Cabinet Resolution No. (90) of 2021
Concerning the Executive Regulations of Federal Law No. (8) of 2019 Concerning Medical Products, Pharmacy Profession and Pharmaceutical Establishments

The Cabinet,

Having reviewed:

- The Constitution;
- Federal Law No. (1) of 1972 Concerning the Competences of Ministries and the Powers of Ministers, as amended;
- Federal Law No. (14) of 1995 On the Combating of Narcotic Drugs and Psychotropic Substances, as amended;
- Federal Law No. (2) of 2019 on the Use of Information and Communication Technology in Health Fields;
- Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments;
- Federal Decree No. (9) of 1988 Approving the Accession to the Single Convention on Narcotic Drugs, amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971;
- Federal Decree No. (55) of 1990 Approving the Accession to the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Cabinet Resolution No. (39) of 2015 on the Strategic Medical Stock;
- Cabinet Resolution No. (20) of 2017 Approving the Unified Standards for Licensing Health Professionals at the State's Level, as amended;
- Cabinet Resolution No. (32) of 2020 on the Executive Regulations of Federal Law No. (2) of 2019 on the Use of Information and Communication Technology in Health Fields; and

— Based upon the proposal of the Minister of Health and Prevention, and the approval thereof by the Cabinet,

Hereby resolves as follows:

Article (1)

Definitions

The definitions mentioned in Federal Law No. (8) of 2019, referred to in the present Resolution, shall apply. Otherwise, the following words and expressions shall have the meanings assigned thereto respectively, unless the context otherwise requires:

Health Authority	:	Any federal or local government entity concerned with health affairs in the State.
Product Suspension	:	Suspension of the circulation or use of the product.
Healthcare Profession	:	A health profession licensed to be practiced in the State, as determined in Cabinet Resolution No. (20) of 2017, referred to above.
Narcotic Drug	:	A medical product that contains any of the active ingredients listed in Schedules Nos. (1,2,3 or 4) attached to Federal Law No. (14) of 1995, referred to hereinabove, or listed in INCB Schedules Nos. (I, II, III or IV) annexed to the 1961 Single Convention on Narcotic Drugs, amended by the 1972 Protocol, as amended.
Psychotropic Substance	:	A medical product that contains any of the ingredients listed in Schedules Nos. (5,6,7 or 8) attached to Federal Law No. (14) of 1995, referred to hereinabove, or listed in INCB Schedules Nos. (I, II, III or IV) annexed to the Convention on Psychotropic Substances of 1971, as amended.
Controlled Substances	:	Narcotic drugs and Psychotropic Substances.

Visiting Pharmacist : A pharmacist licensed in a pharmaceutical establishment or health facility in the State and permitted to work on a part-time basis for another pharmaceutical establishment or health facility; or a pharmacist coming from abroad to practice the pharmacy profession in the State for a specified period, in accordance with the conditions and controls set out in the present Resolution.

Law : Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments.

Article (2)

Price of Medical Products

1. Discounts from the prices set by the Ministry may not be granted, but special prices may be set in the course of applying the drugs dispensing system by the Health Authority, as the case may be, or through the government health insurance schemes.
2. Special prices may be set in the course of applying the drugs purchase system by the health bodies. In such case, drugs shall be dispensed, depending on the purchase price applicable for the health facility.
3. Without prejudice to the provision of Clause (1) of this Article, pharmacies may be granted a quantity of medical products for free and the granted quantity shall not exceed the percentage of the overall quantity sold to the pharmacy as set by a resolution of the Minister.

Article (3)

Suspension of the Medical Product

The Body Concerned may suspend the medical product's circulation at public and private health facilities falling within their respective areas of competence, and shall report the same to the Ministry within twenty-four hours from the date of issuance of the suspension decision, on the

form designated thereby for such purpose. Accordingly, the Ministry shall take the necessary decision in this regard.

Article (4)

Controls for Bringing the Medical Product

The medical product shall be brought, possessed or held by any person upon entering the State for personal use in accordance with the conditions and rules set out in Annex No. (1) attached to the present Resolution.

Article (5)

Obligations of Non-Pharmaceutical Establishments

Non-pharmaceutical establishments that are determined under a resolution of the Minister and that are permitted to sell, display, store and circulate Over-the-counter (OTC) medical products shall:

1. Purchase the medical product from the warehouse licensed by the Ministry;
2. Adhere to the types of OTC medical products, according to the classification approved by the Ministry;
3. Obtain the approval of the entity licensing the establishment;
4. Comply with the approved storage conditions as for each product; and
5. Adhere to the price set by the Ministry, if any.

Article (6)

Requirements for Practicing the Pharmacy Profession

No person may engage in any activity in the field of pharmacy profession or work as a pharmacy technician, unless such a person is duly licensed by the Health Authority, in accordance with the

conditions and controls set out in Cabinet Resolution No. (20) of 2017, referred to hereinabove, as amended.

Article (7)

Record of Practitioners

1. Those who are entered in the national record created in the Ministry and the special record created in the Body Concerned shall be pharmacy and pharmacy technician practitioners and shall be licensed to practice the profession in the State.
2. The national and special records shall contain a section for pharmacists and another section for pharmacy technicians.
3. The following data shall be listed in the national and special records:
   a. Personal data of the practitioner;
   b. Data of the license granted to the practitioner;
   c. Current status of the practitioner, i.e. licensed and on the job, his license is expired, etc.); and
   d. Any other data determined by the Health Authority, as the case may be.
4. The national and special records shall be numbered and may be in paper or electronic form.
5. Deletion, scraping or erasing in the national record or special record may not be made, except in accordance with the procedures set by the Health Authority, as the case may be.
6. The national and special records shall be updated on a periodic basis at least once every year.
7. The information contained in the national and special records shall be subject to the information protection system, as decided by the Health Authority, as the case may be, and shall also be subject to the provisions related to maintaining confidentiality in accordance with the legislation in force in this field.
8. Pharmacists and pharmacy technicians shall be classified in the national record into the following categories:
   a. Record of pharmacists and pharmacy technicians working in drug factories;

b. Record of pharmacists and pharmacy technicians working in pharmaceutical laboratories;
c. Record of pharmacists and pharmacy technicians working in pharmaceutical consulting firms;
d. Record of pharmacists and pharmacy technicians working in marketing firms;
e. Record of pharmacists and pharmacy technicians working in public and private health facilities;
f. Record of clinical pharmacists working in public and private hospitals;
g. Record of pharmacists and pharmacy technicians working in public and private health centers;
h. Record of pharmacists and pharmacy technicians working in pharmacies and medical warehouses; and
i. Record of pharmacists and pharmacy technicians working in health bodies.

Article (8)

License and Renewal of the License to Practice the Profession

The Health Authority shall, as the case may be, consider and decide on the applications submitted for licensing or renewing the licenses of persons to practice pharmacy profession and pharmacy technician profession in accordance with the controls and conditions set out in Cabinet Resolution No (20) of 2017, referred to hereinabove, as amended.

Article (9)

Requirements for Licensing Visiting Pharmacists

The following requirements and controls shall be met to issue a temporary license for a visiting pharmacist to practice the profession:

First: The requirements and controls for visiting pharmacists inside the State:

1. He shall be licensed to practice the pharmacy profession in his original employer in the State under a valid license.

2. He shall submit a copy of the certificate of good conduct issued by the Health Authority, proving his good conduct and that no judgment or disciplinary decision has been rendered against him to prevent him from practicing the pharmacy profession or restricting his practice thereof.
3. He shall submit the approval of his employer.
4. He shall meet any other requirements set by the Health Authority, as the case may be, without prejudice to the provisions of the Law and the present Resolution.

Second: The requirements and controls for visiting pharmacists outside the State:

1. He shall submit a certified copy of the certificate of good conduct issued by the state in which he works, proving his good conduct and that no judgment has been rendered against him to prevent him from practicing the pharmacy profession or restricting his practice thereof.
2. He shall submit proof that he practices the pharmacy profession in the state in which he works.
3. He shall submit a copy of the academic qualifications and degrees.
4. He shall meet any other requirements set by the Health Authority, as the case may be, without prejudice to the provisions of the Law and the present Resolution.

The Health Authority may exempt the visiting pharmacist from outside the State from any of the requirements and controls set forth hereinabove, as it deems appropriate.

Article (10)

Adherence to the Scope of Work and Area of Activity

The pharmacist who is licensed to practice the pharmacy profession shall abide by the scope of work and area of activity as defined in the license granted to him to practice the profession in the State. He shall also perform his job duties accurately and honestly as required by his profession, according to the acknowledged scientific and technical principles, and the responsibilities and principles contained in the Approved Code of Ethics and Professional Conduct for Health Professionals.

Article (11)

Providing First Aid

A pharmacist may provide first aid, provided that he holds a training certificate regarding such aid issued by an accredited body in this field.

Article (12)

Requirements for Dispensing Medical Prescriptions

In addition to the requirements set forth in Article (49) of the Law, a medical prescription shall:

1. Be written in a non-erasable, unchangeable material if the prescription is written.
2. Contain electronic signature and electronic code if the prescription is electronically printed out.
3. Contain the administration method of the drug or preparation dispensed therein.
4. It has not been issued for more than sixty days, unless it contains controlled substances or products.
5. Contain the patient's gender.
6. Contain the treatment duration and determine the repetition times, if necessary, even if it exceeds the duration mentioned in Clause (4) of this Article. Drugs may not be dispensed against repeat dispensing prescriptions if thirty days have passed since the date set by the physician for repeat dispensing.
7. Contain the licensing number of the healthcare practitioner who issued the prescription, along with the seal of the health facility, provided that such seal contains the name of the emirate where the facility exists.

Article (13)

Validity Period of Prescriptions of Controlled Substances and Products

Controlled substances and products may not be dispensed if more than three years that may be extended by a further period have passed since the issuance of the medical prescription, subject to the approval of the Health Authority, as the case may be.

Article (14)

Conditions for Replacement of Medical Products

1. A pharmacist may replace a pharmaceutical product with an equivalent pharmaceutical product after giving advice and counseling to the patient in this regard so as to provide an opportunity to the patient to choose the pharmaceutical product he prefers. The pharmacist shall explain to the patient that the equivalent pharmaceutical product contains the same formula of the pharmaceutical product prescribed or previously dispensed.
2. The pharmacist shall, upon replacing a pharmaceutical product with an equivalent pharmaceutical product, take into account the following:
    a. The patient's consent of the replacement of the product with an equivalent one.
    b. The prescribed pharmaceutical product shall not be one of the narrow therapeutic index drugs, which require accurate monitoring and control of their concentration in blood.
    c. The prescribed pharmaceutical product shall not be one of the narcotic drugs and psychotropic substances or other drugs determined by the Ministry.
    d. The prescribed pharmaceutical product shall not be one of drugs with therapeutic indications.
    e. The prescribed pharmaceutical product shall not be one of the biological and biosimilar drugs, except in case of ensuring the possibility of replacement by the Ministry.

Article (15)

Controls for the Custody of Controlled and Semi-Controlled Substances and Products

1. The pharmacist in charge of the custody of controlled and semi-controlled substances and products shall enter the dispensed medical prescriptions of such substances in the records determined by the Minister, in accordance with the following controls and requirements:
   a. All controlled and semi-controlled substances and products shall be entered in a special record for all of such products, provided that the dispensing of each item is recorded in separate pages, taking into account that a sufficient number of pages is dedicated to each item as for paper records and the product is not recorded in separate pages. The pharmacist shall, when necessary, write the page and record numbers as an indication of the stock shown in the page.
   b. The drug scientific name and trade name, concentration and pharmaceutical form shall be listed at the top of each page of the records.
   c. The data shall be listed in chronological order, provided that the date of each transaction is clear and the data are listed on the day of the transaction, along with the signature to this effect.
   d. The ink used in writing data on the pages of the paper record shall be indelible.
   e. No amendment, scraping or deletion shall be made to any of the data contained in the record. If it is necessary to make any correction, a comment or note shall be written in the "notes" column in the record, then the correct data shall be written in the next line.
   f. The custody officer shall keep the record in a safe place at the facility, provided that it is available for inspection at any time. A separate record shall be kept for each facility.
2. The controls and requirements set forth in Clause (1) of this Article shall be observed as for electronic records, in accordance with the requirements and characteristics of electronic formats of the record, provided that it includes, in particular, the characteristics of back-up and tracking of any change or amendment to the data, in addition to the conditions set forth

in Federal Law No. (2) of 2019, referred to hereinabove, and the Executive Regulations thereof.

3. The period of keeping the records, referred to in this Article, shall be specified by a resolution of the Minister.

Article (16)

Term of the License of the Pharmaceutical Establishment

The license for starting up a pharmaceutical establishment shall be valid for at least one year, renewal for a similar term, upon a request to be submitted for such purpose.

Article (17)

Assignment of Ownership of the Pharmaceutical Establishment

Subject to the approval of the Health Authority, as the case may be, ownership of the pharmaceutical establishment may be assigned to third parties, in accordance with the following conditions:

1. Verifying the conditions related to the transfer of ownership;
2. Submitting the duly certified assignment documents; and
3. Submitting proof of settlement of any financial claims on the pharmaceutical establishment to the licensing authority or the insurers.

Article (18)

Serious Violations which Require the Closure of the Pharmacy

The following violations shall be deemed serious violations. The Health Authority may, as the case may be, issue a decision on the temporary closure of the pharmacy for a period not exceeding one month in case of performing any of the following actions:

1. Failure to comply with the recall and suspension decisions of some medical products issued by the Health Authority, as the case may be;

2. Circulation of medical products purchased from non-licensed bodies;
3. Absenteeism of the pharmacist who is in charge of the pharmacy and practice of the pharmacy profession by persons who are not licensed;
4. Dispensing of controlled or semi-controlled drugs in an illegal manner;
5. Sale of expired, counterfeit or smuggled medical products or those products failing to get marketing authorization from the Ministry if this is necessary or if their expiry date or any of the data written on the package have been manipulated;
6. Forgery of the documents related to the medical products;
7. Failure to comply with the health or technical requirements set by the Health Authority, as the case may be, and repetition of the violations; or
8. Practice of the activity before obtaining the final license.

Article (19)

Serious Violations which Require the Revocation of the Pharmacy's License

The following violations shall be deemed serious violations. The Health Authority may, as the case may be, issue a decision on the revocation of the pharmacy's license in case of performing any of the following actions:

1. Manipulation in the records of controlled or semi-controlled drugs and circulation of the same in a manner contrary to the legislation in force in the State;
2. Repetition of manipulation of the expiry date of the medical products with the precedent of temporary closure if the establishment because of that;
3. Continuation of the practice of the activity after the expiry of the time limit for renewal of the license as determined by the legislation in force in this regard;
4. Transfer of ownership of the pharmacy, subject of the license, to another person without obtaining the approval of the Health Authority, as the case may be; or

5. Failure to implement the directives of the Health Authority, as the case may be, to correct the violations related to the health and technical requirements, because of which the pharmacy has been temporarily closed.

Article (20)

Absenteeism of the Pharmacist in-charge

In case of absenteeism of the pharmacist who is in charge of the management of the pharmacy, the pharmacy owner shall assign its management and supervision over it to another pharmacist licensed to practice the pharmacy profession to act as another pharmacist existing in the same pharmacy or another licensed pharmacy within the same emirate. The owner may also assign the same to a visiting pharmacist, provided that a pharmacy technician exists in the pharmacy. In all cases, the period of absenteeism shall not exceed three months, whether consecutive or non-consecutive, over the year.

Article (21)

Pharmacy Chain

A license may be issued for starting up more than one Pharmacy in accordance with the pharmacy chain system, provided that the following requirements are satisfied:

1. The number of pharmacies within the chain shall be within the limits permitted by the Health Authority, as the case may be.
2. The pharmacies within the chain shall be owned by one natural or legal person.
3. All pharmacies within the chain shall obtain a separate license for the establishment and shall satisfy the health and technical requirements and the required controls.
4. In case of adding one or more pharmacy owned by another person(s) to the pharmacy chain, the necessary actions shall be taken with the competent authorities in the State to transfer their ownership to the owner of the chain before licensing the addition thereto.

Article (22)

Area of Activity of the Pharmacy

1. Without prejudice to the provision of Article (10) of this Resolution, a pharmacy may not be used as a medical clinic or for any other purpose and its work shall be restricted to the following activities:
   a. Storage, display, dispensing and sale of medical products, including food and milk for infants and young children; and
   b. Composition or preparation of medical products in accordance with the legislation in force in this regard.
2. In addition to the activities set forth in Clause (1) of this Article, the pharmacy may perform the following sub-activities:
   a. Storage, display, dispensing and sale of medical supplies for personal use;
   b. Measurement of weight, height, blood pressure or temperature or conducting a finger-prick blood sugar test or any other tests decided by the Health Authority, as the case may be, for the purpose of providing advice and guidance to the patient, without diagnosing the health condition;
   c. Provision of pharmaceutical education services to the person who inquires about the method of use of medical products;
   d. Storage, display, dispensing and sale of dietary supplements;
   e. Storage, display, dispensing and sale of household insecticide products;
   f. Sale of cosmetics and perfume; and
   g. Any other activities determined by a resolution of the Minister.

Article (23)

Conditions for Licensing Certain Pharmacies

The Health Authority may, as the case may be, may issue a license for starting up private pharmacies affiliated to a governmental non-healthcare body, a public establishment or

associations or organizations of public welfare, or the private hospitals and medical centers, provided that the following requirements are satisfied:

1. A license application shall be submitted to the Health Authority, as the case may be.
2. The pharmacy shall be managed by a licensed pharmacist.
3. The pharmacy shall satisfy the technical and health requirements necessary for the operation thereof, with the possible exception of any of such requirements as determined by the Health Authority, as the case may be.
4. The pharmacy shall not provide its services to the public and its area of activity shall be limited to the employees of the body to which the pharmacy is affiliated or the beneficiaries of the services of such body.

The body to which the pharmacy is affiliated shall set the work rules of the pharmacy, provided that such rules are not contrary to the provisions of the Law and the present Resolution.

Article (24)

Technical and Health Requirements for Medical Warehouses

The medical warehouse shall satisfy the technical and health requirements set out in Annex No. (2) attached to the present Resolution.

Article (25)

Serious Violations Which Require Closure of Medical Warehouse

The following violations shall be deemed serious violations. The Licensing Authority may, within its scope of competence, issue a resolution either to close the Medical Warehouse on precautionary grounds or to suspend its license temporarily in case of performing any of the following actions:

1. Practice of the activity before obtaining the license;
2. Circulation of counterfeit, falsified or defective products;

3. Failure to comply with the decisions on recall or suspension of circulation of some medical products;
4. Circulation of medical products purchased from non-licensed bodies without obtaining the approval of the Ministry;
5. Absenteeism of the pharmacist in charge of the warehouse and practice of the pharmacy profession by non-licensed persons;
6. Failure to comply with the rules and controls related to the circulation of controlled and semi-controlled substances and products or precursor chemicals or those related to the relevant records;
7. Circulation of medical products from companies not registered with the body in charge of registration in the State without obtaining a permission from the Ministry;
8. Breach of the technical and health requirements for starting up a medical warehouse;
9. Failure to implement the recommendations related to the violations committed by the warehouse; and
10. Manipulation in the documents or data written on the package of the medical product, such as the expiry date, etc.

Article (26)

Serious Violations Which Require Revocation of the License of the Medical Warehouse

The following violations shall be deemed serious violations. The Licensing Authority may, within its scope of competence, issue a resolution to revoke the license of the Medical Warehouse in case of performing any of the following actions:

1. Manipulation in the records of controlled and semi-controlled drugs and precursor chemicals;
2. Repetition of manipulation of the expiry date of the medical products with the precedent of previous notice and temporary closure for the same reason;

3. Continuation of the practice of the activity after the expiry of the time limit for renewal of the license as determined by the legislation in force in this regard; or
4. Repetition of any of the violations set forth in Paragraphs (b), (c) and (d) of Clause (1) of Article (70) of the Law for more than two times in a year.

Article (27)

Competences of Pharmaceutical Consulting Firms

Pharmaceutical consulting firms shall be competent to:

1. Provide strategic guidance to pharmaceutical establishments;
2. Provide good management advice in the pharmaceutical field;
3. Provide professional training and development in the pharmaceutical field;
4. Provide consultations in the development of medical products;
5. Provide consultations in the field of studies, researches and management of pharmaceutical projects;
6. Provide consultations related to pharmacovigilance and the safety of pharmaceutical products;
7. Provide consultations related to the quality of the services of the pharmaceutical establishments and pharmaceutical products;
8. Provide consultations regarding the satisfaction of the licensing conditions and the applications for the licenses necessary for the pharmaceutical establishments;
9. Provide advice regarding the Good Manufacturing Practice for factories and assist them to obtain the required approval certificates; and
10. Provide consultations in the following fields:
    a. Marketing and circulation of pharmaceutical products;
    b. Studies related to the prices and costs of medical products;
    c. Satisfaction of the conditions and procedures for marketing approval of medical products; and

d. Any other studies and advice necessary for the smooth operation in pharmaceutical establishments.

Article (28)

Conditions for the Person in Charge of Pharmaceutical Laboratory or Research Center

The person in charge of the pharmaceutical laboratory or research center shall be qualified, available on a full-time basis for technical supervision and licensed in accordance with the following conditions:

1. He shall hold an academic qualification from one of the universities or centers recognized in the State in any of the following specializations: pharmacy, one of the specializations of chemistry, microbiology or other relevant disciplines.
2. He shall have at least five years of experience in the area of specialization.

Article (29)

Serious Violations Which Require Closure of the Factory

The following violations shall be deemed serious violations. The Ministry may, on its own and in coordination with the Competent Bodies or based on the recommendation of the Competent Bodies, issue a resolution either to close the factory on precautionary grounds or to suspend its license temporarily in case of performing any of the following actions:

1. Establishment of repetition of the factory's failure to apply the basis of Good Manufacturing Practice in a manner that affects the quality and safety of the medical product and the public health although a notice is served thereupon;
2. Establishment of non-safety of the products of the factory;
3. Repetition of non-conformity of the product to the approved quality standards upon conducting the laboratory examinations to be performed at the accredited laboratories in the State although a notice is served thereupon;

4. Concealing any information related to the quality of its products and failure to notify the Ministry immediately upon being aware of the same;
5. Failure to comply with the rules and controls related to the circulation of controlled and semi-controlled substances and products or precursor chemicals or those related to the relevant records; or
6. Establishment of failure to observe the waste disposal best practice, posing a risk to the public health.

Article (30)

Possession of Controlled Substances and Products

The licensed physician (anesthesiologist or surgeon) may possess controlled substances and products to be used for the purposes of his/her professional duties within the following quantities:

First: Health Facilities with no internal pharmacy:

1. **For Narcotic Substances**: Based on the standard quota approved by the Health Authority in accordance with number of patients receiving treatment and dosages recognized, provided that the quantity shall not exceed the threshold needed to cover the needs of use for a maximum period of two months.
2. The standard stock of narcotic drugs may be replenished more than once within a single month from the medical warehouses, provided that there is a proportion between the standard stock and expected monthly usage (one to three times per month). The standard quota shall be reviewed and amended on a case-by-case basis for each establishment whenever required, based on two former quarterly consumption reports for each establishment.
3. **For Psychotropic Substances**: In accordance with the quantity used based on the number of patients treated with the controlled drug, provided that the quantity shall not exceed the threshold required to cover the needs of use for a maximum period of two months.

4. In all cases, the physician shall abide by the applicable laws and resolutions on storage of controlled substances and products and shall record the same in the official register, subject to the provisions of Article (15) of this Resolution.

Second: Health Facilities having an internal pharmacy:

The physician of such facilities may not possess controlled substances and products.

Article (31)

Import Controls for Certain Products

The following requirements shall apply as a prerequisite for completing the customs clearance procedures for any import shipment containing controlled substances and products or raw materials involved in the manufacturing of controlled substances and products:

1. An import license and import permission shall be issued by the Ministry for private facilities. For government entities, however, only an import license issued the ministry shall be sufficient.
2. A document shall be submitted to prove that the substances imported are conforming to the documents of shipment and labels placed thereon.
3. The approval of the Ministry's inspector at the border crossing points shall be obtained for importing controlled substances or products contained in the shipment after ensuring that they satisfy the conditions applicable in this regard and are conforming to the shipment documents.
4. The pharmacist in charge of the entity applying for import shall be present for receiving the shipment, while the Ministry's inspector shall also be present.
5. A duly authorized representative shall be present in case the import application is submitted directly by the government entities, as well as a representative of Clearance Company. In case the import application is submitted by licensed medical warehouses, the pharmacist in charge of controlled substances and products at the warehouse as well as the Ministry's inspector shall both be present.

Article (32)

Termination of Possession and Custody of Controlled Substances and Products

In case the holder of a license for possession of controlled substances and products ceases to operate or where the person in charge of its custody gives up the same for whatever reason, the license holder shall take appropriate actions for conducting an inventory count on such controlled substances and products and initiating the handover procedures of the same as follows:

1. In case the holder of a license for possession of controlled substances and products ceases to operate, the license issuer shall be duly notified. In case such controlled substances and products are narcotic substances, the Ministry as well as the license issuer shall both be notified. In addition, an inventory count shall be conducted on the controlled substances and products and their quantities shall be counted by the custody officer in order to be delivered back to the medical warehouse concerned with such controlled substances and products. However, the possession of psychotropic substances may be transferred to any other branch of the same establishment and the license issuer shall be notified of the same.

2. In the event that the custody officer of controlled substances or products gives up the same, a deed of clearance shall be furnished together with a letter from the employer establishment to the license issuer. If such controlled substances and products are narcotics, the Ministry as well as the license issuer shall both be notified. The notice shall include the date of clearance and shall be signed by the owner or manager of the establishment and stamped with the seal of the establishment, and shall be accompanied by a record of handover of the custody the a new custody officer licensed to possess controlled substances or products, along with a detailed statement of the remaining quantities of such controlled substances or products at the establishment.

3. In the event that the custody officer of controlled substances or products gives up the same in the absence of a substitute officer, the manager of the establishment shall lay hold of and shall

not permit the controlled substances or products to be used, and shall notify both the Ministry and relevant Health Authority within two business days in order to approve their delivery back to the medical warehouses concerned with such controlled substances or products. In addition, the psychotropic substances may be transferred to any branch of the same establishment.

4. The Ministry and / or relevant Health Authority shall review the custody of controlled substances or products in order to approve their handover to the new custody officer or their return to medical warehouses or domestic agents. In all cases, the Ministry shall be notified.

Article (33)

Making Medical Products Available

1. The Ministry shall, in coordination with the relevant Health Authority, create and periodically update a list of products of strategic medical stock, in order to ensure that the necessary medical products are made available to meet the society's needs on a permanent basis.

2. Pharmaceutical establishments shall make the products included in the strategic medical stock list available, in order to ensure permanent availability of basic or necessary drugs at medical warehouses and pharmacies of public and private hospitals in quantities that are proportional to the patients' needs. The Health Authority shall monitor the balances of products included in the strategic medical stock according to appropriate mechanisms.

3. The holder of marketing right, or its representative in the State, shall, on a permanent basis, provide the drugs that have the marketing priority in the State, particular life-saving drugs, whether brand-name or generic drugs, through both maintaining a sufficient stock of them at the medical warehouses in the State and distributing the necessary quantities to the licensed pharmacies in all emirates of the State based on their respective orders.

4. The holder of marketing right, or its representative in the State, shall make available the pharmaceutical products and medical supplies that fall within the scope of its business, under an undertaking to be enclosed with each application for product marketing approval and also upon submitting each marketing renewal application.

5. The holder of marketing right, or its representative in the State, shall take all necessary precautionary measures in order to ensure permanent availability of the medical products referred to in this State within the State.

6. If a particular medical product cannot be imported for any reason beyond the reasonable control of the holder of marketing right or its representative in the State, either of them shall forthwith notify the Ministry and take the necessary actions for managing the stock at its warehouses in the State in the best manner that is beneficial to the largest number of patients, and shall also take necessary actions for making the underlying product available in the State as soon as possible once the reasons impeding its important cease to exist.

7. If the representative of marketing right holder fails to make the products referred to in this Article available, the same shall notify the Ministry of the same. In which case, the Ministry may permit any other licensed medical warehouse or government entity to have the same product imported through any other licensed importer, provided that the underlying product shall be sold to the public at the same market price or at a fixed price under a mechanism to be established by the Ministry, or to provide a substitute product.

8. The ministry may permit that the drugs having the marketing approval be imported by any medical warehouse to satisfy the requirements of drug security in the State.

9. The Ministry shall, in coordination with the Ministry of Economy, reserve the right to revoke the marketing approval of the medical products referred to in this Article, if such products are not available in the State without necessary justifications, in respect of the medical products carrying exclusive agencies issued by Ministry of Economy.

Article (34)

Donation of Medical Products

The donation of medical products shall be subject to the following controls and conditions:

1. Donation shall take place for the benefit of charities, government entities, public institutions or public welfare organizations or directly to persons whose medical condition requires such

products and who have a valid medical prescription yet are falling short of the funds needed to acquire them.

2. A relevant permit shall be obtained from the Health Authority.

3. The donation shall satisfy the requirements and criteria established to ensure quality and validity of the medical product throughout all circulation phases, starting from its release by the donor until it reaches the hands of the donee.

4. If the donee does not belong to the persons to whom the drug is to be prescribed as an end consumer, the same shall satisfy the storage and safekeeping requirements that ensure validity of the medical product until it is released to the end consumer.

5. If the donation process involves controlled substances or products, the Ministry's approval shall be obtained beforehand.

6. The medical products donated shall both be valid for use and have a future expiry date of not less than six (6) months.

7. Donations made by individuals shall only be permitted after the underlying drugs are duly evaluated by the competent department or the competent entity, as the case may be.

8. Drugs that are opened or partly used may not be accepted for donation.

9. The medical products permitted to be accepted from individual donors shall be holding a marketing approval in the State, and the batch required to be donated shall be imported under an official permission from the Ministry, shall be stored under the temperatures recommended on their outer packages and may not belong to the controlled substances or products category.

10. If the medical products are intended to be donated for the benefit of charities or public welfare organizations, the storage conditions at the latter shall be verified beforehand, in order to ensure quality and validity of the product donated.

11. Any other controls to be determined under a resolution of the Minister in coordination with the competent entities.

Article (35)

Pharmacy Maintenance Conditions and Controls

In the course of carrying out maintenance for a pharmacy, the following conditions and controls shall be observed to ensure quality and validity of the medical products:

1. The medical products may not be vulnerable to any factors that might adversely affect their quality and safe use. Failing which, the medical products available at the pharmacy shall be relocated to any other place that satisfies the requirements of ensuring their quality and validity, provided that the Health Authority shall, as the case may be, approve the relocation mechanism and storage location before the relocation actions start. Should the pharmacy contain controlled substances or products, the Health Authority shall, as the case may be, shall be notified of the same. In addition, such products may be delivered back to the relevant medical warehouse subject to prior approval of the Ministry.
2. Once the maintenance work is completed, the Health Authority shall, as the case may be, shall be notified. However, the medical products may only be placed at the pharmacy following their maintenance after the pharmacy is inspected in order to ensure satisfaction of re-operation requirements.
3. Any other controls to be determined based on a resolution of the Minister.

Article (36)

Amendment of Resolution's Annexes

Under a resolution of the Minister and subject to coordination with the remaining health authorities, the provisions of Annex No. (1) and Annex No. (2) attached to this Resolution may be amended.

Article (37)

Adjustment of Affairs

All bodies governed by the provisions of this Resolution shall adjust their respective affairs in conformity with the provisions hereof, not later than six (6) months of its issuance date.

Article (38)

Executive Resolutions

The Minister shall issue any other resolutions deemed necessary for implementing the provisions of this Resolution.

Article (39)

Repeals

Any other provision that goes against or conflicts with the provisions of this Resolution shall be repealed.

Article (40)

Publication and Entry into Force

This resolution shall be published in the Official Gazette and shall enter into force of the day following its publication date.

Mohammed bin Rashid Al Maktoum

Prime Minister

Issued by Us

On: 21 Safar, 1443 AH

Corresponding to: 28 September, 2021 AD

Annex No. (1)

Attached to Cabinet Resolution No. (90) of 2021 Concerning the Terms and Controls for Bringing, Possession or Holding of a Medical Product by any Person Upon Entering the State for Personal Use

Article (1)

The provisions of Articles (2 through 7) of this annex shall apply to those coming to or departing from the State in case of holding any of the controlled substances:

1. N-Narcotic drugs
2. Psychotropic substances

Article (2)

The controlled substances (N-Narcotic drugs and psychotropic substances) shall include the medical products containing any active ingredients listed in the following schedules:

1. INCB Schedules Nos. (I, II, III or IV) annexed to the 1961 Convention on Narcotic Drugs, amended by the 1972 Protocol, as amended.
2. INCB Schedules Nos. (I, II, III or IV) annexed to the Convention on Psychotropic Substances of 1971, as amended.
3. Schedules Nos. (1, 2, 3, 4, 5,6,7 or 8) attached to Federal Law No. (14) of 1995 referred to hereinabove.

Article (3)

Those coming from abroad shall comply with the following requirements when bringing the controlled substances:

1. Obtain prior approval of the ministry for bringing substances via its website, and they shall disclose the same the official ports of the State. It is required to submit the following documents in Arabic or English for the purpose of obtaining the permission:

a. Medical report to be issued by the health facility, at which the patient is treated, authenticated by the health body of the State in which he is treated, by the embassy of the State therein or any accrediting body in that State, provided that not more than one year has passed following its issue date.
b. The medical report shall contain the data, personal information of the patient (full name of the patient), medical diagnosis, scientific or trade name of drug, quantity prescribed, treatment plan and period, date of report, name and specialization of the physician, and number of license, accompanied by the address and stamped by the official seal of the health facility.
c. A copy of the medical prescription in the name of the patient, provided that not more than three months has passed since its date of issue. It shall include the full name of the patient, scientific and trade name of drug as the case may be, pharmaceutical form, dose prescribed, date of issuing medical prescription, duration of treatment, name of the physician, his stamp and stamp of the treatment body, ratified by the health entity of the State, in which the patient was treated, by the embassy of the State or by the accrediting body in that State.
d. Copy of the passport or ID card.

2. In the absence of prior approval, the customs authorities shall coordinate with the ministry to take the necessary actions based in the documents available with the traveler.
3. Without prejudice to the provisions of paragraphs (1 and 2) of this Article, if the drugs are in the possession of a relative of the patient or his representative, a power of attorney executed by the patient shall be provided after being authenticated by any accrediting body in that State, accompanied by a copy of ID card.
4. The approval of the ministry shall be obtained for bringing controlled substances by those coming to the State within the limits of the quantity proportional to the duration of treatment, provided that the same may not exceed the patient's need for (3) three months.

Article (4)

The terms and controls provided for in this annex shall apply to the diplomatic missions, official government entities, delegations involved in sports activities and others when they are in possession of controlled substances at the time of coming to or departing from the State. In all cases, it is required to coordinate with the ministry in order to complete the necessary actions in this regard.

Article (5)

1. The patient, who leaves the State and needs to take possession of psychedelic drugs, shall obtain the approval of the ministry based on both a valid medical prescription and a report of the treating physician, within the limits of quantity appropriate to the duration of treatment.
2. If the patient, who leaves the State, is in need to be injected with psychedelic drugs during the duration of travel, he shall be accompanied by a healthcare practitioner. The patient shall be allowed to hold drugs at an appropriate quantity under the approval of the ministry based on a valid medical prescription and report of the treating physician.
3. If the patient, who leaves the State, is in need of psychotropic substances (non-narcotic) for treatment abroad, he may apply for the approval of the ministry in order to hold a specific quantity under medical prescription. If the prescription includes re-dispensing of the psychotropic substances, the patient shall be allowed to hold the necessary quantity that is sufficient for a maximum period of (3) three months.

Article (6)

1. In case a transit traveler is holding controlled substances, he shall be allowed to hold the quantity sufficient for the period of his stay in the State. The excess quantity shall be seized and retained, and shall be returned to the transit traveler upon leaving the State.
2. In case a traveler coming to the State is holding controlled substances, quantities in excess of the allowed threshold or in excess of the quantity proportional to his treatment period as

mentioned in the medical prescription or the medical report shall be seized and destroyed by the competent authorities according to the relevant applicable procedures.

3. When the quantity of allowed drugs is out of stock, the patient shall see a licensed physician at any health facility licensed in the State and approved by the health authority, in order to verify the patient's need to continue to use the same drug or to prescribe generic drugs registered in the State. In case the underlying drug is not available in the State, the health facility may provide the same as per the applicable procedures.
4. If the traveler coming to the State brings medical supplies that contain controlled substances, the same shall be subject to the provisions of this Resolution, noting that the traveler shall only be allowed to bring such supplies for personal use according to his medical condition and treatment requirements.

Article (7)

The following controlled drugs may not be brought by anybody coming to the State:

1. Drugs that do not display details of the active ingredient in Arabic or English.
2. Expired drugs for personal use.
3. Drugs that are of unknown components or having no label showing their components.
4. Drugs whose circulation in the State is prohibited according to the lists specified under a resolution of the Minister or his designee, and those described as prohibited on the Ministry's website.

Article (8)

The provisions of Article (9) et seq. shall apply to the persons coming to or departing from the State in case they bring any of the following drugs or medical supplies for human use:

1. Semi-controlled drugs;
2. Non-controlled drugs that are dispensed under a prescription-only medicines (POM) for human use (not including controlled drugs);

N3. on-controlled drugs that are not dispensed under a prescription-only medicines (POM) for human use;

4. Preventive medicine's drugs;

5. Biological drugs;

6. Herbal or supplemental drugs; and

7. Medical supplies for human personal use.

Article (9)

Semi-controlled drugs, non-controlled drugs and medical supplies brought by the traveler coming to the State shall be subject to the following provisions:

1. For POMs:

The traveler coming to the State may bring, for his / her personal use, non-controlled drugs that are dispensed only based on a POM for personal use, within the limit of a quantity that is proportional to the period of his / her stay in the State, provided that the quantity of such drugs may not exceed the traveler's personal use for a maximum period of six (6) months. In addition the traveler shall have in place a medical report or copy of a prescription indicating the patient's data.

2. For Over-the-counter (OTC) Drugs:

The traveler coming to the State may bring, for his / her personal use, OTC drugs, within the limit of the quantity that is proportional to the period of his / her stay in the State, provided that the quantity of such drugs may not exceed the traveler's personal use for a maximum period of six (6) months.

3. For herbal or supplemental drugs:

Any traveler coming to the State shall be prohibited from bringing supplemental drugs or items or herbal substances that are banned or prohibited inside the State according to the lists specified under a resolution of the Minister or his designee, and those described as prohibited on the Ministry's website.

4. For Medical Supplies:

Any traveler coming to the State may bring medical supplies for his / her personal use. If, however, such supplies contain any controlled substances, they shall be subject to the procedures set out in this Resolution in connection with the travelers' bringing of controlled drugs upon coming to or departing from the State. If the supplies in question contain any of the drugs described in Article (2) of this Annex, the applicable steps shall be observed depending on the classification of the active ingredient.

Article (10)

The terms and controls provided for in this annex shall apply to the diplomatic missions, official government entities, delegations involved in sports activities and others when they are in possession of drugs or medical supplies at the time of coming to or departing from the State. In all cases, it is required to coordinate with the ministry in order to complete the necessary actions in this regard.

Article (11)

Possession of preventive medicine's drugs shall be subject to the following provisions:

1. Travelers coming to the State shall provide a medical report or document indicating the type of disease and treatment required or a copy of a medical prescription indicating the patient's details.
2. Travelers coming to the State may be in possession of preventive medicine's drugs within the limit of the quantity required for their personal use, in proportion to the length of their stay in the State but not exceeding the quantity required for their personal use for not more than six (6) months. In addition, the excess quantity shall be delivered to the preventive medicine center located at his / her place of residence in order to complete the treatment program, and the remaining quantity shall be delivered to the traveler upon departure, provided that a proof of the departure date is furnished.

3. If the traveler intends to stay in the State, he / she may only be allowed to be in possession of preventive medicine's drugs in quantities sufficient for six (6) months, so that the excess quantity shall be delivered to the preventive medicine center at the place of his / her residence in order to complete the treatment program. The same rules and procedures shall apply to the UAE traveler coming to the State.

Article (12)

The traveler departing from the State may be in possession of semi-controlled or non-controlled drugs or medical supplies for personal use, by virtue of a permission or license from the Ministry whenever requested.

Article (13)

The drugs governed by the provisions of this Resolution and referred to in this Annex shall satisfy the following requirements:

1. They shall be placed in their original packages that are tightly closed, or in packages having a label issued by health or pharmaceutical establishment indicating the drug composition, the patient' name and the storage temperature that ensures the patient safety.
2. Controlled drugs shall be included in the Ministry's lists posted on the Ministry's website or are permitted by the Ministry to be imported.
3. The technical requirements on transporting the drugs that require cooling shall be observed.
4. The drug quantities exceeding the quantity permitted by the competent authorities shall be seized, retained and eventually returned to the traveler upon departing the State under the Ministry's consent, in the event that the traveler is in transit or not residing in the State. In case the traveler is among of the state's residents, the excess quantity shall be destroyed pursuant to the procedures applicable in this regard.
5. When the quantity of allowed drugs is out of stock, the patient shall see a licensed physician at any health facility licensed in the State and approved by the health authority, in order to

verify the patient's need to continue to use the same drug or to prescribe generic drugs registered in the State. In case the underlying drug is not available in the State, the health facility may provide the same through a certified distributor and shall obtain the approval as per the applicable procedures.

6. Any person coming to the State may, if prevented from brining non-controlled drugs, medical supplies or healthcare products into the State, take the same out of the State within a time limit to be determined through coordination between the Ministry and the Competent Authority.
7. A quantity of drugs may, in exceptional cases and based on the Ministry's consent, be brought into the State for a period of time exceeding the quantity set forth herein, for the purpose of personal use of the persons who come back to the State after undergoing treatment abroad.

Article (14)

First: The following drugs shall be prohibited from being brought into the State with the coming persons:

1. Drugs without the leaflet of the active ingredient in Arabic or English;
2. Radioactive drugs;
3. Expired drugs for personal use;
4. Drugs of unknown ingredients or without a leaflet indicating the ingredients;
5. Drugs of alternative medicine and medical herbs that contain unknown ingredients;
6. Drugs whose circulation is prohibited within the State in accordance with the lists specified by a resolution of the Minister or his designee, provided that they are listed on the Ministry's website.

Second: The Ministry's inspectors shall provide technical support to the employees tasked with monitoring the travelers and commodities at the border crossing points of the State whenever requested.

Annex No. (2)

Attached to Cabinet Resolution No. (90) of 2021 Concerning Technical and Health Requirements for Medical Warehouses

First: General Security and Safety Requirements:

1. The medical warehouse shall satisfy general security and safety requirements, including, among others, usable fire extinguishers, fire suppression system, emergency exit as well as the other security and safety requirements approved by the official authorities (Certificate from the Civil Defense);
2. A backup power generator shall be available in each warehouse for emergency use;
3. First aids toolkit or first-aid locker shall be provided, containing the medical products and tools used for first aids. Such a locker shall have the word "first aid" written on its outer part or the well-known first-aid logo shall be posted thereon.
4. The electrical wires shall not be uncovered so as to avoid any danger to warehouse workers;
5. Flammables, chemical materials, expired drugs and any hazardous substances shall not be disposed of in public sewage or other sewage paths, so that they shall be disposed of and destroyed by the means defined in the laws and regulations issued in this regard. In addition, it is necessary to engage the Municipality or any company specialized in the disposal of medical waste for managing the disposal process.
6. The spill kit shall be provided in the event of the existence of chemical or hazardous substances, which shall be disposed of and destroyed by the means defined in the laws and regulations issued in this regard.
7. The storage area shall be adequately safe and separated from the offices, and there shall be a mechanism for identifying the employees allowed to get access thereto, such as the electronic access system.

8. All employees shall wear a protective uniform to safeguard them from work hazards and shall maintain personal cleanliness. The employees shall hang their personal business card badges at all times;
9. Posters that contain emergency numbers and posters that show the phrase "No Smoking" shall all be placed at visible locations.

Second: Infrastructure-Related Requirements:

1. The location and internal plan of the medical warehouse shall be conforming to the last engineering drawing approved by the Municipality or any governmental licensing body.
2. The location intended to be used as the premises of the medial warehouse required to be licensed shall both be distant from residential areas and situated on the ground floor. It shall not also have any outlet connected to medical clinic, or dwelling, pharmacy or any premises that engages in any activities irrelevant to its own activity.
3. The exterior walls and ceilings shall be made of bricks or reinforced concrete. It is allowed to use false ceilings and walls made of (gypsum boards) only for the purposes of design and fitting-out of facilities rather than at storage places.
4. The height of ceilings shall not be less than (270 cm) (Two Hundred seventy centimeters). If the warehouse consists of two or more floors, the height of each floor shall not be less than (270 cm) (two hundred seventy centimeters).
5. All roofs shall have walls, ceilings and doors and other such items painted with anti-bacterial material that is easy to wash and clean, non-flammable, waterproof, heat and moisture insulator.
6. The storage area of the medical warehouse shall be at least (50 M^2) (Fifty square meters) not including the offices of the management, and shall be proportional to the volume of stock. If the warehouse has two or more floors, such floors shall be directly connected to each other through inside stairs or elevator. The area of the floors shall be part of the total area of the warehouse, provided that the storage area on the ground floor shall not be less than (35 M^2)

thirty-five square meters, without prejudice to any other conditions stipulated in this Article. The storage area of all floors shall not be less than (50 M^2) fifty square meters.

7. The floor of the medical warehouse shall not be at a level lower than the level of public road and shall be covered with ceramics or any other similar items (incombustible and easy to clean).
8. The doors shall be of width allowing the trucks carrying the materials intended for storage to pass (at least 120 cm, one hundred and twenty centimeters).
9. The floors, walls and ceiling shall have solid and smooth posture, shall be free of pores and shall be cleanable.
10. All widows of the medical warehouse for ventilation and lighting shall be coated with tight wire to prevent flies and other insects.
11. All woods shall be painted with oil or its alternative and shall be repainted whenever required.
12. The medical warehouse shall have a water closet and hand washbasins for the employees. The water connected to the medical warehouse shall be directly generated from the public water source. The water closets shall not be open to storage places, but it may be located outside the warehouse yet in the same building or in warehouses complex. These water closets shall only be used by the employees of the warehouse and shall be part of the layout approved by Licenses Departments.
13. Ordinary waste of the medical warehouse shall be disposed of as per the system applicable in the Municipality of each emirate. It shall be necessary to engage specialized bodies for safe disposal of the liquid and solid medical waste, and manholes shall be covered with firmly-closed iron covers.
14. Name of the medical warehouse shall be written in both Arabic and English on a visible board in capitalized letters. Working hours of the warehouse shall also be clearly displayed.

Third: Requirements for Interiors and Design:

1. Upon fitting out the medical warehouse for licensing purpose, the general professional appearance and smooth traffic movement shall both be observed, in addition to ensuring the availability of areas that accommodate the materials stored and are proportional to the work volume and the type of the materials needed to be stored.
2. The establishment shall have a sufficient number of shelves, solid and durable metal lockers of stainless steel and suitable for storing the medical products.
3. There shall be a distance of at least (90 cm) ninety centimeters as passageways between the shelves to facilitate the movement of employees or cranes.
4. The loading boards and wood platforms shall be anti-insect, made of a suitable industrial material, well-preserved and clean.
5. The lighting shall be adequate and proportional to the scope and range of the activities or services provided.
6. The following sections shall be determined at the warehouse: handover area, storage places, an area suitable for distribution and transport, quarantine area, as well as offices for the employees and management staff.
7. Specific and separate places shall be allocated for the storage of the following materials:
    a. Chemicals.
    b. Radioactive substances (subject to prior approval of the Competent Bodies).
    c. Narcotic Drugs.
    d. Psychotropic Substances.
    e. Expired drugs.
    f. Rejected or unusable products.
    g. Medical equipment and supplies.
    h. Flammable or explosive materials such as natural gases (subject to prior approval of the Competent Bodies).
8. There shall be a place for iron locker or lockers that are tightly closed with a dual lock to preserve the controlled materials and products with the registers of the same in a separate

place containing CCTV cameras, or to be kept in a safe room of dual electronic closure and its exterior walls are built of reinforced concrete or cement or bricks and have CCTV cameras.

9. There shall be a place dedicated for the expired products or products on which a circular is issued for recall or suspension of their circulation or use, with the phrase (**Not Valid For Use and Sale**) written on the outer part in red color, provided that they shall not be kept at the warehouse for more than (6) six months.
10. Free medical samples, if any, shall be kept in places totally separate from the other products. If these samples are controlled drugs, they shall be kept in the locker of the controlled drugs inside the warehouse, and their incoming and outgoing items shall be recorded in separate pages of the controlled drugs record.
11. The medical warehouse shall include the following equipment and appliances: (a warehouse management office, fixed telephone, fax, computer, internet connection and e-mail address of the warehouse).
12. There shall be a place for the archive (paper or electronic) to keep the relevant papers, documents, laws and scientific references, as well as a file for keeping the circulars and resolutions to be issued by the Ministry. Such items shall be kept for the period of time described in the applicable legislations.
13. The license of the warehouse along with the licenses of the pharmacists shall all be displayed at a visible place.
14. The warehouse shall establish an effective stock management mechanism (handover and takeover), including the stock management information (the scientific name of the product, trade name, manufacturer's name, expiry date, batch number, storage conditions and invoices numbers, etc.).

Fourth: Temperature and Humidity of the Warehouse:

1. The warehouse, intended to be used as a premises for the medical warehouse required to be licensed, shall have a sufficient number of air conditioners to keep the temperature inside the

warehouse between (^{0}15) and (^{0}25) Celsius and to keep the humidity less than (60%) on a permanent basis. It is preferable to provide means at the doors that prevent penetration of cold during loading and unloading.

2. The sun-exposed glass facades shall be protected by providing curtains appropriate to protect the products from heat and sunlight.
3. The medical warehouse shall include refrigerators and freezers or chilling or freezing rooms designated for preserving medical products that are in need of cooling or freezing. The refrigerators or rooms shall contain more than one thermometer, and Temp-Mapping shall be made to record heat and cool of refrigerators or rooms without being used for any other purpose.
4. The medical warehouse shall include calibrated digital mechanisms for continuously measuring the temperature and humidity by Data Loggers, which shall be distributed in the warehouse in a manner appropriate to the area and size.
5. All devices shall be periodically calibrated based on global criteria.

Fifth: Cleaning Requirements:

1. The medical warehouse's building, facilities, floors, furniture, shelves, locker and other accessories and equipment shall always be well cleaned, and a schedule shall be prepared for recording the completion of daily cleaning work.
2. The medical warehouse shall engage a specialized cleaning company, or standard methods shall be provided for rodent and pest control.
3. The medical warehouse shall have devices designated for disinsection, and their number shall be based on the size of the warehouse.

Sixth: Requirements for Receiving and Transporting Medical Products:

1. The medical warehouse shall provide a secure and suitable means for transporting the medical products, and which satisfies the relevant applicable conditions. In addition, the medical warehouse shall observe the following:
    a. Keep the safety and quality of the medical product, in addition to ensuring prevention of any harm during the transportation process.
    b. Provide the controls necessary for the maintenance of storage conditions during the transportation process, such as the temperature and relative humidity.
    c. During the transportation of chilled or frozen medical products, it is required to monitor the temperature and cold level for each item in accordance with the criteria required during the transportation, in addition to recording the same at regular intervals. The medical warehouse shall have Temperature Loggers during the transportation. In this regard, it is preferable to use Temperature Loggers for the sake of recording the temperature electronically.
    d. Ensure that the refrigerated vehicles and means of transport are well maintained and kept safe on a monthly basis.
2. The establishment shall use refrigerated vehicles licensed to transport products from the health facility, as the case may be, within its competencies in accordance with the necessary conditions set by the health facility.
3. It is required to unload the medical products from the carrying vehicles and place them in the warehouse as soon as possible, in order to avoid the same being in the area of receiving.
4. The shipping record shall be kept and shall include the following:
    a. Description of goods received (pharmaceutical form of "drugs", form and size of one unit as well as the number of units in one package, in addition to any other important details).
    b. Quantities.
    c. Batch number provided by the manufacturers.
    d. Invoice No.
    e. Expiry date.

f. The method of placing the items during the transportation process.

5. All documents and registers in connection with the transportation of products shall be kept, in addition to a register for each received shipment shall be kept for a period of more than the validity period for one calendar year.
6. It is not allowed to use any means of transport for transporting medical products if it does not satisfy the requirement determined for the safety and quality of products to be transported in accordance with what is determined and set by the health facility.
7. The medical warehouse shall take additional preventive measures upon transporting the vaccines, biological drugs, controlled substances or products, chemicals or radioactive substances.

Seventh: Requirements of Good Storage and Distribution of Medical Products:

1. In case there is an intention to store controlled drugs in the warehouse, it is required to provide a tightly-closed independent area equipped with necessary security equipment, such as a protection fence, CCTV cameras, control system for access and exit, and alarms, in addition to providing security guards on a 24-hour-a-day basis, together with obtaining the approvals of competent bodies in this regard.
2. Arrange and place the medical products on shelves, in lockers and on pallets in an organized manner and to prevent the cartoon boxes of medical products from direct contact with the ground.
3. The medical products shall be arranged in an alphabetical order by scientific name and by pharmaceutical form for drugs, in addition to allocating specific and separate areas for storing the drugs of various pharmaceutical forms.
4. Adequate space shall be kept between the product and the other one, in addition to keeping adequate space between the storage area of a pharmaceutical form of drugs and the other forms.

5. Medical products shall be stored in conformity with the manufacturer's instructions and comply with the information and requirements of storage described on the label, the storage conditions of products typically include the following:
    a. Products that need cooling (8-2 ºC).
    b. Products that need freezing (-18 ºC or lower).
    c. Products that need to be stored at the ambient temperature (between 15 ºC and 25 ºC).
    d. Products that need to be kept away from lighting sources.
    e. Flammable products.
6. Along with the data loggers that record the temperature on a continuous case as per the mechanisms referred to in Clause (4) of Section IV of this annex "temperature and humidity of the warehouse", it is required to manually measure and record the temperature (temperature profile) at least twice per day for drugs kept under (25 ºC) and thrice for drugs kept in the refrigerators.
7. The boxes shall be arranged and placed in a specific manner, so that the product and expiry date and identification card can be clearly seen. Wherever this is not possible, a poster containing such information shall be placed in an apparent spot on the box.
8. Hard and liquid products shall be kept at the lower shelves or at the lowest part of the pallets.
9. The expired and damaged products, or those items in respect of which a circular is issued for recall or suspension of circulation and use, shall be separated from other products and stored in the places designated for them until they are destroyed or disposed of, provided that the period of warehousing them may not exceed (6) six months.
10. For the purpose of stock turnover and monitoring, it is required to adopt the First Expiry- first Out-FEFA basis for release of the items stored.
11. The medical warehouse shall engage a waste recycling company for destroying, disposing of and treating expired and damaged products.

Eighth: Requirements for Qualified Professionals and Employees of Medical Warehouse:

1. If the medical warehouse is used as a place for storage, importation, exportation or distribution of drugs, it shall be managed and supervised by a pharmacist licensed by the relevant licensing authority. Such a pharmacist shall work on a full-time basis and shall be present at the warehouse throughout all working hours. In case of storage, importation, exportation or distribution of medical devices and supplies other than the drugs, the warehouse may be supervised by a qualified person (for example a medical equipment engineer).
2. The pharmacist in charge of supervising the medical warehouse of drugs shall be responsible for recording the controlled drugs, if any, in the relevant records, in accordance with the rules, systems and procedures applicable in respect of the controlled drugs, and the remaining procedures relating to the conditions, tasks and obligations assigned to the pharmacist in charge of the warehouse shall also apply.
3. The employees of the medical warehouse shall comply with the relevant laws, legislation, resolutions and regulatory guides.
4. The employees of the medical warehouse shall abide by the Code of Ethics and Professional Conduct for relevant health professions.
5. The employees of the medical warehouse shall abide by the grounds of storage practices and good distribution.

Ninth: Requirements for Documents, Records and Papers to be kept in the medical warehouse (or their electronic alternatives):

1. The documents of the medical warehouse and its employees:
    a. The valid license for opening the medical warehouse (the annual renewal receipt).
    b. Valid license issued by the Municipality.
    c. Valid commercial license.
    d. Licenses of the pharmacists and technicians (annual renewal receipt).
    e. The record of warehouse's employees, including their data.

f. Job description for all employees as well as the licensed pharmacists and technicians of the medical warehouse.
g. Record of continuous pharmaceutical development and education for each licensed pharmacist and pharmacist assistant at the warehouse.
h. The statement of the names, positions and training of the employees.
i. Training files for each basic employee, noting that all employees shall be qualified in their respective positions.

2. Contact Details:
   a. Contact numbers and details of relevant departments and divisions of the Health Authority for the purpose of making a complaint or inquiring about any relevant issue.
   b. Contact numbers and details of pharmacovigilance units of the Health Authority.
   c. Contact numbers and details of medical and toxicological information centers in the State.
3. Records, Documents and Reports:

A. Release and Distribution Records: They contain the information described in the release registers (orders), including the following details at a minimum:

1. Release date.
2. Name and address of the purchaser or customer.
3. Product description (name, pharmaceutical form, concentration, size of the package and quantity).
4. Batch number.
5. Storage conditions.
   a. A record for documenting daily temperature and humidity for both the warehouse and the refrigerator so that the data are kept and preserved for a period of (24) twenty-four months.
   b. Record for controlled drugs, which shall be serially numbered and stamped with the official seal of the Ministry, or shall be saved electronically.
   c. A file that includes the monthly and periodic reports on controlled drugs.

d. A file that includes the reports on complaints in connection with the drugs or medical products.
e. A file that includes all irregularities and violations committed by the warehouse and its employees.