Supreme Council of Health

Resolution (63) for the year 2019

TO ISSUE THE REGULATION OF THE REQUIREMENTS AND PROCEDURES FOR THE PRACTICE OF PHARMACY PROFESSIONS, LICENSING OF PHARMACEUTICAL CENTERS, MEDICINES AND PHARMACEUTICAL PRODUCTS FACTORIES, AND PHARMACEUTICAL FACILITIES

President of the Supreme Council of Health:

National Health Regulatory Authority:

After consideration of buildings regulations law, issued by decree-law no. (13) for the year 1977, and its amendments,

And decree-law no. (7) for the year 1989 on the practice of medicine and dentistry professions,

And decree-law no. (14) for the year 1989 approving the accession of Bahrain to the single convention on narcotic drugs of the year 1961, as amended by the protocol of the year 1972 and the convention on psychotropic substances of the year 1971,

And the decree-law no. (5) for the year 1990 on civil defense, as amended by law no. (22) for the year 2014,

And the decree-law no. (18) for the year 1997 with respect to the regulation of pharmacy profession and pharmaceutical centers, as amended by law-decree no. (20) for the year 2015,

And the commercial companies' law, issued by law-decree no. (21) for the year 2001, and its amendments,

And the unified customs regulation (law) of The Cooperation Council for The Arab States of The Gulf issued by decree-law no. (10) for the year 2002,

And the law no. (15) for the year 2007 with respect to narcotic and psychotropic substances,

And the Law no. (38) for the year 2009 establishing the National Heath Regulatory Authority (NHRA), and its amendments by decree-law no. (32) for the year 2015,

And the decree-law no. (21) for the year 2015 with respect to private health facilities, and its amendments by law no. (1) for the year 2019,

And decree no. (5) for the year 2013 establishing the Supreme Council of Health, and its amendments,

And resolution no. (4) for the year 2013 with respect to medicines or pharmaceutical substances and products pricing, and the determination of its trading profits and publishing of its prices,

And resolution no. (12) for the year 2015 with medicines registration regulation,

And resolution no. (17) for the year 2016 to determine the National Heath Regulatory Authority licensing and services fees,

And resolution no. (2) for the year 2019 with respect to health facilities classification, health and technical requirements, and its mandatory safety requirements,

And upon the National Heath Regulatory Authority – Chief Executive Officer submission,

And after the Supreme Council of Health approval,

Decided the following:

ARTICLE (1)

The provisions of the requirements and procedures regulation for the practice of pharmacy professions, licensing of pharmaceutical centers, medicines and pharmaceutical products factories, and pharmaceutical facilities, accompanied to this resolution shall be in force.

ARTICLE (2)

Any provision contrary to the provisions of the regulations accompanying this resolution shall be repealed.

ARTICLE (3)

The Chief Executive Officer of the National Heath Regulatory Authority shall implement the provisions of this resolution and shall come into force from the day following its publication in the Official Gazette.

President of the Supreme Council of Health

Lieutenant General

Dr. Mohammed bin Abdullah Al-Khalifa

Issued on: 28 Dhul Hijjah 1440 Hijri

Corresponding to: 29 August 2019

REGULATION OF THE REQUIREMENTS AND PROCEDURES FOR THE PRACTICE OF PHARMACY PROFESSIONS, LICENSING OF PHARMACEUTICAL CENTERS, MEDICINES AND PHARMACEUTICAL PRODUCTS FACTORIES, AND PHARMACEUTICAL FACILITIES

CHAPTER (1)
DEFINITIONS

ARTICLE (1)

In the application of the provisions of this regulation, the words and phrases contained therein shall have the meanings set forth in the decree-law no. (18) of the year 1997 with respect to the regulation of pharmacy profession and pharmaceutical centers, and the following words and phrases shall have the meanings assigned to each, unless the context otherwise requires:

The Kingdom: Kingdom of Bahrain.

The Law: the decree-law no. (18) of the year 1997 with respect to the regulation of pharmacy profession and pharmaceutical centers.

Health Facilities Resolution: resolution no. (2) for the year 2019 with respect to health facilities classification, health and technical requirements, and its mandatory safety requirements.

The Council (SCH): Supreme Council of Health.

The Authority (NHRA): National Health Regulatory Authority.

The Concerned Department (PPR): the concerned party in the Authority to regulate the profession of pharmacy and pharmaceutical facilities.

License Applicant: any professional or establishment applying for a license to practice a pharmacy profession.

Medicines Promotions: presentation of information on medicines and pharmaceutical products for the purpose of promotion in accordance with the law.

Raw Materials: materials used in the processing, compounding or preparation of pharmaceutical products.

The Products: medicines, pharmaceutical products, and raw materials.

The Products Warehouse: a pharmaceutical facility licensed to import, export, store, distribute, and wholesale of The Products.

Pharmaceutical Services Center: a pharmaceutical facility specialized in the management, development, and organization of medicines and pharmaceutical products businesses.

Scientific Office: a facility provides scientific, technical, and marketing insights about medicines and pharmaceutical products.

Scientific Research Facility: a facility that provides support to the pharmaceutical, bio-technology and medical devices industries, in the form of research services assigned to the facility from third parties on a contractual basis.

CHAPTER (2)
LICENSING DOCUMENTS FOR PHARMACY PROFESSIONS AND THEIR DUTIES, AND RECORDS OF MEDICINES PROMOTERS

ARTICLE (2)
LICENSING DOCUMENTS

Any person wishing to obtain a license to practice the profession of pharmacy, pharmacy technician, or promotion of medicines, must submit an application on the form prepared for that to the concerned department, accompanied by the following documents:

1. Letter from the pharmacy center for which the applicant will be employed, stating the desire to license him, for non-Bahraini applicants.
2. The required scientific certificate to be certified and legalized by the competent authorities.
3. Data verifying the qualification of vocational education, practical experience, and the professional license in the last place of work for the license applicant.
4. The license applicant's CV, a white background photo, and copies of the applicant passport and Bahraini ID card (CPR).
5. Certificate of good conduct.
6. Certificate stating that the pharmacist has been practicing the profession for a minimum of five years, and that the pharmacy technician practiced the profession for a minimum of three years, if the license applicant is non-Bahraini.
7. Certificate from an accredited health center stating the health fitness of the license applicant.
8. Copy of the receipt of the license application fee payment.
9. Any other documents requested by the Authority - for the license of a pharmacist or pharmacy technician - based on The Council decision.

ARTICLE (3)
DUTIES

The licensed pharmacist, pharmacy technician and medicines promoter should consider the following:

1. Placing a professional license in a prominent place where others can easily access it.
2. Not to switch from his/her employer to another party, unless he/she obtain a permit from the Authority.
3. Commitment to the health professions code of ethics.
4. To cooperate with the Authority members and inspectors in the performance of their duties to implement the provisions of the law.
5. Compliance with the applicable laws, regulations and resolutions regarding the profession.

ARTICLE (4)
RECORDS

The Authority shall prepare records for the registration of licensed pharmacists, pharmacy technicians and medicines promoters licensed to practice the profession. Each record shall include the following:

1. The name of the pharmacist, the pharmacy technician, or the medicines promoter, his/her age and nationality.
2. His/her educational qualifications, its sources and issuing dates.
3. Workplace and place of residence.
4. The license number, and the date of issue by the concerned department.

CHAPTER (3)
PHARMACY CENTERS

SECTION (1)
REQUIREMENTS AND PROCEDURES FOR LICENSING PHARMACEUTICAL CENTERS

ARTICLE (5)
GENERAL REQUIREMENTS FOR LICENSING PHARMACEUTICAL CENTERS

Subject to the provisions of the law, the following is required to license a pharmacy center:

1. The center shall have its own separate entrance and shall not have direct or indirect contact with a private dwelling in the form which makes it a part of it.

2. The center's surface-area should be sufficient to provide suitable corridors for the distribution of medicines and pharmaceutical products, and to facilitate their dispensing and storage movement. The center should be well-lit and ventilated.
3. The daily working hours shall be determined and announced at the entrance of the pharmacy center.
4. Written and announced policies and procedures applied to deal with medicines and pharmaceutical products in case of power failure or exceeding the temperature and/or humidity limits.
5. The storage of medicines and pharmaceutical preparations should be organized with a label indicating the name of the medicine and its expiry date. It is prohibited to place medicines on the floor or stack them on the top shelves without keeping a distance of (45) cm away from the ceiling.
6. Allocating adequate storage space for medicines and pharmaceutical products.
7. Chemical disinfectants, sterilizers and medicines intended for external use should be stored separately from internal-use and injectable medicines.
8. Maintain a record or system to identify the expired and/or damaged medicines and pharmaceutical products, and how to deal with them, and a clear mechanism to deal with the medicines recalls from the market.
9. Keep a special record in which the temperature and humidity are recorded once every (12) hours.
10. Keep a record of the incoming and dispensed quantities of the controlled medicines, including the dispensation date, and the name of the prescribing physician of these medicines.
11. Prescriptions containing semi-controlled medicines, should be maintained for one (1) year.
12. Prescriptions containing narcotics, psychotropics, or precursors, should be maintained for five (5) years.
13. Foods, beverages and biological samples should not be placed in the refrigerator of medicines and pharmaceutical products.

ARTICLE (6)
PHARMACY CENTERS LICENSING DOCUMENTS

Those wishing to license a pharmacy center must submit an application to the concerned department, accompanied by the following documents:

1. The application form available on the Authority's website, depending on the type of pharmacy center to be licensed.
2. Copy of the passport and identity card of the applicant and partners, if any.
3. Certified engineering drawing showing the location of the public pharmacy and its internal area.

4. Copy of the initial approval of the medical facility, upon requesting to license a private pharmacy attached to it.
5. Certified engineering drawing showing the location of the private pharmacy, if its license is requested by a medical facility.
6. Copy of valid lease contract, or ownership document if the applicant owns the pharmacy center.
7. Copy of the receipt indicating the payment of the submission fee for the license application.

ARTICLE (7)
INITIAL APPROVAL

A. The Authority's inspector shall inspect the pharmacy center to verify that it meets the legal requirements; and prepare a report accordingly.

B. If the inspection proves that the legal requirements are met, the initial approval for the opening of the pharmacy center shall be issued.

C. The owner of the pharmacy center shall obtain the commercial register (CR) from the Ministry of Industry, Commerce and Tourism, if the legal requirements are obtained.

ARTICLE (8)
EQUIPPING THE PHARMACY CENTER

A. The pharmacy center shall be executed, furnished and equipped for operation in accordance with the requirements approved by The Council.

B. A library or an electronic system containing scientific references and laws related to the profession must be provided.

C. Requirements for keeping records and prescriptions must be provided.

D. The pharmacy center and all the medicines and pharmaceutical products refrigerators and freezers, shall be monitored with appropriate thermometers or similar apparatus approved by the Authority for the measurement of temperature and humidity.

E. A refrigerator should be provided for storing medicines that need to be stored in cold temperatures, while maintaining an appropriate temperature of the refrigerator ranging from (2) to (8) °C, and the freezer temperature ranging from (-10) to (-25) °C, attaching to the refrigerator a list of its contents (medicines and pharmaceutical products), and their expiry dates.

F. After fulfilling the approvals, licenses and requirements required by other relevant official authorities, and equipping the center for operation in accordance with the conditions on which the initial approval was granted, the owner of the pharmacy center shall apply for the final inspection.

ARTICLE (9)
PUBLIC PHARMACIES LICENSING REQUIREMENTS

Subject to the provisions of the law, to license a public pharmacy, its entrance and facade should overlook the main street, and if it will be inside a commercial complex, its entrance must be separate from other commercial projects.

ARTICLE (10)
SECURITY AND SAFETY MEASURES IN PUBLIC PHARMACIES

A license to open a public pharmacy shall be subject to the following security and safety measures:

1- There should be clear identification cards with the names of all employees of the pharmacy.

2. A list of hazardous substances should be placed in the places of storage or use, in a manner that facilitates their visibility.

ARTICLE (11)
PUBLIC PHARMACIES TO BE LICENSED BY THE OWNER

It is not permissible to authorize any normal or legal person, alone or as a partner in a company, to open more than five public pharmacies. And this number may be exceeded by one pharmacy in a commercial complex, or in any area with no existing pharmacy of more than five kilometers.

ARTICLE (12)
REQUIREMENTS FOR LICENSING PRIVATE PHARMACIES

Without prejudice to the requirements set out in Annex (8) attached to the Health Facilities Resolution, it is not permissible to open a private pharmacy unless it is attached to a medical facility, body or a certain category of the public; and this private pharmacy is prohibited from selling medicines and pharmaceutical products to non-patients of those entities.

ARTICLE (13)
SECURITY AND SAFETY MEASURES IN PRIVATE PHARMACIES

The license to open a private pharmacy shall comply with the security and safety measures stipulated in Annex (8) attached to the Health Facilities Resolution.

SECTION (2)
ISSUING THE LICENSE AND THE DUTIES OF THE LICENSEE

ARTICLE (14)
ISSUING THE LICENSE

The Authority's inspector shall carry out a final inspection on the pharmacy center when it is ready for operation; and prepare a report accordingly. And after paying the licensing fee, the Authority shall issue the license valid for a period of three years, renewable for similar periods, and shall notify the Ministry of Industry, Commerce and Tourism through its website.

ARTICLE (15)
DUTIES OF THE LICENSEE TO OPEN A PHARMACY CENTER

The licensee to open a pharmacy center shall abide by the following:

1. Prepare an internal regulation that includes the structure and job description of the center's employees, their rights, duties and working hours.
2. Complete the procedures of appointing technical and administrative cadres and issuing licenses for practicing their professions.
3. Appoint a director of the center in accordance with the conditions set forth in this regulation, and notify the Authority of his/her name, license number, mobile phone and e-mail address.
4. Not to practice any other activity in the center other than the licensed one.
5. Not to make any modification to the center before notifying the Authority to obtain the necessary approvals.

SECTION (3)
SYSTEM OF WORK IN PHARMACY CENTERS

ARTICLE (16)
CONDITIONS OF TECHNICAL STAFF IN PUBLIC PHARMACIES

The technical staff of the public pharmacy shall meet the following conditions:

1. They must be qualified and licensed to practice the profession.
2. The pharmacy manager shall be a licensed pharmacist with a bachelor's degree in pharmacy and licensed to practice the profession from the Authority.
3. The pharmacy shall have at least one pharmacist, in each shift, if it is operating over (24) hours.

4. The pharmacist shall supervise the work of pharmacy technicians.

ARTICLE (17)
CONDITIONS OF TECHNICAL STAFF IN PRIVATE PHARMACIES

The technical staff of the private pharmacy shall comply with the conditions stipulated in Annex (8) attached to the Health Facilities Resolution.

ARTICLE (18)
MEDICINES AND PHARMACEUTICAL PRODUCTS MANAGEMENT IN PHARMACY CENTERS

Each pharmacy center should have policies and procedures that include mechanisms for the management of medicines and pharmaceutical products and methods of disposal, in particular:

1. Ordering, protecting, and storing of medicines and pharmaceutical products, and placing tariffs and price tags on them.
2. Patient awareness.
3. Identifying and reporting errors and harmful effects of medicines and pharmaceutical products.
4. Withdrawing medicines and pharmaceutical products from the market.
5. Controlled medicines management.

ARTICLE (19)
MEDICINES COMPOUNDING AND PREPARATION

The pharmacy center is not allowed to perform medicines compounding and preparation without obtaining the Authority’s approval, in compliance with the guidelines/procedures for the compounding and preparation of medicines available on the Authority's website and any other requirements requested by the Authority upon a decision of The Council.

ARTICLE (20)
THE PUBLIC PHARMACY WAREHOUSE FOR MEDICINES AND PHARMACEUTICAL PRODUCTS

The public pharmacy should be licensed in order to license its medicines and pharmaceutical products warehouse; and this warehouse should be limited to the storage of medicines and pharmaceutical products, and not for other raw materials.

ARTICLE (21)
LABORATORY TESTS IN PUBLIC PHARMACIES

The licensed pharmacist in public pharmacies, with the prior license of the Authority, and after payment of the related fee, may conduct simple laboratory tests for individuals to examine blood sugar, fat, hemoglobin and blood pressure, by mobile devices, and the pharmacist has to know how to use it.

If the results are above normal ranges, the pharmacist should ask the patient to consult a physician.

ARTICLE (22)
CONDITIONS FOR PUBLIC PHARMACIES DELIVERY SERVICE

Subject to the requirements stipulated in Annex (37) attached to the Health Facilities Resolution, the public pharmacy is not allowed to provide medicines and pharmaceuticals products delivery service without obtaining the Authority's approval, while committing to the following:

1. The person-in-charge of the service shall be a licensed pharmacist licensed in the name of the pharmacy; and shall ensure that the service is appropriate for the patient before providing it.
2. Compliance with prices according to the price list issued by the Authority.
3. The pharmacy shall have a 24-hour social media platform, e-mail or fax to allow the service applicant to communicate with the pharmacy, and the Authority should be notified with the verified means of receiving the prescriptions.
4. The pharmacy shall have a mechanism for receiving complaints in case of error in the performance of the service and the Authority should be notified with such mechanism.
5. Copies of the prescriptions shall be kept, and the dispensed medicines shall be recorded in a register allocated for this purpose.
6. Establishing an internal regulation for the delivery service system, and the followed policies and procedures in this regard; and keeping this regulation in the pharmacy for the review by the professional staff or the Authority's inspectors upon request.
7. Patient information shall be encrypted to prevent its leakage to any unauthorized entity.
8. The Authority shall approve in advance the means of transport vehicle of medicines and pharmaceutical products.
9. One of the pharmacy staff shall deliver the medicines and pharmaceutical products to the patient.
10. Medicines and pharmaceutical products, especially liquids, shall not be exposed to damage during delivery.
11. The pharmacy may, with the prior approval of the Authority, contract with a company to deliver medicines and pharmaceutical products, if possible.

ARTICLE (23)
SCOPE OF DELIVERY SERVICE

A. Delivery service is limited to prescription and over-the-counter medicines and pharmaceutical products.

B. The delivery service does not include controlled medicines and those for which there are restrictions on dispensing, particularly narcotic drugs, psychotropics and precursors.

ARTICLE (24)
DUTIES OF THE DELIVERY SERVICE PERSON-IN-CHARGE

The pharmacist in charge of the delivery service shall comply with the following:

1. Receive the prescription via social media, email or fax.
2. The pharmacist in charge shall prepare by himself/herself the medicines according to the prescription.
3. Verify the identity of the patient and communicate with him/her or his/her family to ensure that the treatment is appropriate to his/her condition and meet his/her needs, if required.
4. To write the medicine's usage instructions in a clear handwriting on its outer packaging, mentioning the name of the pharmacist who dispensed it.
5. The patient, or his/her relatives, shall provide the pharmacy staff with a copy of his/her original identity card and medical prescription for retention, with a signature from the patient or his/her relatives indicating receipt of the medicine.
6. To communicate with the prescribing physician to clarify some of the prescription data, or request modification if there is a change in the medicine dosage or in the rate of use.

ARTICLE (25)
RECORDS

The director of the pharmacy center shall keep the following registration records:

1. Record for the registration of narcotic drugs, psychotropics and precursors, indicating the brand name, the pharmaceutical form, strength, and the number of units.
2. Record for the pharmaceutical preparations and the compounded medical prescriptions, in which it shall be written in a clear handwriting and serial numbers, the date of recording, the name of the prescribing physician, names and quantities of the substances included in the composition, the medicine's usage method and the price, and the pharmacist who prepared the prescription shall sign in this record.

3. Record to monitor the temperature and humidity.
4. Record of the medicines and pharmaceutical products quantities received by the pharmacy, indicating the date of receipt, types, quantities and source.

And the pages of each of these records shall be numbered and stamped with the pharmacy stamp, and in the custody of the manager or his representative in case of absence.

Such records shall be kept in the pharmacy for a period of five years from the date of their last registration.

CHAPTER (4)
PRODUCTS WAREHOUSES, AND MEDICINES AND PHARMACEUTICAL PRODUCTS MANUFACTURING SITES, AND THEIR REGISTRATION

SECTION (1)
PRODUCTS WAREHOUSES

ARTICLE (26)
REQUIREMENTS FOR LICENSING PRODUCTS WAREHOUSES

The following are required to license products warehouse:

1. The applicant must be a Bahraini national or a commercial company established in the Kingdom in accordance with the provisions of the Commercial Companies Law.
2. The applicant must not have been issued a final criminal judgment in a felony or misdemeanor involving moral turpitude or dishonesty, unless he has been rehabilitated.
3. The warehouse must meet all the requirements and specifications required by law.
4. All products to be imported, exported, stored, distributed or sold, shall be registered or licensed by the Authority.
5. The warehouse manager should be a licensed pharmacist.

ARTICLE (27)
GENERAL CONDITIONS IN PRODUCTS WAREHOUSES

The following conditions shall be met in the products warehouse:

1. The location of the warehouse should be away from sources of direct and/or indirect pollution.
2. The warehouse shall not have direct or indirect contact with any other shop.

3. Name of the warehouse should be written, in both Arabic and English languages, on its facade with clear fonts and letters.
4. The warehouse area, lighting and ventilation shall be commensurate with the volume and quantities of the products to be stored in.
5. The building shall be constructed from reinforced concrete or iron, well insulated and equipped with iron doors and tight locks.
6. The materials used in construction and decoration should be easy to clean, safe to use, and protect the products to be stored from insects, rodents, dust, odors and severe heat and humidity changes.
7. The warehouse shall have one or more ports for loading and unloading separate from the storage area, in addition to the emergency exits.
8. The storage area shall be divided into area for receipt (inbound), area for delivery (outbound), and storage area (with appropriate shelves), and an isolated area for damaged or expired products for decision.
9. The building should be air conditioned, and the temperature of the storage area should not exceed (25) °C, with devices to measure the temperature in clear, and different places.
10. The temperature and humidity measuring devices shall be distributed in different places and heights based on the temperature mapping of the warehouse; or installing one temperature measuring device for each (50) fifty square meters of the warehouse area.
11. To commit to the international principles of good distribution and storage practice (GSDP).
12. There should be a cold chamber (refrigerator) with temperature ranging between (2 - 8) °C to store the products, that need to be stored at low temperature, with a temperature measuring device, and to provide a plan to be followed in case of a technical failure in the refrigerator.
13. A freezer to store any products that require extremely low temperatures and to be equipped with appropriate shelves for storage, an automatic temperature monitoring device recording the readings in a form that can be reviewed for a period of not less than one year, and to provide a written and declared plan to be followed in case of a technical failure in the freezer.
14. The lower shelf should be at least 15 cm away from the floor and the upper shelf away from the actual ceiling by at least one meter.
15. Provide a data management system that includes the following:
    a. Inbound: It shows the scientific and trade names of the medicine, its concentration, packaging, pharmaceutical form, the invoice number and date, batch number, expiry date, and the country of origin.
    b. Outbound: It shows the quantity, the destination of the invoice, the invoice number and date, the remaining products quantities, the signature of the dispensing person, the batch number and the manufacturing date.

16. Barriers separating different products should be used, with appropriate ventilation to prevent cross-contamination.
17. To keep a file containing the approvals issued by the Authority to import the products.
18. Use of appropriate and air-conditioned vehicles for the transport and distribution of products.
19. Contracting with a company specialized in the safe disposal of medical waste and damaged or expired products.
20. Not to practice any activity in the warehouse other than the licensed activity.
21. Obtain an approval from the Authority in the event of selling, assigning or disposing of the warehouse in any way, or changing its name, address or the responsible manager.
22. Provide management offices attached to or separate from the warehouse.
23. Facilitate the task of the Authority's employees in inspecting the warehouse at any time to ascertain the storage conditions, take random samples for inspection, and control violations.
24. Provide means to eradicate insects and rodents; and maintain a record of the same.
25. Comply with the requirements and instructions of the General Directorate of Civil Defense when storing flammable or explosive materials, with the use of protective masks by the involved personnel.
26. Provide a fire extinguishing system and means for security, safety and others, in accordance with the instructions of the General Directorate of Civil Defense.

ARTICLE (28)
STORAGE CONDITIONS OF NARCOTIC DRUGS, PSYCHOTROPICS, AND PRECURSORS

The products warehouse shall follow the below, in case of storing of narcotic drugs, psychotropics or precursors:

1. Allocation of a special record, whose pages shall be serially numbered and written in indelible ink, with signature in the pages upon amendment. The record shall include the following data:
    a. The scientific name of the products, their pharmaceutical form, and concentration.
    b. The previous balance of the materials, their type and quantities, the total sum of them, date of their receipt, source, the number and date of their issued license.
    c. The quantity of materials discharged, type, batch number, date of discharge, the destination and address, discharge documents and the remaining quantity.
    d. Retention of records for a period of five years, after their expiry is destroyed by a committee of three members formed by the warehouse manager or his deputy, and the committee’s meeting minutes should be prepared.

2. Storage shall be in accordance with the storage conditions and precautions decided by the manufacturer.
3. Storage to be in a closet or warehouse dedicated to them only, and to be equipped with a security alarm system for protection, tightly sealed and cannot be removed, broken or reallocated.

ARTICLE (29)
LICENSING DOCUMENTS

Any person wishing to obtain a license to establish a products warehouse shall submit an application on the form prepared for this purpose, which is available on the Authority's website, to the concerned department, accompanied by the following documents:

1. An engineering drawing showing the location of the warehouse within its area, and the names of the streets surrounding it.
2. Copy of the warehouse lease contact or a copy of the ownership document.
3. Copy of the identity card and passport of the owner and partners, if any.
4. Copy of the license to practice the profession of the pharmacist in charge of the warehouse.
5. Approvals of other relevant official authorities.
6. Copy of the receipt indicating the payment of the submission fee for the license application.

ARTICLE (30)
INITIAL APPROVAL

A. The Authority’s inspector shall inspect the warehouse to verify that it meets the legal requirements; and prepare a report accordingly.

B. If the inspection proves that the legal requirements are met, and the owner of the pharmacy center obtained the commercial register (CR) from the Ministry of Industry, Commerce and Tourism, the initial approval for the opening of the pharmacy center shall be issued.

ARTICLE (31)
EQUIPPING THE WAREHOUSE

A. The warehouse shall be executed, furnished and equipped for operation in accordance with the requirements available on the Authority’s website.

B. The owner of the warehouse must apply for licenses to practice the pharmacy professions for his/her employees.

C. After fulfilling the approvals, licenses and requirements required by other relevant official authorities, and equipping the warehouse for operation in accordance with the conditions on which the initial approval was granted, the owner of the warehouse shall apply for the final inspection.

ARTICLE (32)
FINAL LICENSING

The Authority's inspector shall carry out a final inspection on the warehouse when it is ready for operation; and prepare a report accordingly. And after paying the licensing fee, the Authority shall issue the license valid for a period of one year, renewable for similar periods, and shall notify the Ministry of Industry, Commerce and Tourism through its website.

ARTICLE (33)
CONTROL OF PRODUCTS TRANSFER

Products shall be transferred from the warehouse to other entities according to the following rules:

1. The personnel in the distribution chain should be qualified and trained on the medicines' good transportation and distribution practices and be trained on the tasks assigned to them based on standard working methods, and in a written and documented program.
2. Document all distribution-related activities, including receipts and records, and make all documents available if requested by the Authority, and to include in the transport records the following:
    a. Date of loading and transport.
    b. Name and address of the institution or establishment to which it is sent.
    c. Description of the medicine or pharmaceutical product, including name, pharmaceutical form, concentration, quantity, packaging type, batch number, date of production, and expiry date.
3. In case of transferring the products by a transport and distribution company, its name and address shall be mentioned, this shall be with the consent of the concerned parties, and a contract shall be edited specifying the responsibilities of each party.
4. Ensure that the transport and distribution company comply with the instructions of good transport and distribution practice, taking in consideration the nature of the materials and any other special precautions.
5. Products should be received and delivered in areas that protect them from atmospheric impacts, and the receiving areas should be designed and prepared to allow the containers of the products to be clean.

6. Vehicles and equipment used in transport, storage or handling of products shall be suitable and in such a manner that no product shall be exposed to conditions that affect the medicine's stability and efficacy, and to prevent any kind of contamination.
7. Provide equipped vehicles used in the transport and distribution of products to ensure that they are not exposed to temperatures or storage conditions detrimental to their quality and affect the stability and effectiveness of the drug, and the elapsed time since loading the shipment must be documented.
8. Provide vehicles with temperature monitoring devices, which are used to transport and distribute products that should be kept at low temperatures, to ensure the maintenance of temperature and storage conditions in the vehicle or insulated containers and in accordance with the approved storage conditions of the transferred products, and the temperature data logger report should be kept in a record for one year from the date of transport.
9. The packages' identification labels should be clear and contain information on the content, source, the conditions on how to store, transport and deal with them, and the precautions that ensure their safety during transport and at all times.
10. Abbreviations or symbols recognized locally or globally should be mentioned on identification labels.
11. Take special care when using dry ice with packages and ensure that it is not in direct contact with any of the products that ice may have a negative impact on them.
12. Provide written procedures for handling containers that may be damaged or destroyed, especially if it contains toxic or hazardous substances.
13. Provide mechanisms to allow the separation of withdrawn or rejected products, and securely wrapping it, and attach with the supporting documents.
14. Provide measures to prevent unauthorized persons from entering or tampering with vehicles and equipment, or theft or embezzlement.

SECTION (2)
MEDICINES AND PHARMACEUTICAL PRODUCTS MANUFACTURING SITES, AND THEIR LICENSING

FIRST: MEDICINES AND PHARMACEUTICAL PRODUCTS MANUFACTURING SITES

ARTICLE (34)
REQUIRMENTS FOR LICENSING MEDICINES AND PHARMACEUTICAL PRODUCTS MANUFACTURING SITES

Without prejudice to the provisions of the laws regulating industrial activities and factories, no normal or legal person may establish medicines and pharmaceutical products manufacturing site, except after

obtaining a manufacturing licensing from the Authority and meeting the Good Manufacturing Practice (cGMP) standards and specifications, set in the guidelines, in particular the following:

1. The plant should be located in a location far from residential areas, sources of pollution, vapors, and flammable chemicals.
2. The factory's wastes shall be discharged by a mechanism that prevents pollution of the surrounding environment and harming the public health.
3. The factory premises shall meet all the necessary technical and health requirements to ensure the safety of its employees.
4. All manufacturing processes should be specific and reviewed taking into account the previous practices, as well as the ability to produce different batches of the same quality and conformity to specifications.
5. Ensure the correctness of all critical manufacturing steps and the significant changes that occur.
6. All necessary facilities for good manufacturing practice shall be available, in particular:
    a. Adequate places and areas.
    b. Appropriate equipment and services.
    c. The correct materials, containers and labels.
    d. Procedures and instructions related to the manufacturing process.
    e. Proper storage and transportation.
7. The factory employees should be properly qualified and trained.
8. The procedures and instructions should be written in a clear manner.
9. To comply with all instructions and procedures followed in the manufacturing process; resulting in a product complying with specifications and quality, and the recording of any changes related to quality and effectiveness, and to be investigated.
10. Maintain comprehensive factory records - including distribution records - and be made available in such a way that the full batch history can be tracked.
11. Provide a mechanism through which any manufactured batch can be unconditionally recalled either at the market or distribution levels.

ARTICLE (35)
MEDICINES AND PHARMACEUTICAL PRODUCTS MANUFACTURING SITES LICENSING PROCEDURES

For licensing a medicines and pharmaceutical products manufacturing site, the following procedures shall be followed:

First - License Application:

Any person wishing to establish a medicines and pharmaceutical products manufacturing site shall submit to the Authority a request to get a no objection letter to establish the manufacturing site, and if approved, the Authority shall notify him/her to submit the necessary documents.

Second - Initial Approval:

Those wishing to establish the manufacturing site shall obtain the approvals of the relevant official authorities as follows:

1. To apply for the license to the Ministry of Industry, Commerce and Tourism through its website with the required data. Upon approval, the application shall be forwarded to the Authority for its initial approval for the establishment of the manufacturing site.
2. Prepare the initial approval form, which is available on the Authority's website, and submit it along with its approval on the manufacturing site design, the approvals of the Ministry of Industry, Commerce and Tourism, the Ministry of Municipalities Affairs, the Supreme Council for Environment, the General Directorate of Civil Defense, and any approvals from other relevant official authorities.
3. After an inspection visit by the Authority's team to the manufacturing site, and paying the fee for initial approval, the Authority shall issue its initial approval to establish the manufacturing site.

Third – Manufacturing Site Operation:

A. The owner of the manufacturing site shall submit to the Authority, upon completion of its construction, an application for a manufacturing license, together with the following documents:
    1) Copy of the form, which is available on the Authority's website, to issue the site manufacturing license.
    2) Copy of the Authority approvals on the manufacturing site design and its initial approval.
    3) Copy of the approvals of the Ministry of Industry, Commerce and Tourism, the Ministry of Municipalities Affairs, the Supreme Council for Environment, the General Directorate of Civil Defense, and any approvals from other relevant official authorities.
    4) Copy of the Site Master File (SMF).
    5) List of medicines and pharmaceutical products to be manufactured or packaged, and a list of raw materials suppliers.

B. A team from the Authority shall inspect the manufacturing site after the completion of its construction, and a further inspection after the installation of the equipment and machinery. Once the manufacturing site is verified for operation, the Authority shall issue the site manufacturing license, after paying the related fee.

C. The site manager and the production manager shall be full-time dedicated licensed pharmacists.

D. A team from the Authority shall inspect the factory after preparing the required studies and producing validation batches. Once the manufacturing quality is verified, the Authority shall issue the site's Good Manufacturing Practice (GMP) certificate, which allows the site to start the production.

E. It is prohibited to make any modifications in the factory before obtaining the prior approval of the Authority.

SECOND: MEDICINES AND PHARMACEUTICAL PRODUCTS REGISTRATION

ARTICLE (36)
MEDICINES REGISTRATION PROCEDURES

Subject to the provisions of Article (65) of The Law, the following medicines registration procedures shall be followed:

1. The pharmaceutical establishment representing the medicine manufacturer in the Kingdom shall submit to the concerned department via e-mail a request for an appointment through the prepared form on the Authority's website, provided that the manufacturer is registered by the Authority.

2. The concerned department shall specify a date for submitting the medicine registration application, and the pharmaceutical establishment shall submit a file with the required documents according to the latest medicines licensing guidelines available on the Authority's website, in particular the following:

    a. A request for medicine registration on the form prepared for this purpose, accompanied by the required documents and samples, and a copy of the receipt indicating the application submission fee payment.

    b. Complete electronic medicine dossier (eCTD) in terms of quality, clinical and non-clinical studies.

    c. Certificate proving on the form prepared for this purpose (Price Certificate Form), the ex-factory price, CIF price, and the public price in the country of origin, and in the countries where the medicine is registered.

3. The applicant for the medicine registration shall, after accepting the dossier by the Authority, pay the medicine registration application submission fee.

4. The concerned department shall perform the medicine pricing procedures in accordance with the guidelines set for that purpose, and the retail price shall be determined in Bahraini Dinars based on the CIF price set in US Dollars.
5. The concerned department shall study the medicine dossier in terms of quality, efficacy and safety.
6. The concerned department shall submit the medicine dossier with its recommendations to the Medicines Registration Committee for the final registration and pricing decision, and if it agrees, the concerned department shall issue the medicine registration certificate after paying the licensing fee.

ARTICLE (37)
PHARMACEUTICAL PRODUCTTS REGISTRATION PROCEDURES

Subject to the provisions of Article (65) of The Law, the following pharmaceutical products registration procedures shall be followed:

1. The representative of the pharmaceutical product manufacturer in the Kingdom shall submit to the concerned department via e-mail a request for an appointment through the prepared form for that on the Authority's website.
2. In the event that the Authority determines a date for the submission of pharmaceutical products, the representative of the manufacturer shall submit a dossier enclosed with the required documents, in accordance with the latest list of requirements for the pharmaceutical products registration, available on the Authority's website, in particular the following:
    a. Application for pharmaceutical product registration on the form prepared for this purpose, accompanied by the required documents and samples, and a copy of the receipt indicating the payment of the application submission fee.
    b. Samples for laboratory analysis accompanied by the required documents.
3. The concerned department shall study the pharmaceutical product in terms of quality, efficacy and safety.
4. The concerned department shall submit the dossier with its recommendations to the Medicines Registration Committee for the final registration decision. In case of approval, the concerned department shall issue the pharmaceutical product registration certificate, after paying the licensing fee.

ARTICLE (38)
RESPONSIBILITY FOR QUALITY

It is the responsibility of the medicine or the pharmaceutical product Marketing Authorization Holder (MAH) to be accountable for its quality, efficacy and safety during its life cycle, from its registration to the license cancellation. The pharmaceutical establishment representing the manufacturer is obliged to inform the Authority of any updates on the medicine or the pharmaceutical product quality, efficacy and safety.

CHAPTER (5)
MEDICINES AND PHARMACEUTICAL PRODUCTS IMPORTATION FOR PERSONAL USE

ARTICLE (39)

Subject to the provisions of the Law, it is prohibited to import medicines and pharmaceutical products for personal use in the form of parcels or others without an approval from the Authority, except in accordance with the following regulations:

1. The parcel owner must have a medical report or prescription confirming his/her need for the medicines or pharmaceutical products, and the prescription shall include the patient name, medicine or pharmaceutical product name, dosage, duration of treatment, and the purpose of use.
2. The quantities to be imported are suitable for the usage period specified in the prescription, and to be in non-commercial quantities.
3. The containers shall be sealed and written on its label the required data indicating the contents of the medicine or the pharmaceutical product and its storage conditions to ensure the user’s safety.
4. Submit the customs declaration of the parcel and a copy of the owner's identity card.
5. Not to buy medicines and pharmaceutical products through the Internet and should not use the method of network marketing or pyramid scheme to market any product.
6. The Authority shall return the parcels containing narcotic drugs, psychotropics or precursors to the Customs for transfer to the Ministry of Health.
7. The Authority may refrain from releasing the parcel to its owner if the parcel contains prohibited goods imported in violation of the provisions of The Law and these regulations.
8. The parcel owner shall sign indicating knowledge and receipt, in the event of the Authority refusal to release the parcel.
9. The Authority shall be entitled, after one month from the receiving date of the unreleased parcel, to return it back to the Customs.

CHAPTER (6)
SCIENTIFIC OFFICE, PHARMACEUTICAL SERVICES CENTER, AND SCIENTIFIC RESEARCH FACILITY

SECTION (1)
SCIENTIFIC OFFICE

ARTICLE (40)
SCIENTIFIC OFFICE ACTIVITIES

The Scientific Office undertakes the following activities:

1. Following up the registration of medicines and pharmaceutical products for the companies that affiliated to the office.
2. Providing accurate pharmaceutical information about the company's products - traded in the Kingdom - to the beneficiaries, healthcare sector employees, and regulatory authorities, according to the scientific basis.
3. Ensure the accuracy of the information used in marketing the registered products and its conformity with the information recorded with the Authority.
4. Follow up on updating the registered product leaflet and the outer pack, and ensure it conforms with what is approved by the Authority.
5. Following up the company's products after registration and marketing, and immediately report to the Authority any observations concerning the quality and efficacy of the product, or any new post-marketing side effects.
6. Providing free medical samples of registered medicines and pharmaceutical products, if possible, and storing them according to the approved storage conditions, and it is prohibited to sell the free medical samples or distribute them to the public, and each sample should be stamped that it is free and not for sale.
7. Contribute to the scientific pharmaceutical studies and research in cooperation with the specialized scientific centers in accordance with the rules and ethics of scientific research.
8. Supporting scientific activities in the fields related to the company's products, participating in the activities of scientific societies, and contributing to continuous medical education programs.
9. Training the company's employees to be familiar with the activities of the marketing facility.
10. Contribute to raise the health awareness and medical education.
11. Support the attendance of healthcare sector employees to the scientific conferences.
12. Follow up on the protection of patents and manufacturing rights of the company's products.

13. Implement the decisions and instructions issued by The Council.

ARTICLE (41)
SCIENTIFIC OFFICE LICENSING CONDITIONS

The following conditions are required for licensing the scientific office:

1. The applicant must be a Bahraini national or a commercial company established in the Kingdom in accordance with the provisions of the Commercial Companies Law.
2. The office director shall be a dedicated full-time licensed pharmacist.
3. The medicines and pharmaceutical products promoter in the office should be a dedicated full-time licensed pharmacist.
4. Provide the equipment, offices, and references necessary for the performance of the office activities.
5. Provide a suitable place for the storage of the registered products free medical samples in accordance with the approved storage conditions.

ARTICLE (42)
SCIENTIFIC OFFICE LICENSING DOCUMENTS

Any person wishing to license a scientific office must submit an application on the form prepared for this purpose, which is available on the Authority's website, to the concerned department, accompanied by the following documents:

1. Copy of the receipt indicating the payment of the application submission fee.
2. Copy of the company's authorization for the agent to open the scientific office.
3. Copy of valid lease contract or ownership document if the applicant owns the office location.
4. Engineering drawing of the office.
5. Copy of the identity card and passport of the applicant and partners, if any.
6. Copy of the identity card and passport of the office director, and the license issued to him to practice the profession from the Authority.
7. Copy of the identity card of the person responsible for following up the license application with the Authority and the authorization issued by the applicant.
8. Approvals of other relevant official authorities.
9. Copy of the receipt indicating the payment of the licensing fee.

ARTICLE (43)
ISSUING THE LICENSE

The concerned department shall issue the scientific office license, after paying the licensing fee, which shall be valid for a period of one year, and renewable for similar periods.

SECTION (2)
PHARMACEUTICAL SERVICES CENTER

ARTICLE (44)
PHARMACEUTICAL SERVICES CENTER ACTIVITIES

The Pharmaceutical Services Center performs the following activities:

1. Providing pharmaceutical consultations.
2. Pharmaceutical development studies for medicines and pharmaceutical products.
3. Management and assessment of bioavailability and bioequivalence studies.
4. Stability studies of medicines during their shelf-life.
5. Medicines quality control.
6. Determine the levels of medicines in biological fluids.
7. Preparation of medicines dossiers (eCTD).
8. Pharmaceutical and toxicological studies.

ARTICLE (45)
PHARMACEUTICAL SERVICES CENTER LICENSING PROCEDURES

The following are the procedures for licensing a pharmaceutical services center:

1. Apply to the concerned department for the initial approval, through the form available on the Authority's website, accompanied by the required documents.
2. The inspector of the Authority shall inspect the center to verify that it fulfills the legal requirements; and prepare a report accordingly.
3. If the documents are complete and all the law requirements are met, the concerned department shall issue an initial approval to the center, which does not give the applicant the right to practice the activity.

4. After the equipping is completed according to the requirements, the application for licensing the center shall be submitted on the form available on the Authority's website along with the required documents.
5. The Authority's inspector shall conduct a final inspection of the center; and prepare a report accordingly.
6. If the documents are complete and the requirements stipulated by law are met, the license shall be issued by the concerned department and shall be valid for a period of one year, and renewable for similar periods.

ARTICLE (46)
INITIAL APPROVAL CONDITIONS

The following is required to apply for the initial approval of a pharmaceutical services center license:

1. The applicant must be a Bahraini national or a Bahraini company established in the Kingdom in accordance with the provisions of the Commercial Companies Law.
2. The director of the center should be a dedicated full-time licensed pharmacist.
3. The center should be in an independent building, once it commences the activity of bioequivalence and bioavailability studies or pharmaceutical laboratory analysis.
4. Provide a statement about the center including its total area and the area allocated to each section, and a detailed explanation of the activities to be carried out in it, and its initial administrative structure.

ARTICLE (47)
INITIAL APPROVAL DOCUMENTS

The applicant who requests the initial approval for a pharmaceutical services center license must submit an application to the concerned department with the following documents:

1. The application form available on the Authority's website.
2. Copy of the company's memorandum of association, if the application is submitted in its name, provided that it is approved by the Ministry of Industry, Commerce and Tourism.
3. Copy of the commercial register (CR) of the company.
4. Copy of the valid lease contract or ownership document if the applicant owns the center's location.
5. Statement about the center including a detailed explanation of its role in the activities to be practiced and its initial administrative structure.
6. The total area of the center with the determination of the space allocated to each of its sections.

7. Copy of the applicant identity card and passport and partners, if any.
8. Copy of the identity card and passport of the center director, and the license issued to practice the profession.
9. Copy of the identity card of the person responsible for following up the initial approval application with the Authority and the authorization issued for that by the applicant.
10. Approvals of other relevant official authorities.
11. Copy of the receipt indicating the payment of the application submission fee.
12. Any other documents requested by the Authority upon a decision of The Council.

ARTICLE (48)
GENERAL CONDITIONS TO LICENSE A PHARMACEUTICAL SERVICES CENTER

The following is required to license a pharmaceutical services center:

1. Obtaining a license from the General Directorate of Civil Defense.
2. Obtain a license from the relevant municipality.
3. Appointing a director of the center who shall be a dedicate full-time Bahraini pharmacist licensed to practice the profession.
4. An electronic database is available in which all data and documents are archived in a manner that facilitates review, access and retrieval when needed.
5. The center should have its own stamp.
6. Provide the necessary equipment, offices and references to perform the center’s activities.
7. Provide a suitable place for the products’ samples storage according to the recognized international storage standards.

ARTICLE (49)
GENERAL DOCUMENTS TO LICENSE A PHARMACEUTICAL SERVICES CENTER

Those wishing to license a pharmaceutical services center should submit an application on the form prepared for this purpose, which is available on the Authority's website, to the concerned department, accompanied by the following documents:

1. Copy of the initial approval.
2. Copy of the valid license of the General Directorate of Civil Defense.
3. Copy of the licenses issued to the medical staff working in the center.

4. Copy of the receipt indicating payment of the licensing fee.
5. Submitting the center's organizational structure and determining the activity of each department.
6. Any other documents requested by the Authority upon a decision of The Council.

ARTICLE (50)
BIOEQUIVELENCE AND BIOAVAILABILITY STUDIES CENTER LICENSING REQUIREMENTS

The following should be considered to license a bioequivalence and bioavailability studies center:

1. No bioequivalence and bioavailability study shall be carried out without obtaining the Authority's approval.
2. The places of conducting clinical tests, laboratory, reception and administration should be separated from each other.
3. Compliance with the Declaration of Helsinki for clinical studies.
4. Commitment to the Good Clinical Practice (GCP) guidelines issued by the ICH.
5. The area of the center is the appropriate area for clinics.
6. The section dedicated to the bioequivalence and bioavailability studies should contain separate rooms, each dedicated to the selection and registration of medicinal tests volunteers, their accommodation, medicines administration, and samples withdrawal and storage.
7. An ambulance should be available at the center.
8. The center should have an intensive care room equipped to receive any emergency case, and contains the equipment required for cardiopulmonary resuscitation and important emergency medicines.
9. Conclude an agreement with one of the qualified hospitals to receive any emergency case after dealing with it inside the center.
10. The center should have a doctor for 24 hours during the bioequivalence and bioavailability studies.
11. The center should have a laboratory to perform biopharmaceutical analysis.
12. The different sections in the laboratory (microbiology, chemical analysis and animal experiments - if any) should be separate from each other.
13. Separate laboratory analysis locations in a manner that minimizes the chances of contamination.
14. Sensitive devices should be placed in separate private rooms to prevent them from being affected by any other devices.
15. The walls and floors of the laboratory shall be non-flammable and do not react with chemicals and easy to clean.

16. Once clinical analyzes are performed in an in-house laboratory, the laboratory must be separate from the laboratory of biopharmaceutical analysis.

17. If there is a laboratory to conduct clinical analysis, the responsible person must be a licensed and dedicated full-time laboratory specialist, holding a master's degree in one of the medical laboratory specializations with two years of experience in quantitative analysis, qualitative analysis or quality testing, or have at least five years of experience in quantitative analysis, qualitative analysis or quality testing.

18. The responsible person for the biopharmaceutical laboratory should be a dedicated full-time licensed pharmacist or chemist, and holds a master's degree in analytical chemistry, pharmaceutical chemistry or pharmaceutics from a recognized university, and have a minimum of two years of experience in quantitative analysis, qualitative analysis, quality testing, or pharmaceutical products control.

19. The responsible person for the bioequivalence and availability studies should have an appropriate qualification in the field of bioequivalence and bioavailability studies from a recognized university; and has a minimum of two years of experience in the field of bioequivalence and bioavailability studies in a recognized institution.

20. The responsible person for quality should be a dedicated full-time licensed pharmacist or laboratory specialist, holds a master's degree in one of pharmaceutical sciences or quality control from a recognized university, and have a minimum of two years of experience in quantitative analysis, qualitative analysis, quality testing or pharmaceutical products control.

21. Contracting with a company specialized in the safe disposal of medical and chemical wastes.

ARTICLE (51)
BIOEQUIVELENCE AND BIOAVAILABILITY STUDIES CENTER LICENSING DOCUMENTS

Those wishing to license a bioequivalence and bioavailability studies center should submit an application to the concerned department, accompanied by the following documents:

1. Copy of the identity card and passport of the official responsible for the laboratory analysis of pharmaceuticals in bio-fluids, and a copy of his/her professional license if he/she is a pharmacist, and a copy of his/her certificates and experiences legalized by the embassy, for non-Bahrainis.

2. Copy of the identity card, passport, professional license for the person responsible for bioequivalence and bioavailability studies, and a copy of his/her certificates and experiences legalized by the embassy, for non-Bahrainis.

3. Copy of the identity card, passport, professional license for the person responsible for quality, and a copy of his/her certificates and experiences legalized by the embassy, for non-Bahrainis.

4. If there is a laboratory to conduct clinical tests, a copy of the laboratory official identity card, passport, and professional license, and a copy of his certificates and experiences legalized by the embassy, for non-Bahrainis.

5. Copy of the ambulance license for the center.
6. Copy of the contract concluded with a hospital to receive emergency cases.
7. Copy of the contract signed with a company specialized in the safe disposal of medical and chemical wastes.

ARTICLE (52)
PHARMACOLOGY AND TOXICOLOGY DATA CENTER LICENSING REQUIREMENTS

The below is required to license a pharmacology and toxicology data center:

1. The center should have the sources of information, equipment and office furniture suitable for the nature of work.
2. The responsible person for the center should be a dedicated full-time licensed pharmacist with a master's degree in clinical pharmacy and have at least three years of experience in clinical pharmacy.

ARTICLE (53)
PHARMACOLOGY AND TOXICOLOGY DATA CENTER LICENSING DOCUMENTS

Those wishing to license a pharmacology and toxicology data center must submit an application to the concerned department, accompanied by the following documents:

1. Copy of the identity card and passport of the center official, and a copy of his professional license.
2. Copy of the certificates and experiences of the center official, legalized by the embassy, for non-Bahrainis.

SECTION (3)
SCIENTIFIC RESEARCH FACILITY

ARTICLE (54)
SCIENTIFIC RESEARCH FACILITY ACTIVITIES

The scientific research facility for medicines, biotechnology and medical devices provides support to the pharmaceutical, biotechnology, and medical devices industries in the form of research services outsourced to the facility on a contractual basis.

ARTICLE (55)
LICENSING REQUIREMENTS

The below is required to license a scientific research facility on medicines, biotechnology and medical devices:

1. The facility shall be managed by a dedicated full-time Bahraini physician or dentist and have a minimum of ten years of experience.
2. The safety officer in the facility should be a dedicated full-time having a bachelor's degree in medicine or dentistry and has a minimum of ten years of experience, and if he/she is a pharmacist, his/her experience in the field of pharmacovigilance and medicines safety should be not less than ten years.
3. The monitoring and control officer in the facility should be a medical doctor, a dedicated full-time pharmacist or dentist, or hold a bachelor's degree in biology, clinical pathology or biophysics with a minimum of ten years of experience.
4. The technicians working in the establishment must have a bachelor's degree in medicine, dentistry, nursing, biology, clinical pathology or biophysics and have a minimum of ten years of experience.
5. Provide adequate equipment, offices and references necessary for the performance of the establishment's activities.
6. Providing a suitable place for the storage of the samples of the registered researches, according to the technical principles of storage.

ARTICLE (56)
LICENSING DOCUMENTS

Those wishing to license a scientific research facility on medicines, biotechnology, and medical devices must complete the following documents:

1. Copy of the identity card and passport for all the facility’s employees, and the agent authorized to open in the Kingdom.
2. Academic certificates legalized by the Ministry of Education and the Ministry of Foreign Affairs; and translated into English if necessary.
3. Commercial registration number.
4. Copy of the power of attorney issued to the commissioner to inaugurate the establishment in the Kingdom, legalized by the Ministry of Foreign Affairs, and translated if necessary.
5. Copy of the valid lease contract or ownership document if the applicant owns the establishment's location.
6. Map of the facility’s location showing the name of the city, building number, road, and block, and the nature of the facilities adjacent to the site, with the writing of the phone numbers of the applicant.

7. Approvals of other relevant official authorities.
8. Nominate the director of the establishment and indicate the number of those who will work in it, and the CV of each of them.
9. List of activities provided by the establishment.
10. Detailed statement of the establishment.
11. Copy of the receipt indicating the payment of the licensing fee.

ARTICLE (57)
LICENSING PROCEDURES

Those wishing to license a scientific research facility must observe the following:

1. Submit the application form for the initial approval of the establishment's license, which is available on the Ministry of Industry, Commerce, and Tourism website.
2. Attach all required documents.
3. Once the facility’s documents are complete and all the requirements are met, the concerned department shall issue an initial approval that does not give the applicant the right to practice the activity.
4. If the facility passes the initial technical inspection conducted by the Authority's inspectors, the concerned department shall issue its approval to prepare the facility for operation.
5. The applicant for the license shall, after completing the equipment and getting the approvals of the other relevant official authorities, apply for the final inspection of the establishment by the Authority's inspectors.
6. The concerned department shall issue the license of the establishment after paying the licensing fee, which shall be valid for a period of one year, and renewable for similar periods.

CHAPTER (7)
MISCELLANEOUS PROVISIONS

ARTICLE (58)

The provisions of this regulation shall not prejudice any requirements, permits, licenses or other obligations stipulated by any or other law.

ARTICLE (59)

Pharmaceutical establishments may contract with a provider of support services determined by the Authority, if they are not available within the services of the pharmaceutical facility.

The applicant must provide proof of contracting with the support services provider if needed.

ARTICLE (60)

The license for the pharmaceutical establishment shall specify the sections and units for which the license has been issued, and it is prohibited to operate other sections or units without the Authority's prior approval and its addition to the license.

Article (61)

Without prejudice to the provisions of the building regulation law, any modification to the pharmaceutical facility premises by construction, full destruction, partial destruction, extension, ramping, addition of any part, or change in the internal order shall not be carried out, except after obtaining the Authority's approval.

Article (62)

Each licensed pharmaceutical facility shall, prior to the provisions of this regulation, adjust its status in accordance with these provisions within a period not exceeding six months from the date of its operation or from the date of the last renewal of the license, whichever comes first.