one may be engaged in the profession of pharmacy without obtaining a license to do so, according to the provisions of the law. The requirements needed to obtain a license to practice are as follow:

1. To be a Bahraini national, and the Minister may exempt from this requirement if there are reasons to justify it.
2. Must hold a bachelor's degree in pharmacy or equivalent from a accredited program.
3. Any document certifying the applicant's success in local concessions or interviews organized by a special committee established for this purpose.
4. A Certificate proving that no criminal judgments have been passed against applicant prejudicing his integrity and honour unless he has been forgiven by competent authorities.

Article (3)
Person wishes to obtain a license for practicing the pharmacy profession shall submit an application on the application form intended for this purpose to the Ministry of Health accompanied with the following documents:
1. Original academic certificate/certificates obtained by the applicant or an official document evidencing that these certificates have been obtained.
2. Non-Bahraini applicants shall submit any document certifying that the applicant has a minimum of five years experience in the field of pharmacy profession.
3. Any other documents or papers prescribed by an order from the Minister.

Article (4)

No one may be engaged in the profession of pharmacy technician without obtaining a license to do so, according to the provisions of the law. The requirements needed to obtain a license to practice are as follow:

1. To be a Bahraini national, and the Minister may exempt from this requirement if there are reasons to justify it.
2. Any document certifying the applicant's success in local concessions or interviews organized by a special committee established for this purpose.
3. A Certificate proving that no criminal judgments have been passed against applicant prejudicing his integrity and honour unless he has been forgiven by competent authorities.

Article (5)

Person wishes to obtain a license for practicing the pharmacy profession shall submit an application on the application form intended for this purpose to the Ministry of Health accompanied with the following documents:
1. Original academic certificate/certificates obtained by the applicant or an official document evidencing that these certificates have been obtained.
2. Non-Bahraini applicants shall submit any document certifying that the applicant has a minimum of three years experience in the field of pharmacy profession.
3. Any other documents or papers prescribed by an order from the Minister.

Article (6)

A professional is granted a license to practice his profession for a period of two years renewable for periods similar. The application for license renewal must be submitted before the expiry date by at least a month along with fees payment slip.
In case of delay in submitting renewal request; a late fee of double the amount of the original registration fee will be imposed. The Ministry has the authority to reject the request for renewal if the request for renewal was delayed by more than two months and without an acceptable justification. The license or renewed license must be exhibited in a prominent place of the premises.

Article (7)

The Ministry shall decide on the licensing or renewals of licensing requests and shall issue its resolution within thirty days from the date of submission of the application. In case the license application is refused, the decision must be justified. The application is also considered rejected if a decision was not reached with 30 days.

An applicant whose application was refused may appeal against the decision to the Minister of the Ministry within thirty days from the date of his receipt to the decision of the Minister.

An applicant whose is refused may to appeal against the decision before the High Civil Court within a date not exceeding 45 days from the date of applicant notification by registered letter or within 45 days within his knowledge of the decision if he is not notified.

Article (8)

The Ministry shall maintain specific register to list all the licensees who are authorized to practice pharmacy professions and a separate register for pharmacy technicians; the register shall include the following details on the licensee:

1. Full name, title, age and nationality.
2. Academic certificates and qualifications and date of obtaining them.
3. The details of the premises at which the licensee will practice.
4. Date and number of the license issued by MoH office of Licensure.

Article (9)

Any person licensed to practice pharmacy profession, shall notify the Ministry, by a registered letter with 15 days of starting work of the address of the premises at which the licensee will practice and he shall do the same if he changes the place of work.

Chapter II
The duties of pharmacists and prohibited acts on them

Article (10)

A licensee authorized to practice the profession shall carry out his duties with due accuracy and honesty, and shall maintain the integrity and honour of the profession. The relationship between pharmacists must be based on mutual respect and trust and close cooperation in serving the patients, and they should avoid illegal competition and preserve the dignity and the reputation of all pharmacists, doctors.

Article (11)

A licensee authorized to practice the profession shall not combine the practice of pharmacy and medicine or dentistry or veterinary medicine, even if he/she holds the required qualifications.

The licensee is not in violation of the practice of medicine if practice First Aid in cases of emergency and/or accidents within the premises of his/her pharmacy. The licensee must however refrain from prescribing medicine or other conditions in violation of the law for practicing medicine.

Article (12)

Any pharmacists may not conduct any publicity for himself by any means whatsoever that could prejudice the integrity of the profession whether this publicity is carried out through publications or any other means.

Article (13)

Any pharmacist may not divulge any confidential secrets that may have come to his knowledge through his profession without obtaining court permission.

Chapter III
Pharmaceutical Centers

Section I
General Provisions

Article (14)

A pharmaceutical center may not be opened without obtaining a license from the Ministry of Health, as per the conditions set by the minister of health. A license for opening a pharmaceutical center shall only be given for licensed Bahraini pharmacist age 21 years at least or a company where more than one pharmacists own at least 50% of the company's shares.

If the owner died, the pharmacy may be managed by a pharmacist for the benefit of the heirs.

Article (15)

Licenses for establishing pharmaceutical centers are personal, and may not be assigned to other parties.

The license shall be considered cancelled by law if it was is transferred to a different owner. In order to approve the license, the new owner shall fulfil all the conditions required by the law.

Article (16)

The ministry shall not grant the licenses set forth in the preceding articles, if the requirements set by the minister and all other governmental agencies are not fulfilled by the applicants.

Article (17)

The distance between the requested pharmacy and the nearest pharmacy must not be less than two hundred and fifty meters, with the exception of centers licensed pharmacy at the time of this law.

Article (18)

The Ministry shall maintain specific register to list all licensed pharmaceutical centers; the register shall include the following details:

1. The name and address of the pharmaceutical center.
2. The name of the owner of the center.
3. The name of the director of the Centre.
4. The date and the center license number.
5. Any other data specified by the Ministry.

Article (19)

The granted license to open a pharmaceutical center is valid for a period of three years renewable for similar periods. The application for renewal must be submitted before the expiration of the license by at least one month. The applicant must also pay the set renewal fees and other requirements for the license to be renewed.

The registration fee will be doubled if renewal request was delayed by no more than two months without justification.

The ministry is authorized to administratively close the premises if the pharmacist fail to submit a request to renew the license within the time limit stipulated in the preceding paragraph.

Article (20)

The ministry must decide on the submitted application for licensing or renewal of license within thirty days from the date of submission. The decision to reject an application must be justified.

An application is considered rejected if no response was issued by the Ministry within thirty days from submission.

Those whose application is rejected is entitled to appeal to the Minister within thirty days from the date of notification of the decision of rejection or after thirty days of initial application. The minister shall response to the appeal within thirty days from the date of submission. The lapse of thirty days without receiving a response to the appeal shall be

considered a rejection; this decision may be challenged before the High Civil Court within forty-five days from the date of notification of appeal rejection or from the date his/her appeal is considered rejected.

Article (21)

Pharmaceutical centers may not be used for other purposes than the ones licensed for. It also may not have direct or indirect contact with a private residence or a clinic or another shop.

Article (22)

Pharmaceutical centers shall keep all records specified by the Ministry.

Article (23)

Pharmaceutical centers must make available all the necessary equipment specified by the Ministry. Pharmaceutical centers must store all medicines and other pharmaceuticals products properly and in good condition. Additionally, pharmaceutical centers shall not store any expired pharmaceutical products.

Article (24)

The Name of the Pharmaceutical center must be written in both Arabic and English language
clearly.

Article (25)

Licensee must obtain in advance written approval from the ministry for every major change he wants to undertake in the center. A detailed application must be submitted along with a precise description of the requested amendments. The ministry shall make the necessary changes to its records accordingly.

Article (26)

The Minister has the authority to cancel the license of a pharmaceutical center in the following circumstances:

1. If the license was not utilized within one year from the date of issue (I did not translate the
second part of this statement because it was not clear) .
2. The premises was continuously closed for over a year (I did not translate the second part of
this statement because it was not clear) .
3. Changing the location of the pharmaceutical center without the ministry consent.

Section II
Special provisions for each type of pharmaceutical centers
First: public pharmacies

Article (27)
With the exception of pharmacies existing at the time of this law, a license to open a pharmacy is only issued to a licensed Bahraini pharmacist. As a general rule, a pharmaceutical center must be managed at all time by a pharmacist licensed to practice in the State of Bahrain but shall not manage more than one center at the same time.

Article (28)
A license owner of a pharmaceutical center may not own or be a partner to more than one pharmacy with the exception of pharmacies and their affiliates licensed at the time of the provision of this law.

Article (29)
A pharmacy branch under the provisions of this law is considered one pharmacy. The general pharmaceutical centers provisions apply to the pharmaceutical centers branches.

Article (30)
The entrance of the premises must open on a main road or within a shopping mall.

Article (31)
The Minister has the authority to determines the number of pharmacies in each city and village, based on the actual needs of these areas. He may also decide to discontinue issuing new licenses.

Article (32)
A director of Pharmacy may be assisted by a technician working under his supervision and be
responsible for any error committed by the technician.
The pharmacy Technician is allowed to manage the pharmacy temporarily on behalf of the
director during his absence for a compelling reasons for a period of not more than two weeks
per year. The director is expected to notify the Ministry via a registered mail.

Article (33)

1. The director in charge of the pharmacy must notify the ministry immediately of his/her resignation/expulsion by registered letter. The owner of the pharmacy must appoint a new director within sixty days from the date of resignation/expulsion of previous director, and must notify the Ministry via a registered mail. The new director requires the Ministry written consent to carry out his/her duties.
2. The director of a pharmacy must handover what is in his/her custody of controlled substances – to be specified by ministerial order – to his successor. He/she also must prepare three copies of a report by both of them (the former and new directors) and send one to the ministry, keep the second copy in the pharmacy, while the director of the pharmacy, keeps the third copy.
3. If a new director is not appointed, the resigned/expelled director must deliver the controlled substances in his/her custody to the owner of the pharmacy in the presence of a representative of the ministry. The Ministry representative shall seal the cupboards or cabinets containing controlled substance using the ministry seal. The seal can be removed only in the presence of a ministry representative.

Article (34)

If a director cannot be appointed; the owner may designate a licensed pharmacy technician to assume the directors role pending the ministry's approval temporarily for a period not exceeding sixty days per year (without violating the second paragraph of Article (32) of this law) This provision is also apply during the pharmacy's director annual leave which should not exceed sixty days per year.

Article (35)

If a new director or a temporary one is not appointed in accordance with the preceding two articles; the owner shall close it immediately. Otherwise, it will be closed administratively by the ministry pending the appointment of a director and without violating Clause (2) of Article (26) of this law.

Article (36)

The owners of pharmacies or directors are responsible for notifying the ministry via a registered letter before starting to liquidate the pharmacy by at least two weeks. A list of controlled substance must be attached to the notification letter. The ministry must approve the recipient of the controlled substance or it should be delivered to the Department of Pharmacy at the ministry until a decision is taken in accordance with this law. The liquidated pharmacy's license is automatically cancelled.

The ministry must be notified when an inventory of the pharmacy's contents is carried out or in cases of theft or damage resulted from whatever cause.

Article (37)

Each and every pharmacy that prepares medications and drugs must:

1. Have a secluded place where the medication preparation take place equipped with clean running water and a washbasin.
2. Meet the requirement set by the Directorate of Pharmacy and Drug Control and the ministry for the preparation of drugs.
3. Have a copy of the latest edition of a internationally accredited pharmaceutical reference determined the Directorate Pharmacy and Drug Control in the Ministry.
4. Any other conditions determined by the Directorate of pharmaceuticals and Drug Control in the ministry.

Article (38)

All materials used in the preparation of medications must be properly stored in a good condition and clean containers. All containers must have a label with the necessary information, including the name of the substance and life shelf. All expired and suspected expired substance must be confiscated.

Article (39)

1. Pharmacies must keep a special register recording all medications and pharmaceutical products received by the pharmacy indicating date of delivery, type, quantity and source.
2. Medications prepared in the pharmacy must be based on a prescription and complying with the specifications set forth by the Ministry unless instructed differently in the prescription.
3. All pharmacies must have an updated registry recording all medications prepared on a daily basis indicating the product serial numbers, date of registration, name of the physician prescribe the product, and the names and quantities of the substances used in the preparation of the medication, method of administration and the price along with the concerned pharmacist signature.
4. All prepared medications must be stored in containers fit for purpose. It must also have the name of the pharmacy, the address, patients name, serial number, preparation date, and mode of administration.

Article (40)

Only persons referred to in Articles (2.4) of this law are authorized to intervene in the preparation, dispensing of prescriptions or the sale of medications and pharmaceutical products to the public.

Article (41)

To ensure accessibility to pharmacies around the o'clock; a ministerial order shall be issued to
set pharmacies working hours night shifts and holidays working hours.

Second: Private pharmacies

Article (42)

A private pharmacy is to be licensed only if attached to the medical institution and authority or is expected to serve a specific group of people.

Article (43)

Private pharmacies are required:

1. To be within one of the categories set forth in the preceding article.
   2. Medications are dispensed for patients with those mentioned in the previous article and they should not sell medications to the public not set forth in the preceding article.

Article (44)

The provisions applying to public pharmacies are also valid for private pharmacies.

Pharmaceutical manufacturing

Article (45)

No person is to establish a pharmaceutical manufacturing company without the prior approval
from the Ministry of Oil and Industry.
A request shall be submitted to Directorate of Pharmacy and Drug Control along with all documents and data requested by the ministry.
If Ministry of Health approved the request; the ministry refers the request to the Ministry of Oil and Industry for the licensing of the establishment of the pharmaceutical manufacturing company.

Article (46)

Licenses are granted only if the World Health Organization requirements for pharmaceutical products manufacturing are met as well as other requirements set by the ministry of health and other relevant government agencies.

The process of applicants notification pertaining to the rejection of an application or the grievance or appeal is the same as those stipulated in Article (20) of this law.

Article (47)

A pharmaceutical manufacturing factory shall contain the necessary requirements to function and in particular the following sections:

1. Production: containing the necessary machinery and equipment specified by the Ministry.
2. Drug Control section: includes three parts:

A) The chemical laboratory equipped with raw substances and technical equipment for
analysis during the production process.

B) Sterilization laboratory equipped with modern technical equipment for the sterilization
of produced drugs.

C) Microbiology laboratory equipped with appropriate devices to measure the rate or the
presence of bacteria and fungi etc.

Article (48)

The following storage areas must be attached to each and every pharmaceutical manufacturing factory:

1. a store for raw materials, ensuring the appropriateness of the premises conditions in terms
   of temperature, humidity, and external factors, for the purpose. A designated area must be
   identified in the store to keep raw material prior to testing.
   2. a store for manufactured products meeting the conditions set forth in the preceding item.
   3. A store for hazardous and inflammable materials determined by a ministerial order. Such
   store must be located away from the main factory buildings.
   4. Any other stores issued by a ministerial order.

Article (49)

The director of the pharmaceutical product manufacturing and the production manager must
be licensed to practice the profession of pharmacy in the State of Bahrain.

Article (50)

The supervision of each laboratory in the Drug Control must be a licensed pharmacist, or specialists in the field of laboratories, licensed to practice in the State of Bahrain.

Article (51)

The Director of the pharmaceutical factory, the production manager and director of Drug Control jointly share the liability for everything that is produced in the factory and without prejudice to criminal liability that may arise before them.

Article (52)

The pharmaceutical manufacturing company management must notify the ministry immediately of the factory director resignation/expulsion by registered letter. A new director must be appointed within three months from the date of resignation/expulsion of previous
director. The factory shall be temporarily managed by one of the head of the different sections
in the factory after obtaining the written approval of the ministry.

Article (53)

Pharmaceutical manufacturing companies shall not be used for purposes other than the ones for which the factory was licensed.

Article (54)

The external label for each product must contain the following data: –
1. The name of the medicine or pharmaceutical product.
2. The name of the active ingredients involved in the composition of the drug or the pharmacist and the quantities.
3. The registration number of the drug or pharmaceutical product in the ministry.
4. Batch number, date of production and expiration of the drug or pharmaceutical product.
5. The name of the factory or company, and the name of the state.
6. The proper storage for the drug or pharmaceutical product.
7. Any other data set by the ministry.

The bulletin of each drug or pharmaceutical product must contain data listed in Article (70) of this law.

Article (55)

Each pharmaceutical manufacturing company must keep records of the following:

1. Register of raw materials and tests performed upon receipt at the factory.
2. Register of medications and pharmaceutical products produced in the factory and tests performed.
3. Register of toxic substances, which shall be determined via a ministerial order. Register of dangerous drugs which shall be determined via a ministerial order.
4. Any other records that are required by the ministry. These records must be sealed with ministry seal and that the pages be numbered with serial numbers, and that it should be updated constantly and discloses all the operations performed in the factory.

Article (56)

The factory must keep samples of each medication manufactured for five years from the date of production or one year after the end of the expiry date, whichever is longer, for periodical analysis, and to be used as a reference when required.

Chapter IV
Import of medicines and pharmaceutical products, export

Article (57)

The import of medications and pharmaceutical products, even free samples must be via pharmaceutical centers, in compliance with specifications set by a ministerial order. The ministry's approval is a must. The pharmaceutical center must submit to the ministry all the data on the type and the quantity to be imported and any other data requested by the Directorate of Pharmacy and Drug Control.

Article (58)

A person is allowed to import medications and/or pharmaceutical products for personal use under the following conditions:

1. The person importing the medication and/or pharmaceuticals products must have evidence/reports confirm his/her need to use those medications and/or pharmaceuticals products.
2. The quantities to be imported for the time period specified in the prescription.

3. The medication containers must be sealed and labelled with the appropriate pharmaceutical data.

Article (59)

A person who import medicines and/or pharmaceutical products in violation of the provisions of the two preceding articles, has the right to re-export the quantity within a period not exceeding one month from the date the product is delivered on his/her own expense.

Article (60)

The import of controlled drugs is subject to the following conditions:

1. The importer must submit a request specifying the types and quantities of drugs to be imported after reviewing the products records at the Directorate of Pharmacy and Drug Control.
   2. The approval for the import of the product is in compliance with the accredited procedure set by international organizations.

Article (61)

No imported drugs or pharmaceuticals are released without the consent of the ministry to authorized persons. The centers must keep records of imported pharmaceuticals, which shall include quantities imported, the date they were received, the quantities dispensed and the recipient of these quantities and the exact dates.

Article (62)

All pharmaceuticals products must be sold in their original sealed containers, with the exception of controlled drugs, which must be sold according to the quantity and for the duration specified in the prescription.

Article (63)

The Minister may issue an order to ban the export of any drugs or pharmaceutical products if deemed necessary.

Chapter V
Registration of medicines and pharmaceutical products

Article (64)

The circulation of both locally manufactured and imported medications and pharmaceutical products is prohibited unless registered in the ministry. A registration request must be submitted to the Directorate of Pharmacy and Drug Control in the ministry together with the following:

1. An official certificate from the health authority in the country of origin to prove that the drug or pharmaceutical product is registered, authorized to be used, and is already being traded with the same specifications.
2. A valid certificate proving that the manufacturer or the manufacturer of the drug or product adapt a scientific approach throughout production and that they are subject to routine health inspections.
3. A valid certification of the selling price of the imported medication or pharmaceutical product in the country of origin and the export prices to Bahrain neighbouring countries.
4. Samples of the drug or product to be registered.
5. Three copies of the product leaflet.
6. A summary report of relevant scientific studies and its effectiveness under different weather conditions and method of analysis.

Article (65)

A specialized technical committee shall be formed by an order from the Minister called the “Committee for Drug Registration” to register pharmaceutical products. The committee’s decision to reject a request must be justified and applicant must be notified via registered mail. Those whose application is rejected are entitled to appeal to the Minister within a month from the date of notification of the decision of rejection. The minister shall response to the appeal within a month from the date of submission.

Article (66)

All registered drugs and/or pharmaceutical products in accordance with the provisions of the preceding article are documented in records designated for that purpose under specific serial number. The applicants is given an official documentation that can be used as a valid license to the circulation of the drug or product. Once registered; a change of the drug or pharmaceutical product components, indications and mode of administration, change of the packaging or the expiry date is prohibited unless approved by the ministry.

Article (67)

The Directorate of Pharmacy and Drug Control has the authority to place any restrictions on exchange or marketing of any registered drug or pharmaceutical it deems necessary.
Pharmacy centers, hospitals and health centers, clinics and doctors, has the obligation to report to the Ministry any adverse consequences related to use of a drug or pharmaceutical post-marketing.

Article (68)

Drugs or pharmaceutical products registration might be revoked via a ministerial order under the following circumstances: –

1. If the Drug Registration Committee receive new information that indicate harmful side effects of certain products or for any other technical reasons determined by the Committee.
2. If the product is banned based on the recommendation of the World Health Organization or any other reputable global pharmaceutical authorities.
3. If the product's registration is revoked or is no longer being produced in the country of origin.

Chapter VI
Promotion of medications

Article (69)

The text and illustrations in the advertisements directed at doctors and health professionals must be in accordance with approved scientific data and that these texts are clear and unequivocal or unambiguous.

Article (70)

The leaflet of each pharmaceutical drug or pharmaceutical must the following information in both Arabic and English: –

1. List the active components, and the scientific name of each component.
2. The quantities of active components in accordance with the required doses or regimen.
3. List components that may interfere or affect the use of the medicine or pharmaceutical product.
4. The internationally accredited therapeutic uses of the product.
5. The forms of drug doses.
6. The side effects and major adverse reactions of the product or pharmaceutical product.
7. Required precautionary measures, prohibitions and taboos.
8. Main interactions.
9. The product name and address.
10. A list of the scientific references used.

Article (71)

It is completely prohibited to advertise for prescription drugs. As for the non prescription drugs; a written consent from the ministry is required.

Article (72)

The pharmaceutical product advertisements must be consistent with the declared contents of
the product and should not contain expressions contrary to public morals or which would
mislead the public.

Article (73)

No person may be engaged in the promotion of pharmaceutical product unless licensed by the State after paying the licensing fees.
Those to be licensed to practice this profession, must possess a university degree or diploma from a credited college or institute.

Article (74)

The licensee of drug promotion is granted a license to practice for two years renewable for similar periods. The licensee must pay the set fees prior to receiving his/her license.

Article (75)

A licensee authorized to practice the profession shall carry out his duties with due accuracy and honesty, and shall maintain the integrity and honour of the profession. The licensee should also provide complete information to those prescribing drugs.

Article (76)

It is not allowed to trade or offer for sale drug specimens intended for advertising. These specimens must be labelled clearly “Free medical samples” in both Arabic and English.

Article (77)

Doctors may be provided with free samples of drugs, when requested. As for injection; a record should be kept of the quantities handed out and used. It is prohibited to promote free samples to the public.

Article (78)

All scientific seminars held by pharmaceutical companies must be relevant to pharmacy related topics and be limited to the concerned professionals.

Chapter VII
Prescriptions

Article (79)
All prescriptions must be issued by a licensed physician and must include the name, address and the physician's signature along with the date issued. Exception to this rule are simple medications which are specified via a ministerial order. Repeated dispensing of medicines may only be with new prescription.

Article (80)
It is prohibits the dispense any controlled substances, which were not written on special prescriptions issued by the ministry.

Article (81)
Controlled drugs may only by dispensed by a licensed pharmacist and a register must be kept of all amounts received, dispensed, the date the drug dispensed, the name of the doctor who issued the prescription. The prescription must be retained for a period of one year.

Article (82)
Prescription must be written in clear handwriting for the pharmacist to prepare the medicine or pharmaceutical product listed without confusion or ambiguity.

Article (83)
A pharmacist must obtain the concerned physician prior to replacing any medication or pharmaceutical product indicated in the prescription with an alternative even if it is compatible.

Article (84)
The pharmacist must refrain from dispensing a product or pharmaceutical product if he suspected an error in the prescription and must consult the concerned physician.
The pharmacist has no permission to make any changes to the medications and/or pharmaceutical products recorded in the prescription with respect to the quantity, type or method of use, without prior written consent from the concerned physician.

Article (85)
The pharmacist must in case of keeping a prescription to ward off liability give the holder of the prescription or the patient's physician a copy upon request without charge.

Chapter VIII
Pricing of medications and pharmaceutical products

Article (86)
A ministerial order will set the ceiling for the maximum profit allowed in the trade (wholesale and retail sell) of drugs and pharmaceutical products. The profit is calculated for each product based on the basis of the actual cost paid by importer as shown in the official invoices.
The Ministry has the authority to requests all data and documents required in this regard.

Article (87)
It is not permissible for importers or distributor to increase the set prices of pharmaceutical products without a written consent from the ministry.

Article (88)
The official price of all pharmaceutical products must be declared and must be shown on the package. The pharmacies should keep a list of all prices set by the ministry.

Chapter IX
Simple medications and health products
Article (89)

It is prohibited for all non pharmaceutical centers the sale of drug which are restricted via a ministerial order unless permitted by the ministry.

Article (90)
The sale of health product determined via a ministerial order is limited to pharmacies or stores or places designated for that purpose, which are regulated via a ministerial resolution.

Chapter X
Inspection of Pharmaceutical Centers
Article (91)
The ministry staff who are permanently delegated by an order from the Minister, shall have the right to carry out inspection, and shall ensure implementation of the provisions and orders of this law. Those inspectors are required to be licensed pharmacists.
The inspectors are also entitled to take samples of medicines, pharmaceutical products and health products for analysis, as well as access to relevant records and documents.

The inspectors have the authority to record any violations of the provisions and orders issued in implementation of this law and refer them to the public prosecutor when applicable.

Chapter eleven
Sanctions

Article (92)
Without prejudice to the civil or criminal responsibility, Disciplinary actions which may be imposed on the violator are as per the following articles.

Article (93)
The following violators shall be guilty of an offense punishable by a term of imprisonment not exceeding three months and a fine not more than 1000 BD or by one of these penalties:
1. Any person who open or manages a pharmaceutical center without obtaining a license.
2. Any person who has submitted false information or used fraudulent methods through
which he obtained a license to practice or to be listed in the registers illegally.
3. Any person who is in violation of Article (53) of this law.
In all cases the clinic shall be closed down administratively until the criminal case is resolved.

Article (94)
Without prejudice to any more strict punishment stipulated in the criminal law, The following
violators shall be guilty of an offense punishable by a term of imprisonment not exceeding two
months and a fine not more than 500 BD or by one of these penalties:
1. Any person who practices a profession that requires licensing as per the articles of this law.
2. Any person who has submitted false information or used fraudulent methods through which he obtained a license to practice professions referred to in chapter (1) of this law illegally.
3. Any person who adopts a title of a doctor or adopts a title that is usually used by doctors without being entitled for this.
4. Any pharmacist allowed an unlicensed person to practice the profession under his supervision.

Article (95)

The following violators shall be guilty of an offense punishable by a term of imprisonment not exceeding one month and a fine not more than 300 BD or by one of these penalties:

1. Any person who poses a pharmaceutical product with the intention of selling that are not registered in the ministry.
2. Any person sell drugs or pharmaceutical products or health products at a price exceeding the official price set by the ministry.

Article (96)

The following violators shall be guilty of an offense punishable by a fine not less than 200 BD:

1. A person who store in his pharmaceutical center, drug stores unlicensed pharmaceutical products and/or health product in accordance to the provisions of this law.
2. A person who distributed any drugs or pharmaceutical products for free in violation of the provisions of this law.
3. Imported medications or pharmaceutical products in violation of the provisions of Article (57) of this law.

The violator shall be guilty of an offense punishable by a fine not more than 100 BD anyone who imported medications or pharmaceutical products in violation of the provisions of Article (58) of this law.

4. Any person is in violation of the provisions of Article (76) of this law.
5. Any licensed pharmacist is in violation of the provisions of Article (84) of this law.

Article (97)

In addition to the penalties listed in the proceeding articles , all drugs and pharmaceutical products or health products shall be confiscated for which offenses was committed. The original owner (importer of the product) has no right to demand compensation.

Chapter XII
Discipline

Article (98)

A specialized technical committee shall be formed by an order from the Minister to authority to take a disciplinary action against licensees authorized to practice the profession, if they commit any violations to the provisions of this law or to the rules, requirements and morals of the profession. The disciplinary case shall be filed by a decision from the Undersecretary. The violator shall be notified to be present before the Committee by a registered letter at least one week prior to the time fixed

for holding of the session. This letter shall include a summary of the charges attributable to him, as well as the date and place where the Committee shall convene.
For some special cases, the violator may be summoned immediately to be present before the committee for investigation of the violations attributable to him.
The Committee shall investigate the charges attributable to the violator or delegate one of its members therefore, and the Committee or the person delegated by it to conduct investigation
may on its own will, or upon the request of the violator to summon witnesses to appear to give their testimonies and the violator give his defence orally or in writing.
If case a violator fails to be present before the Committee despite being notified, the judgment shall be issued by default.

Article (99)

Without prejudice to any more strict punishment stipulated in the criminal law, disciplinary actions which may be imposed on the violator are as follows:
1. Warning.
2. Suspension, for a period not exceeding one year.
3. Revocation of the license and crossing off the name of violator from the register of the Ministry of Health.

Article (100)

The decisions of the Committee shall not be carried out unless they become final by certifying them from the Minister of Health. A person whom a decision has been passed against him according to article (99) of this law, to plead against the decision within two weeks from the date on which he has been notified thereof before another committee formed by the Minister of Health to look into his pleading.
This committee shall have the right to support or amend the decision which shall be final after being approved by the Minister.
A person whom grievance has been rejected may challenge the decision before the High Civil Court within 45 days from the date of notification of the rejection by a registered letter.

Article (101)

A person whom an order has been issued against him on revocation of his license, may not apply for a new license for practicing the profession or to open the premises unless until two years have been passed from the issuance of the said order.

Chapter XIII
FINAL PROVISIONS

Article (102)
The Minister of Health shall issue an order after the Cabinet's approval determining the licensing fees for practicing the pharmacy profession as well as the licensing fees for renewal payable under the provisions of this law.

Article (103)
The minister, based on the recommendation of the Ministry Pharmacy and Drug Control Committee has the authority to issue a ministerial order prohibiting the importation, circulation of any medication or preparation of pharmaceutical product or health food with potential harm to public health. In such case, the product is removed from the Ministry's records. The full quantity is either returned to the producer on the expense of the product owner or confiscated by the ministry without compensating the owner.

Article (104)
You must save the records provided for in this law for five years at the side of their existing from the last entry therein, and the owners and directors of centers, pharmaceutical and retail stores that sell simple medicines and health foods, provided upon request of the inspectors provided for in this Law.

Article (105)
Excluded from the application of the provisions of this law are industrial and commercial first aid units established in accordance to labour laws.

Article (106)
Legislative Decree No (26) for 1973 on the regulation of pharmaceuticals, pharmacists and pharmaceutical centers and its amendments is hereby repealed and any provision which is contrary thereto is so repealed.

Article (107)
This law does not repeal Legislative Decree No (4) for 1973 on the regulation of the circulation of narcotic substance and its preparation and use and its amendments.

Article (108)

The Minister shall issue the orders and regulations required for the implementation of the provisions of this law.

Article (109)

Ministers, within their respective areas of jurisdictions, shall implement the provisions of this law, which shall be effective after one month from the date of its publication in the Official Gazette.

Acting Amir of the State of Bahrain
Hamad bin Isa Al Khalifa
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