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 M²) (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 M²)

- 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 $(50 \,\mathrm{M}^2)$ 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 (015) and (025) 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:
 - 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.
- 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 °C).
 - b. Products that need freezing (-18 °C or lower).
 - c. Products that need to be stored at the ambient temperature (between 15 °C and 25 °C).
 - 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 °C) 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.