Encyclopedia of Health Legislation

Book 8: Medical Products, Pharmacy Profession and Pharmaceutical Facilities Legislation

www.doh.gov.ae

DoHSocial

دائـــــرة الـصـــحـــة

DEPARTMENT OF HEALTH

دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

Encyclopedia of Health Legislation

Book 8: Medical Products, Pharmacy Profession and Pharmaceutical Facilities Legislation

www.doh.gov.ae | DoHSocial | Department of Health Abu Dhabi

Encyclopedia of Health Legislation
Book 8: Medical Products, Pharmacy Profession and Pharmaceutical Facilities Legislation

ISBN: 978-9948-786-46-7
Approval of Media Regulatory Office
United Arab Emirates
Print Permission: MC-03-01-5985078
02-May-2023

Third Issue - February 2023

Book 8:

Medical Products, Pharmacy Profession and Pharmaceutical Facilities Legislation

صاحب السمو الشيخ محمد بن زايد آل نهيان

رئيس دولة الإمارات العربية المتحدة

HIS HIGHNESS SHEIKH MOHAMED BIN ZAYED AL NAHYAN

PRESIDENT OF THE UNITED ARAB EMIRATES

المغفور له بإذن الله الشيخ زايد بن سلطان آل نهيان

تغمده الله بواسع رحمته

SHEIKH ZAYED BIN SULTAN AL NAHYAN

المغفور له بإذن الله الشيخ خليفة بن زايد آل نهيان

تغمده الله بواسع رحمته

SHEIKH KHALIFA BIN ZAYED AL NAHYAN

Introduction

The release of the third issue of the Encyclopedia of Health Legislation by the Department of Health - Abu Dhabi reflects the aspirations of the Government of Abu Dhabi to deliver the best services to customers and provide an organizational and legislative knowledge, and is the Department's first step towards legislative digitization in the health field to achieve its vision of "a healthier Abu Dhabi" and hence promote the wellbeing and happiness of community.

"Medical Products, Pharmacy Profession and Pharmaceutical Facilities Legislation" is released in this eight book of the Encyclopedia, given its importance in promoting the healthcare service quality in the emirate and the State, and for the direct influence of this sector on the lives of people, thereby requiring governing legislative controls to be set up.

Legislation on Medical Products, Pharmaceutical Profession and Pharmaceutical Facilities includes the governing laws of this Sector, which establish the controls necessary for regulating and circulating Medical Products for import, export, distribution, registration and control, regulate the clinical and laboratory studies, regulate the pharmacy profession and pharmaceutical facilities in terms of licensing and control, and regulate the administrative and disciplinary liability and penalties in case of breach of the provisions of the law, to ensure an effective and safe support of healthcare services, and enhance the emirate's commitments in international conventions in this field.

DOH will seek to strengthen the body of Medical Products, Pharmaceutical Profession and Pharmaceutical Facilities Legislation with further contributions and initiatives, in order to keep abreast of the developments and advanced technologies in this field, and in compliance with international legislation and international organizations to combat fraud in medical products in particular, and govern pharmaceutical practices and facilities according to the best international standards.

Finally, we would like to express our profound gratitude for the guidance and trust of H.E. the Chairman of the Department of Health and for the follow-up, support and attention of H.E. the Undersecretary. We would also like to extend our thanks and appreciation to DOH partners, all the Encyclopedia team, and the officials of DOH organizational units for their efforts and active participation in completion of this book, looking forward to working together towards further development and modernization to strengthen the body of the health legislation in the Emirate of Abu Dhabi.

Saqr Al Marzooqi

Manager, Legal Affairs Office

Abu Dhabi - February 2023

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

We, Khalifa bin Zayed Al Nahyan, President of the United Arab Emirates:

- Having regard to the Constitution;
- Federal Law No. (1) of 1972 on the Mandates of Ministries and Powers of Ministers, as amended;
- Federal Law No. (8) of 1980 on the Regulation of Labor Relations, as amended;
- Federal Law No. (18) of 1981 on the Regulation of Commercial Agencies, as amended;
- Federal Law No. (4) of 1983 on Pharmacy Profession and Pharmaceutical Institutions;
- Federal Law No. (3) of 1987 Promulgating the Penal Code, as amended;
- Federal Law No. (35) of 1992 Promulgating the Criminal Procedure Code, as amended;
- Federal Law No. (37) of 1992 on the Trademarks, as amended;
- Federal Law No (18) of 1993 on Commercial Transactions, as amended;
- Federal Law No. (14) of 1995 on Combating Narcotics and Psychotropic Substances; as amended;
- Federal Law No. (20) of 1995 on Medicines and Products Derived from Natural Sources;
- Federal Law No. (17) of 2002 on the Regulation and Protection of Industrial Property for Patents, Industrial Drawings and Designs, as amended;
- Federal Law No. (1) of 2006 on Electronic Commerce and Transactions;
- Federal Law No (24) of 2006 on Consumer Protection, as amended;
- Federal Law No. (51) of 2006 on Combating Human Trafficking Crimes, as amended;

* This translation from Arabic to English is provided for your convenience only. In case of any discrepancy, the Arabic version prevails

- Federal Law No. (6) of 2007 on the Establishment of the Insurance Authority and Regulation of its Operations, as amended;
- Federal Law No. (14) of 2014 on the Prevention of Communicable Diseases;
- Federal Law No. (2) of 2015 on Commercial Companies, as amended;
- Federal Law No. (4) of 2015 on Private Health Facilities;
- Federal Law No. (8) of 2015 on the Establishment of Federal Customs Authority;
- Federal Law No. (3) of 2016 on Child Rights (Wadeema's Law);
- Federal Decree-Law No. (4) of 2016 on Medical Liability;
- Federal Decree-Law No. (16) of 2016 concerning the Establishment of Emirates Healthcare Services Establishment;
- Federal Law No. (19) of 2016 on Combating Commercial Fraud;
- Federal Law No. (9) of 2017 on Veterinary Products;
- Federal Law No. (13) of 2018 on Voluntary Work;
- Federal Law No. (2) of 2019 on the Use of Information and Communication Technology (ICT) in Health Fields; and
- Based on the proposal of the Minister of Health and Prevention, and the approval of the Cabinet and the Federal National Council, and the ratification of the Federal Supreme Council,

• **Promulgate the following Law:**

Title One

General Provisions

Article (1)

Definitions

In application of the provisions of this Law, the following words and expressions shall have the meanings ascribed to them, unless the context otherwise requires:

State	: The United Arab Emirates.
Ministry	: The Ministry of Health and Prevention
Minister	: The Minister of Health and Prevention.
Competent Department	: The concerned administrative unit at the Ministry.
Concerned Authority	: Local government health authority or local authority according to their respective competence.
Competent Authority	: Drug Department at the Ministry or the corresponding department at the Concerned Authorities.
Higher Committee of Drug Policies	: A committee in charge of development of policies of Medical Product circulation, pricing and control within the State.
Competent Committee	: Any committee formed by decision of the Minister to consider the issues that were assigned to it in relation to one or more tasks specified herein.
Medical Product	: A Medicinal Product, Medical Device or Healthcare Product.
Medicinal Product	: A product that contains an Active Constituent or a group of Active Constituents that accomplish the intended purpose when applied on/in human or animal through a biological effect. This product is manufactured, sold or made available for application in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of illness. 2. Restoration, renovation, codification or correction of organs' functions.
Medical Device	: A Medical Product that contains any material, instrument, tool, machine, appliance, implant, in vitro reagent, calibrator or a system, including its accessories and operating software, which achieves the intended purpose when applied

on/in humans or animals, without medicinal, immunological or metabolic effect. Medical Devices are manufactured, sold or offered for use in the following cases:

1. Diagnosis; treatment, cure, relief, monitoring, prevention of illness, injury or disability.
2. Diagnosis, treatment, relief or compensation for an anatomical position.
3. Pregnancy control.

Healthcare Product : A Medical Product used for general health of a human and not specific for the diagnosis, treatment or cure, which does not require a prescription on dispensing or direct medical supervision when used.

Veterinary Medical Product : A Medical Product designed to be applied in/on animals only.

Pharmaceutical Product : A medical Product that is produced in a specific pharmaceutical form and has specific applications for human and animal.

New Medical Product : A Medical Product that contains a new Active Constituent, where no other Medical Product containing the same ingredient has obtained Marketing Authorization within the State, while the period during which such product containing the same Active Constituent has been marketed globally has not exceeded two (2) years.

Generic Pharmaceutical Product : A product that is similar to another Pharmaceutical Product in terms of quality and quantity of Active Constituents, Pharmaceutical Form and Bioequivalence.

Defective Product : A product that does neither meet quality specifications nor the requirements set out under this Law or its Implementing Regulations or decisions.

Adulterated Product : A Medical Product that is deliberately and fraudulently produced with intent of deception and fraud, including:

1. Providing its cover, packing, identification label or Product Information Leaflet with false or incorrect information in respect of its identity or origin and in means not identical to the reality.
2. Counterfeiting another Medical Product using the same technical design, cover colors, packing and identification label of the original product.
3. Addition or removal of an active or non-Active Constituent(s) of the formulation prescribed on its cover, packing, identification label or Product Information Leaflet without the permission of the Competent Department.
4. Change of volume or quantity of its Active or non-Active Constituent(s) without the permission of the Competent Department.

Raw Materials : Materials contained within Medical Product's composition or manufacture.

Marketing Authorization : Authorization issued by Ministry to the holder of the right to market a Medical Product within the State.

Marketing Authorization Appendix : An appendix that contains product-related information, description, formulation and volume of Active and non-Active Constituents, applications, doses, route of administration, side effects and any other details defined by the Law, its implementing regulations and executive instructions.

Product Information Leaflet : A leaflet that contains an important brief information of Marketing Authorization Appendix intended for Medical Product users.

Active Constituent	:	Any substance(s) of Major Effects of the Product. Such substances may be derived from human, animal, plant, microorganisms, chemicals or others.
Major Effects	:	Effects on Medical Product user, under which the product is applied according to its indications in its Marketing Authorization.
New Indication	:	A newly introduced indication to the existing indication list of a Medical Product, which marketing is previously authorized within the State, provided that such new indication has resulted from other effects than those Major Effects of the previous indications.
Approved Pharmacopoeia	:	Pharmacopoeia approved within the State as references.
Pharmaceutical Form	:	The form of produced or manufactured Medical Product, including its final form to be administered by the patient.
New Route of Administration	:	A new route of administration, which has not previously obtained Marketing Authorization within the State to obtain the product's Major Effects.
Side Effect	:	A number of indications and effects documented in the Product Information Leaflet, which is expected to occur on some patients and may occur during the application of the Medical Product according to the applications, doses, and routes of administration shown on the cover, label and Product Information Leaflet as set out in the Marketing Authorization.
Adverse Reaction	:	Any unintentional or undesirable effect that occur on Medical Product user as a result of the prescribed doses and authorized applications in the Marketing Authorization, which may occur as a result of effects other than those Major Effects of the Medical Product.

Adverse Event	:	An undesirable medical event occurring on a Medical Product user, which does not necessarily result from product's application.
Unexpected Adverse Reaction	:	Adverse Event unexpected to occur during application of Medical Product and whose nature or occurrence exceeds the limit prescribed in the Marketing Authorization Appendix.
Critical Side Effect or Critical Adverse Event	:	Undesirable or unintentional non-treating occurrence that leads the Medical Product user, by any dose or route, to undergoing the following result(s): 1. Death. 2. Causing an event that threatens the patient's life, which require admission or extends stay at hospital. 3. Causing a permanent disability or deformity. 4. Death, congenital or physical malformation of fetus or any negative effects thereon.
Non-Clinical Trials	:	Toxic or pharmaceutical trials aimed at assessment of Medical Product and that are not conducted on humans.
Clinical Trials	:	Trials or researches observing a specific product and conducted on groups of humans to identify absorption, metabolism, circulation and excretion, to identify its Major Effects, Side Effects and Adverse Reactions to verify the Medical Product's effectiveness, efficiency, quality and safety according to the previously agreed applications subject to the Marketing Authorization granted to the Medical Product, new indications or drugs under research and development.
Non-Intervening Clinical Trials	:	Clinical trials in which Medical Products are applied according to doses, routes of administration, and for applications in line with the Marketing Authorization within the State, which may not

require those undergoing it any change in their Medical Prescription or normal lifestyle.

Bioavailability	:	Speed and extent of Active Constituent absorption and availability of a Medical Product and any of its active metabolites in blood or place of action in body.
Bioequivalence	:	The absence of clear statistical difference regarding the Bioavailability of the Active Constituent in a Pharmaceutical Product with another product having the same Active Constituent.
Research Information	:	Any piece of Information obtained as a result of chemical, Manufacturing, controls, pre-clinical and clinical research to support the safety, efficiency or quality of New Medical Product to obtain Marketing Authorization.
Equivalent Alternative	:	Equivalent alternative Medicinal Product of another product, which is therapeutically equivalent, gives the same therapeutic effect and benefits and the extent of drug safety for the patient according to its approved applications.
Stability Studies	:	Tests performed in similar approved storage conditions or in severe conditions to increase the rate of chemical or physical decomposition of a Medical Product to monitor decomposing interactions or any evidence on invalidity of the product so as to assess the product's validity period under the approved storage conditions.
Batch	:	A quantity of a specific Medical Product produced at one time. A Batch contains a unique identification number and date of manufacture after undergoing the necessary inspections and tests.
Product Withdrawal	:	Withdrawal procedure of the entire product or a Batch due to a defect, or to verify the validity of a report on Adverse Reaction or Critical Side Effect, or any other reasons stated by the authority

requiring Product Withdrawal. Withdrawal may be by the Manufacturer, Distributor, Importer, by an order of the Concerned Authority or by the Ministry.

Reference Country : The country whose approval of Medical Product marketing is adopted to approve product marketing within the State.

Healthcare Professional : Scientifically and technically Qualified Person, licensed to practice a healthcare profession within the State according to the Implementing Regulations of this Law.

Pharmacy Profession : A healthcare profession that aims at improving the health standard of Medical Product users through proper and appropriate usage of such products, based on specialized scientific knowledge. The Pharmacy Profession includes a number of licensed activities to be practiced by the Pharmacist and shall not be limited to Manufacturing, composition, dispensing, administration, sale and storage of Medical Product, or providing pharmaceutical advises, however it includes any other activities determined by ministerial resolution. It also includes a variety of healthcare services to the patient, directly or through an assistance for other licensed Healthcare Professionals, by communicating and providing clinical (technical and scientific) advices.

Clinical Pharmacy : A branch of Pharmacy based on scientific knowledge to ensure utmost patient benefit from medication treatment plan, cure, health enhancement, and disease or complication prevention.

Qualified Person : Scientifically and technically Qualified Person, licensed to practice Pharmacy or medicine profession according to This Law and its Implementing Regulations.

Pharmacist : A person who holds a scientific qualification

that is not less than bachelor of Pharmacy or an equivalent degree from a higher institution, college or university accredited in the State. A Pharmacist must be licensed to practice Pharmacy Profession within the State according to this Law and its Implementing Regulations.

Pharmacist in Charge : A licensed Pharmacist for a licensed Pharmaceutical Facility. The Pharmacist shall be responsible for implementing the provisions of this Law and its Implementing Regulations within the limits of the tasks assigned to him.

Precautionary Closure : A precautionary action taken by the inspector of the Pharmaceutical Facility in case a serious violation that may lead to damages of public health is noticed.

Clinical Pharmacist : A person who holds approved clinical Pharmacy certificates and has extensive experience in this field. A Clinical Pharmacist develops treatment plans for patients, including usage of Medical Products based on scientific analysis of the patient's condition as well as a report on patient's diagnosis. The Clinical Pharmacist also provides professional advices on Drug Therapy plan and the optimal application of Pharmaceutical Products for Healthcare Professionals, who are members of medical staff responsible of the patient, and the patient himself.

Pharmacy Technician : A person who holds a scientific qualification of no less than diploma of Pharmacy, with a study duration of no less than two (2) years after secondary school or an equivalent, from a recognized institution in the State. Pharmacy Technician must be licensed to practice Pharmacy Technician profession under the direct supervision of a licensed Pharmacist according to the provisions of this Law.

Medical Prescription : A written or electronic document issued by a Healthcare Professional duly licensed to

dispense to a Healthcare Professional authorized to dispense according to the Implementing Regulations of this Law, resolutions, orders and instructions issued in this regard. Oral order issued by a Healthcare Professional is deemed a prescription, provided that it is documented later according to a ministerial resolution.

Drug Therapy Plan	:	The plan that includes Medical Product usage plan designed for the patient based on careful analysis of the pathological status and patient condition to obtain the best possible results for treatment. The plan also includes schedule for administration of drugs, which stipulates the name, type, Pharmaceutical Form, titer, route of administration, dosage amount, number of daily doses, duration of treatment and any other instructions such as sequence of use of products or gradual modification of doses ... etc.
Medical Product Application Protocol	:	The system approved by the health establishment or the treating physician, which sets out the cases permitted to apply the Medical Product, contraindications, terms of product application sequence, duration of treatment and route of administration.
Treatment Guidelines of Medical Cases	:	A system that governs the method to advance the treatment of cases according to accurate instructions. Such guidelines set out the terms of diagnosis, determine the Medical Product and the other therapeutic actions for each case and the sequence of their usage and functioning.
Direct Supervision and Control	:	Full knowledge and complete follow-up at all times of all activities carried out by Pharmaceutical Facility staff.
Distribution Channels	:	The Pharmaceutical Facilities that the Medical Product passes through during its distribution process, from the location at which it is finally manufactured to dispensing to end-user in the State.

Pharmaceutical Facility	:	A facility licensed to operate in any discipline of the Pharmacy Profession within the State, including Pharmacy, Pharmacy Chain, Medical Warehouse, Marketing Offices, Pharmaceutical Consulting Offices, Pharmaceutical Laboratory, pharmaceutical Research Centers, Manufacturer and other facilities stipulated by the Implementing Regulations of this Law.
Pharmacy	:	The facility licensed to store, prepare, compound, dispense, display or directly sell the Medical Products to the public through a fixed or mobile, permanent or temporary facility.
Pharmacy Chain	:	A number of Pharmacies owned by a natural or legal person under the same name.
Medical Warehouse	:	A place licensed to store Medical Products according to the provisions of this Law and its Implementing Regulations. The warehouse may be licensed for Import and Distribution or for Distribution purpose only.
Storage	:	Keeping the Medical Product at any time during its cycle in Manufacturing and Distribution Channels.
Distribution	:	Transportation or movement of a Medical Product from the Manufacturer to any other central point to the end user or to an intermediary point, using equipped transportations.
Importer	:	A person licensed to import any quantity of Medical Products from outside the State for the purpose of possession, Storage, Distribution or wholesale.
Distributor	:	A person licensed to practice any activity related to Medical Product circulation, except for importation and direct sale to the public.
Marketing Authorization Holder	:	The legal person authorized to market a specific Medical Product within the State and is responsible of all marketing, promotion and follow-up aspects of the product within the State.

Manufacturing	:	A number of activities including purchase of Raw Materials and equipment used in Manufacturing, production processes including preparation, compounding, extraction, packaging or re-packaging of any Medical Product, product quality control, product approval and other processes according to the Implementing Regulations of this Law.
Manufacturer	:	The facility intended to totally or partially produce Medical Products.
Product Manufacturing Authorization	:	The authorization issued by the Ministry to the Manufacturer licensed in the State to totally or partially produce a specific Medical Product.
Manufacturing Authorization Holder	:	The Pharmaceutical Facility licensed to totally or partially manufacture Medical Product according to conditions and procedures stipulated under the Implementing Regulations of this Law.
Marketing Office	:	The Pharmaceutical Facility licensed to practice introduction of Medical Products to Healthcare Professional and follow up the circulation of such products in the State.
Pharmaceutical Consulting Office	:	The Pharmaceutical Facility licensed to provide specialized consultations in Pharmacy Profession applications field.
Pharmaceutical Laboratory	:	The Pharmaceutical Facility licensed to inspect, test and conduct quality control on Medical Products.
Laboratory Studies	:	Studies and researches performed on Medical Product(s) or its/their Active Constituent(s) within the scope of the laboratory and laboratory tests to identify its toxic, chemical, physical microbiological or technical characteristics. Laboratory Studies are not conducted on human but may be conducted on animal.
Research Center	:	The Pharmaceutical Facility licensed to conduct clinical, Bioavailability or Bioequivalence

		researches and studies related to measurement of the levels of Active Constituents in bio liquids and tissues.
Compounding Pharmacy	:	The Pharmaceutical Facility licensed to compound medical preparations based on prescription or to meet the health facilities needs of necessary compounded products.
Toxic Substances and Plants	:	Substances and plants specified under the legislation governing this type of substances or plants.
Narcotic Drugs and Psychotropic Substances	:	Medical Products and Medicinal Products and others containing any of the Active Constituents according to Federal Law No. (14) of 1995, and its amendments.
Semi-Controlled Substances	:	Substances and drugs not listed as Narcotic Drugs and Psychotropic Substances, but must be controlled inside the State, as their misuse may lead to harm of public health.
Chemical Precursor	:	A chemical substance that is incorporated into Narcotic Drugs and Psychotropic Substances, hazardous substance, psychoactive or toxic Substances during the Manufacturing process according to both lists attached hereto, as subsequently amended.
Prohibited Veterinary Substances	:	Substances specified under the legislation governing this type of substances.
Hazardous Medical Products	:	Products whose determination and scope of prohibited application are specified by decision of the Minister.
Controlled Substances and Products	:	Products and substances whose medical and commercial circulation require controlling actions. such products include: 1. Toxic Substances and Plants. 2. Prohibited Veterinary Substances.

3. Narcotic Drugs and Psychotropic Substances, whether in the form of Raw Materials or incorporated in a Medical Product.

4. Hazardous Medical Products.

Article (2)

Scope of Application

The provisions of this Law shall apply to Medical Products, Pharmacy Profession and Pharmaceutical Facilities in the State, including the free zones, in accordance with the regulations stipulated in this Law and its Implementing Regulations.

Title Two

Regulation and Circulation of Medical Products

Chapter One

Marketing Authorization and Marketing Authorization Holder

Article (3)

Marketing Authorization

Without prejudice to the legislation on veterinary medicines, no Medical Product may be circulated within the State unless after obtaining Marketing Authorization or exclusive Marketing Authorization from the Ministry according to the terms and procedures set out by decision of the Minister.

Article (4)

Assessment of Product Compliance with Research Information

A Marketing Authorization for a New Medical Product, New Indication or New Route of Administration shall be issued by the Ministry based on assessment of compliance with Research Information, which proves efficacy and safety of its use and compliance with the approved quality specifications or the Marketing Authorizations issued for the product by the Reference Countries, provided that the applicant is entitled to market the product according to the intellectual property and trademark regulations.

Article (5)

Product Pricing

A Medical Product for which a Marketing Authorization has been issued must be priced in order to be circulated. Medical Products priced by decision of the Minister are excluded from such pricing.

Article (6)

Marketing Authorization of Generic Pharmaceutical Product

Without prejudice to the provisions of international conventions to which the State is a party, and to the provisions of the referenced Federal Law No. (17) of 2002, the Ministry may issue Marketing Authorization for a Generic Pharmaceutical Product, based on its Bioequivalence and qualitative equivalence to another product on which the legal protection has ended and for which a Marketing Authorization has already been issued according to the provisions of this Law.

Article (7)

Obligations of the Applicant for Authorization

An applicant for the Marketing Authorization for a Medical Product shall:

1. appoint one or more Qualified Persons residing in the State, as determined by decision of the Minister;
2. provide one or more Medical Warehouses to carry out the activities of Import, Storage, Distribution and wholesale of products authorized to be marketed;
3. follow up the Medical Product through Distribution Channels;
4. provide the necessary capabilities and systems to follow up the requirements of Medical Product Marketing Authorization;
5. monitor the performance of the licensed Medical Product and receive reports by the Pharmaceutical Facilities with regard to its effectiveness, safety, usage and quality;
6. inform the Ministry and the Concerned Authority within a maximum period of fifteen (15) days from the date of becoming aware of Unexpected Side Effects, Unexpected Adverse Reactions, Critical Side Effects or Critical Adverse Events reported or observed during circulation or local or global

clinical researches conducted thereon;

7. follow up Medical Product Withdrawal procedures;

8. follow up the product patent and Manufacturing right protection.

Article (8)

Sale of Priced Medical Product

1. A priced Medical Product may not be sold at a price higher than the price fixed by the Ministry.

2. No discounts shall apply to the price fixed by the Ministry. However, special prices may be set according to a dispensing system by entities mentioned in the Implementing Regulations of this Law.

Article (9)

Obligations of the Person Appointed by Marketing Authorization Holder

A Qualified Person appointed by the Marketing Authorization Holder shall:

1. provide pharmaceutical or scientific information on the marketed Medical Product to the health facilities and ensure that it is accurate and consistent with the information approved by the Ministry.

2. inform the Ministry of any change or update in Manufacturing or compounding methods, the origin of Active Constituents, the form, packing or quality inspection of the Medical Product, as well as any New Indication or any change, update, addition or removal of the indications set out within the Marketing Authorization to obtain approval in respect of any of the above. The Ministry shall inform the Concerned Authorities of the reported data and information after its approval.

3. monitor the Side Effects of the Medical Product within the State and inform the Ministry and the Concerned Authorities of any Side Effects, Unexpected Adverse Reaction or Critical Adverse Event caused by the Medical Product inside or outside the State within a period not exceeding fifteen (15) days from the date of its observance.

4. follow up post-marketing Medical Product reports, along with reports of effectiveness, safety and quality of product application within the health facilities in the State.

5. inform the Ministry and the Concerned Authority of any complaint or report to withdraw a Medical Product Batch or the entire product inside or outside the State within a period not exceeding fifteen (15) days from the date the complaint or report is received.

Article (10)

Joint Liability

The Qualified Person shall be jointly liable with the Marketing Authorization Holder for any violation of the provisions of the Law, particularly for recordkeeping in respect of the Storage and Distribution of the Medical Product.

Article (11)

Medical Product Suspension and Withdrawal

1. The Ministry may suspend a Medical Product if the situation requires that information on lack of quality, safety or effectiveness be verified. The Concerned Authority shall issue a decision of Withdrawal of the entire product or a number of Batches thereof within thirty (30) days of the date of suspension in any of the following cases:

    a. If the Medical Product is proved to be Adulterated Product or not conform to the quality, safety or effectiveness specifications approved by the Ministry.

    b. If the Medical Product is proved to be toxic or harmful under the conditions of indication recommended by the Manufacturer or marketer.

    c. If an Unexpected or Critical Side Effect occurs under the conditions of indication recommended by the Manufacturer or marketer.

    d. If the Marketing Authorization of the Medical Product is cancelled or the product's production is ceased in the Reference Country due to reasons related to product's quality.

    e. If it is proved that the Marketing Authorization is obtained based on false documents, incorrect information or illegal means.

    f. In the event of any change in the product's formulation, form, Product Information Leaflet, method of manufacture or place of manufacture without the consent of the Competent Department.

g. In case of violation of any of the conditions stipulated under this Law, its Implementing Regulations and implementing decisions, rules and instructions.

2. In any event, the Ministry and the Concerned Authority shall mutually coordinate in respect of any actions to be taken according to this Article. The Concerned Authorities may, within their respective competence, suspend the product in government and private health facilities and must notify the Ministry accordingly, as specified by the Implementing Regulations of this Law.

Article (12)

Temporary License

If a specific product is proved to be unavailable and an alternative product is absent in the State, a decision shall be issued by the Minister, based on the recommendation of the Competent Committee comprising representatives of the Concerned Authorities, to issue a temporary license for another one or more Marketing Authorization Holders, to provide the unavailable product in the State at such time and for such price approved by the Ministry, and in the agreed quantities, subject to the provisions of the referenced Federal Law No. (17) of 2002.

Chapter Two

Clinical and Non-Clinical Trials

Article (13)

Prohibitions of Clinical and Non-Clinical Trials

Non-clinical Trials shall not be conducted on humans. Clinical Trials may not be conducted before Non-clinical Trials are performed, in order to ensure the extent of safety and effectiveness of medical intervention subject of Clinical Trials.

Article (14)

Clinical Trial Condition

Without prejudice to any other law, no Clinical Trial or Bioequivalence or Bioavailability studies of a Medical Product may be conducted on humans,

unless after obtaining approval from the Ministry or the Concerned Authority, as the case may be, and the subject of Clinical Trial conducts the necessary medical investigations to ensure his/her safety after obtaining a written consent containing an acknowledgment on his/her part of the Clinical Trial and its potential risks. Non-Intervening Clinical Trials shall be excluded from this consent, provided that the Ministry or the Concerned Authority, as the case may be, is notified.

Article (15)

Entities Authorized for Conduct of Clinical Trials

1. The Ministry or the Concerned Authority may authorize the following entities to conduct Clinical Trials:
    a. Public and private hospitals.
    b. Universities and specialized scientific research centres. In the event of inability to conduct Clinical Trials therein, trials may be conducted in authorized hospitals.
    c. Laboratories.
2. Clinical Trials and tests may not be conducted on bio samples of the trials in any entities other than those authorized according to this provision.

Article (16)

Obligations of the Entity in favor of which the Clinical Trial is Conducted

The entity that Clinical Trial is conducted in its favor shall:

1. develop the trial plan to be performed, including scientific justifications.
2. provide licensed physicians to supervise the safety of persons subject of the trial.
3. take out an insurance contract with an insurer operating within the State to cover the damages that may result from the trial.
4. comply with the code of good Clinical Trial practices adopted by the Ministry.

Article (17)

Higher Committee for Clinical Trial Ethics

1. A Higher Committee for Clinical Trial Ethics shall be established within the Ministry and shall comprise all the Concerned Authorities. The formation and functioning of the committee shall be determined by decision of the Minister, and its members shall have experience in healthcare, Sharia and legal fields. The Committee shall be in charge of Clinical Trial ethics, and its functions shall include:

    a. To develop policies related to Clinical Trials ethics at federal level.

    b. To support innovation and scientific research, while respecting Clinical Trials ethics.

    c. To present any suggestions that may contribute to the development of federal legislation supporting scientific research and innovations, subject to the Clinical Trials ethics.

    d. To coordinate between the Concerned Authorities in the field of Clinical Trials ethics.

    e. To approve transition between Clinical Trial phases according to the number of volunteers subject of trials.

    f. Any other activities related to its work as assigned by the Minister.

2. The Concerned Authority shall:

    a. apply the policies and local legislation related to Clinical Trials ethics at Health Authority level.

    b. coordinate with the Ministry's Higher Committee for Clinical Trial Ethics and notify it of any negative or unknown results of the Medical Product that may occur during or after trial.

    c. approve the establishment of sub-committees at the facilities conducting Clinical Trials according to Article 18 of this Law.

    d. Any other activities related to its functions as assigned by the chairman of Health Authority.

3. The Concerned Authority may form one or more committees to carry out the functions mentioned in paragraph (2) of this Article.

Article (18)

Sub-Committee for Clinical Trials

Entity authorized to conduct Clinical Trials shall form a specialized sub-committee comprising qualified and competent persons, including one legal member. The Committee shall be competent to:

1. verify the validity of scientific justifications of the trial.
2. adopt, approve and follow up trial plan and approve transition between Clinical Trial phases.
3. verify the efficiency of research team, its ability to conduct the trial, compliance with the standards approved by the Ministry for good laboratory practice.
4. ensure that the volunteer has consented to undergo the trial of his/her own free will without any influence thereon, after briefing the volunteer with all aspects of the trial and its potential risks, in addition to his/her parents' consent, in the event the volunteer is a minor, taking into account the minor's best interest and applicable Laws in the State.
5. ensure that volunteering is not used for the purpose of financial gain of the volunteer, except for the necessary applicable allowances, such as transportation allowance from and to the premises of Clinical Trial entity and allowance for absenteeism from work.
6. Any other activities assigned by the authorized entity.

Article (19)

Obligations of the Main Researcher and Entity towards Clinical Trials

The main researcher supervising the conduct of clinical trial and the entity at which trial is conducted shall adhere to the trial plan and code of good clinical trial practices and inform the entity in favor of which the trial is conducted, the head of sub-committee of the authorized entity referred to in Article 18 hereof, the Ministry or the Concerned Authority, as the case may be, in any of the following cases:

1. Occurrence of a Critical Adverse Event during the trial, provided that the event is notified within a period not exceeding fifteen (15) days from the date of occurrence.

2. Prior to any changes to the trial plan so as to protect those persons subject of the trial, or in case of urgency to make the change.

3. Reporting the request that caused suspension of trial and in case of withdrawal of any of the persons subject of trial.

Chapter Three

Laboratory Studies

Article (20)

Accredited Laboratory

No laboratory study, product-testing certificate or quality certificate for a Batch/Batches of Medical Product may be approved as a document proving its quality or stability, unless it is conducted and approved by an accredited Laboratory approved by the Ministry or the Concerned Authority according to the guidelines adopted by decision of the Minister.

Article (21)

Laboratory Accreditation Procedures, Controls and Conditions

Laboratory accreditation procedures, controls and conditions stated in Article 20 hereof, and the certificates issued thereto shall be specified by decision of the Minister after coordination with the Concerned Authorities.

Chapter Four

Medical Product Manufacturing

Article (22)

Medical Product Manufacturing Conditions

A Medical Product may not be manufactured within the State unless after obtaining the consent of the Ministry, provided that it is manufactured by a licensed or approved Manufacturer in the State according to the standards and criteria issued by decision of the Minister.

Article (23)

Good Manufacturing

Good Manufacturing conditions and requirements to be met by all Medical Product Manufacturing sites shall be issued by decision of the Minister. The Concerned Authority shall be in charge of monitoring compliance with such conditions and requirements.

Article (24)

Cancellation of Authorization by the Competent Department

The Competent Department may cancel Medical Product Manufacturing Authorization, if the authorization holder fails to apply for product Marketing Authorization without reasonable justification within two (2) years of the date of product Manufacturing Authorization.

Article (25)

Cancellation of Authorization by the Minister or His Deputy

The Minister or his deputy shall, upon recommendation of the Competent Committee, issue a decision to cancel the Medical Product Manufacturing Authorization in the State in any of the following cases:

1. If it is proved that the Manufacturing Authorization or Manufacturer's accreditation is based on false documents.
2. If a decision is issued for prohibition of Product Manufacturing in the State or the country of origin or any of the reference entities approved by the Ministry.
3. If it is proved that the Manufacturer repeatedly failed to apply the principles of good Manufacturing practice, which affects the quality of the Medical Product.
4. If the product is found unsafe or has repeatedly failed to comply with the approved quality standards at the time of laboratory tests performed in the accredited Laboratories in the State. A decision of the Minister shall specify the number of failures that require cancellation of Manufacturing Authorization.
5. If a decision is issued to ban the Manufacturer's activities in the State, the country of origin or any of the reference entities approved by the Ministry.

Chapter Five

Import and Export of Medical Products and Raw Materials

Article (26)

The consent of the Ministry

Medial products and Raw Materials contained therein may not be imported, exported or re-exported unless with the approval of the Ministry. The Minister may delegate the Concerned Authority in this regard, within the scope of Medical Products intended to be used by government health facilities.

Article (27)

Appointment of a Pharmaceutical Facility

The Marketing Authorization Holder shall appoint a Pharmaceutical Facility licensed to import, as an Importer of the Medical Product that the Marketing Authorization Holder has the authorization to market. The Marketing Authorization Holder shall also appoint one or more Pharmaceutical Facilities licensed to distribute, as its Distributors within the State.

In any event, the Marketing Authorization Holder shall obtain approval of the Ministry for the appointment and shall follow up the product's Batches through various Distribution Channels within the State.

Article (28)

Personal Use of Medical Product

The Implementing Regulations of this Law shall specify the conditions and requirements of importation, possession or obtainment of Medical Product for personal use when entering into the State.

Chapter Six

Circulation of Medical Product

Article (29)

Higher Committee for Drug Policies

The Minister shall issue a decision to form the Higher Committee for Drug Policies, which shall comprise representatives of the Ministry and the Concerned Authorities and shall propose policies related to circulation, pricing and monitoring of the Medical Products in the State. The Committee shall also approve the rules, conditions and procedures to obtain Marketing Authorization for Medical Products. Decision of Committee's formation shall set out the Committee's functioning procedures.

Article (30)

Medical Product Provision

Marketing Authorization Holder may not illegally or for purpose of domination refrain from providing the Medical Product that obtained Marketing Authorization according to the provisions of this Law.

Article (31)

Prescription Medical Products

Non-Pharmaceutical Facilities may not sell, display, store or circulate any Medical Products that require a Medical Prescription.

Article (32)

Nonprescription Medical Products

A Minister's decision shall be issued to specify the non-Pharmaceutical Facilities, which are allowed to sell, display, store or circulate Medical Products that may be dispensed without a prescription, along with the names of such products, according to the conditions set out in the Implementing Regulations of this Law.

Article (33)

Information and Data

A Medical Product may not be circulated or marketed unless the information and data shown on the internal and external labels and Product Information Leaflet are identical to those shown on the packing according to its Marketing Authorization Appendix. The Competent Committee shall specify the data to be noted on the internal and external labels and the Product Information Leaflet.

The Product Information Leaflet should be written in at least Arabic and English, except for the cases of necessity determined by decision of the Minister.

Article (34)

External Packing Remark

The Manufacturer, Marketing Authorization Holder and Distributor must insert the following remark with an ineffaceable material on the Healthcare Product: "This Product is not designated for diagnosis, treatment, cure or prevention of any disease".

Article (35)

Reporting Negative or Harmful Results

Pharmaceutical Facilities, healthcare facilities and Healthcare Professionals working at both of them shall report to the Ministry and the Concerned Authority any negative or harmful results of the Medical Product due to quality's non-conformity to the standards adopted by the Ministry within a period not exceeding fifteen (15) days from the date they become aware thereof.

Article (36)

Prescription of Medical Products

1. Physicians may not prescribe a Medical Product to be applied for New Indications other than those specified within Product Information Leaflet or a Medical Product for which no Marketing Authorization has been requested, save where it is necessary to do so, provided that the bioequivalent product is not available and the patient's consent is obtained.

2. Licensed Healthcare Professionals may not advice, prescribe or dispense any Medical Product, unless they are authorized to do so according to the provisions of this Law and its Implementing Regulations.

Article (37)

Other Healthcare Professionals

Licensed Healthcare Professionals other than Pharmacists and Pharmacy Technicians shall not directly or indirectly sell any Medical Product unless after the consent of the Ministry or the Concerned Authority.

Article (38)

Prohibition to Prescribe Products for Personal Gain

Healthcare Professionals shall not prescribe or advise any product for a personal gain.

Chapter Seven

Promotion and Advertisement of Medical Product

Article (39)

Ban on Advertising; Permissible Cases

1. A Medical Product dispended under a Medical Prescription may not be publicized or advertised to the public by whatsoever means.
2. It shall be permissible with the consent of the Ministry:
    a. To publicize, advertise or promote a Medical Product in the scientific fields and sources intended for Healthcare Professionals.
    b. To publicize, advertise or promote to public a Medical Product which is dispensed without Medical Prescription or a Healthcare Product that has obtained a Marketing Authorization.

Article (40)

Marketing Authorization Holder

Marketing Authorization Holder shall ensure that Medical Product advertisements and promotions are in line with the rules and conditions set out by the Ministry.

Article (41)

Licensees

Licensees authorized to manufacture, market or distribute a Medical Product shall not falsify, fraud, steal, or defraud the published studies and research, which affects the intellectual property rights of the owners of such studies.

Article (42)

Prohibitions on Circulation and Sale

1. It shall be prohibited to circulate Adulterated, Defective or expired Medical Products.
2. Free Medical Product promotion samples may not be sold and the external and internal labels of such samples shall be clearly sealed in ineffaceable material with the following remark "Free medical sample, not for sale" in both Arabic and English.

Article (43)

Free Samples

It shall be prohibited to provide other than Healthcare Professionals licensed to prescribe medicines with free medical samples for purpose of prescription to patients. A record shall be kept showing entries of each category of controlled product samples.

Title Three

Regulation of Pharmacy Profession and Pharmaceutical Facilities

Chapter One

Licensing Practitioners of Pharmacy Profession

Article (44)

License required for Commencement of Business and Registration

1. No person may practice any activity in the field of Pharmacy Profession or work as Pharmacy Technician, unless he is licensed by the Ministry or the Concerned Authority according to the controls specified by the Implementing Regulations of this Law.

2. A national register shall be established at the Ministry, in which the data of practitioners of Pharmacy and Pharmacy Technician Profession in the State shall be entered.

3. The Concerned Authority shall create its own register containing data of practitioners of Pharmacy and Pharmacy Technician Profession licensed by the Concerned Authority.

4. Pharmacists listed in the registers stated in this Article shall be classified according to their qualifications and expertise.

5. The Implementing Regulations of this Law shall set out the conditions, procedures and update of the entry in the said registers.

Article (45)

License Applications and License Renewal

1. The Ministry or the Concerned Authority, according to its competence, shall review and approve applications for Pharmacist or Pharmacy Technician license or license renewal, according to the controls set out by the Implementing Regulations of this Law.

2. The Ministry shall issue its decision on the license application within thirty (30) days of the date of application. A decision to reject license application or license renewal must be reasoned. If no reply is received within the above-mentioned period, the licensing shall be deemed as rejected.

Chapter Two

Duties of, and Prohibitions on Pharmacy Profession Practitioners

Article (46)

Licensed Pharmacist Duties

The Pharmacist licensed to practice any activity in the field of Pharmacy Profession shall carry out his Profession in accordance with the rules and traditions of the Profession and shall observe the professional ethics and keep the profession secrets, in accordance with the principles of Pharmacy code of ethics in the State. He shall in particular:

1. work in the Pharmaceutical Facility where he is licensed to work, within the limits of activities he is licensed to practice according to the terms and

conditions stipulated in the Implementing Regulations of this Law.

2. be diligent and honest in carrying out his work.

3. inform the Ministry or the Concerned Authority, as the case may be, of any Unexpected or Critical Side Effects, Unexpected Adverse Reaction or Critical Adverse Events caused by the Medical Product within fifteen (15) days of the date of its observance. The Concerned Authority shall inform the Ministry of any of the events stipulated in this provision.

4. report any communicable diseases, according to the applicable laws and decisions in this regard.

Article (47)

Clinical Pharmacy

Subject to the provisions of Article 46 of this Law, Clinical Pharmacist shall provide his specialized services and practice Clinical Pharmacy, provided that he practices at a licensed health facility providing therapeutic services to patients, in collaboration with the licensed attending physician supervising the patient. He may in particular:

1. prescribe or modify the Drug Therapy Plan, including replacement of a Medical Product with another, unless written or electronic instructions are issued by the attending physician prohibiting any modifications. Clinical Pharmacist may not take any action towards the patient, unless the patient is diagnosed by the licensed attending physician.

2. The prescribed or modified treatment plan must be in accordance with Medical Product Application Protocol and Treatment Guidelines of Medical Cases.

3. Clinical Pharmacist shall participate with the attending physician in the record and data of patients he/she is in charge of.

4. notify the attending physician in writing of implementation or modification of the plan by noting information of the plan and modifications thereto in patient record intended to be reviewed by the attending physician and the Clinical Pharmacist, within twenty-four (24) hours following implementation of the plan.

5. advise patients and provide them with diagnostic information including patient-related information, use of Medical Products and the Drug Therapy

Plan information, and provide such information to Healthcare Professionals, who are members of patient's treatment team.

6. Any of the following activities, provided that they are in line with the general instructions of the Healthcare Facility where he works and the Medical Product Application Protocols:

   a. Request to conduct routine tests on the patient's condition in relation to the selection and determination of Drug Therapy Plan, including measurement of pulse, temperature, blood pressure, and spirometry.

   b. Request to conduct laboratory tests related to the selection and determination of Drug Therapy Plan.

   c. Administer dosages to patients in line with the physician's instructions such as various injections and vaccinations.

Article (48)

Prohibitions on Licensee

A licensee authorized to practice the Pharmacy Profession may not breach the duties of his profession or violate the requirements of honesty and honor. He shall not in particular:

1. conduct any behavior that degrades the profession, such as illegal competition, improper appearance or smoking in the workplace.

2. divulge to anyone the diseases known by him through the Medical Prescription submitted to him, or the drugs mentioned in this prescription in any other way due to the practice of the Profession, unless the applicable laws in the State so require.

3. follow illicit methods to encourage patients to purchase Medical Products from the facility he is working at.

4. withhold, hide or sell the Medical Products at prices different than those specified by the Ministry.

5. change the quantity, type or form of Medical Products in his possession in contrary to the prescribed provisions of this Law.

6. sell Medical Products that are unfit for consumption, Defective or expired Medical Products, products failed to obtain Marketing Authorization from the Ministry, and Adulterated or smuggled Products illicitly entered into the State.

7. practice medical or healthcare activities other than those he is licensed to practice, such as nursing and disease diagnosis, except for first aid stipulated under the Implementing Regulations of this Law.
8. dispense Medical Products that require Medical Prescription, without receiving such prescription.
9. Dispense Medical Prescriptions under codes or references other than those scientifically agreed.
10. agree with the physician or Healthcare Professional authorized to prescribe Medical Products, to make specific prescriptions in a special way or other signs agreed between them.
11. verbally abuse or criticize any Healthcare Professionals before others.

Article (49)

Medical Prescription

A licensed Pharmacist may not dispense any Medical Product without a Medical Prescription, if its dispense requires that. In all cases, a Medical Prescription must:

1. be written in clear handwriting or electronically written in a clear language.
2. be issued by a Healthcare Professional licensed to issue prescriptions.
3. state the name of the healthcare professional who has issued the prescription, his stamp, signature and issue date.
4. contain the generic and trade name or both, Pharmaceutical Form, and dose, route of administration and duration of application.
5. state the patient's full name (first name, middle name and surname), age, weight, address, identity number and phone number.
6. contain information of potential allergic reactions on patient, if any.
7. be consistent with any other requirements set out the Implementing Regulations of this Law.

Article (50)

Prescription of Narcotic Drugs or Psychotropic Substances

1. The Pharmacist may not dispense Medicinal Products containing Narcotic or Psychotropic Substances according to the referenced Federal Law No. (14) of 1995 and its amendments, unless they satisfy the following conditions:

    a. The Medical Prescription shall be issued on the numbered form prepared by the Ministry or the Concerned Authority, according to their respective competence.

    b. It shall be written with an ineffaceable material or electronically written.

    c. The prescription shall include the trade name of the Medicinal Product, the name of the Active Constituent(s), the volume of medicine, the dose in figures and letters, route and duration of administration and the patient's full name, age and address.

    d. The prescribed dose shall not be more than the amount stated in the Pharmacopoeia adopted by the Ministry.

2. Controlled Medical Products Prescription may not be dispensed, if the period since its issue date exceeds the period specified in the Implementing Regulations of this Law.

3. Drugs may be dispensed through electronic prescriptions according to the regulations issued by decision of the Minister.

Article (51)

Alteration or Change of Prescription Items

A Pharmacist may not substitute or change any content of the Medical Prescription except after consulting whomever issued the prescription in writing. However, the Pharmacist may replace a Pharmaceutical Product with a Generic Pharmaceutical Product according to the controls prescribed by the Implementing Regulations of this Law.

Article (52)

Dispensing Refills of Medicines

A Pharmacist may not dispense refills of Medical Prescriptions that include Controlled and Semi-controlled Substances that can accumulate in the body or whose habitual consumption leads to addiction, unless a refill is indicated by whomever has issued the prescription according to the types of products specified by decision of the Minister.

Article (53)

Error in Medical Prescription

If the Pharmacist discovers an error in the Medical Prescription or becomes doubtful about some of its particulars, he must contact whomever has issued the prescription for clarification. He should return the prescription to the physician if he does not accept the clarifications, in which case, the physician shall underline the point of disagreement in the prescription and sign it.

Article (54)

Registration of Medical Prescriptions

The Pharmacist shall enter the Medical Prescriptions of Controlled and Semi-controlled Products and Substances, which he has dispensed, in registers specified by decision of the Minister, according to the controls and conditions set forth in the Implementing Regulations of this Law.

Article (55)

Prohibition on Issuance of Medical Prescription for Self or Relatives

A Healthcare Professional licensed to issue Medical Prescriptions may not issue a Medical Prescription for Controlled Products and Substances for himself, spouse or relatives to the second degree.

Chapter Three

Licensing Pharmaceutical Facilities

Article (56)

License Required

1. No person may open a Pharmaceutical Facility unless he is a citizen of the UAE and holder of the Ministry's or the Concerned Authority's license, according to their scope of competence.

2. In case of Import, export and Marketing of a Medical Product in the State, a license thereto from the Ministry must be obtained.

Article (57)

Duration of License

The license of the Pharmaceutical Facility shall be valid for the period specified by the Implementing Regulations of this Law. License holder shall practice the profession during the validity period of the license.

Article (58)

Prohibition of Unauthorized Activity

A Pharmaceutical Facility may not carry out any unlicensed activities and may not deal with unlicensed facilities in respect of circulation of Medical Products within the State. The facility manager shall be held liable in the event of violation of this Article. The facility manager shall be held liable in the event of violation of this Article.

Article (59)

Relocation of the Pharmaceutical Facility

Subject to the legislation in force in the State, a Pharmaceutical Facility may not be relocated to another location, or the blueprint thereof be altered without the consent of the Ministry or the Concerned Authority, according to their respective competence.

Article (60)

Transfer of Ownership

Without prejudice to the legislation in force in the State, a Pharmaceutical Facility may be transferred to a third party subject to the consent of the Ministry or the Concerned Authority, according to the conditions specified by the Implementing Regulations of this Law.

Chapter Four

Pharmacy Licensing

Article (61)

Licensing Conditions

Without prejudice to the conditions specified in Chapter (3) of this Title, to obtain the license to open a Pharmacy, such Pharmacy must be technically managed by a licensed full-time Pharmacist, and the Pharmacy must fulfill the technical and health conditions set forth by decision of the Minister.

Article (62)

Compounding Pharmacy

Without prejudice to the conditions specified in Chapter (3) of this Title, to obtain the license for a Compounding Pharmacy, this Pharmacy must be technically managed by a licensed full-time Pharmacist, and the Pharmacy must fulfill the technical and health conditions set forth by decision of the Minister.

Article (63)

Temporary Closure of Pharmacy

1. The Ministry or the Concerned Authority, as the case may be, may issue a decision to temporarily close a Pharmacy for a period not exceeding one (1) month in any of the following cases:

    a. Transfer of Pharmacy's ownership to a third party without the consent of the Ministry or the Concerned Authority.

    b. The absence of licensed Pharmacist or non-appointment of licensed Pharmacist to manage the Pharmacy according to the required number

of Pharmacists, as stipulated by the Ministry's decisions, regulations and instructions.

c. Commission of serious violations according to the Implementing Regulations of this Law, which results in causing public health harm if the Pharmacy continues to be opened.

2. In any case, the matter must be referred to the disciplinary committee mentioned in Article 102 of this Law within seven (7) working days from the date of closure to consider and decide on the disciplinary liability, within a period not exceeding ten (10) working days from the date the matter is referred to it.

Article (64)

Cancellation of Pharmacy License

The Ministry or the Concerned Authority, as the case may be, may issue a decision to cancel the license of a Pharmacy after conducting investigations according to the provisions of this Law in any of the following cases:

1. If the Pharmacy conducts an activity other than the licensed activity.
2. If it is proved that the license to open the Pharmacy is obtained based on false documents or incorrect information.
3. The Pharmacy is closed for more than three (3) consecutive months without reasonable justification.
4. Non-commencement of work in the Pharmacy within six (6) months from the date of the license issuance without reasonable justification.
5. Commission of serious violations according to the Implementing Regulations of this Law.
6. Circulation of Adulterated or unusable Medical Products.

Article (65)

Absence of Pharmacist in Charge

Should the Pharmacist in Charge be absent from the Pharmacy, the Pharmacy’s owner shall entrust the Pharmacy and its supervision to another licensed Pharmacist, subject to the approval of the Ministry or the Concerned Authority, as the case may be. In this case, a license may be granted for a

limited period of time according to the conditions set forth in the Implementing Regulations of this Law.

Article (66)

Pharmacy Chain and Electronic Pharmacies

1. License may be granted to open more than one Pharmacy according to Pharmacy Chain regulations set forth by the Implementing Regulations of this Law.

2. A Pharmaceutical Facility may provide its services electronically according to a regulation issued by the Minister.

Article (67)

Inadmissibility of Medical Examinations in the Pharmacy

A Pharmacy may not be used to conduct Medical Examinations and its activity shall be limited to the licensed activities according to the Implementing Regulations of this Law.

Article (68)

Affiliated Pharmacies

The Ministry or the Concerned Authority, as the case may be, may issue a license to open Pharmacies affiliated with non-health government authorities, public institutions, public welfare organizations or associations or private hospitals and medical centres, provided that such Pharmacies are managed by a licensed Pharmacist. The Implementing Regulations of this Law shall set forth the conditions of opening such Pharmacies and their functioning system.

Chapter Five

Medical Warehouse Licensing

Article (69)

Medical Warehouse Licensing Conditions

1. Without prejudice to the conditions specified in Chapter 3 of this Title, a license to open a Medical Warehouse requires that a license be obtained

from the Ministry, and that the Medical Warehouse be managed by a licensed full-time Pharmacist and fulfill the technical and health conditions set forth by the Implementing Regulations of this Law.

2. As an exception to the requirement of a full-time Pharmacist to manage the warehouse referred to in the previous paragraph, if the activity of the Medical Warehouse is limited to medical equipment, it may be managed by a medical equipment engineer, while complying with the rest of the other conditions in the previous paragraph.

Article (70)

Precautionary Closure or Suspension of License

1. The licensing entity may, within the scope of its competence, issue a decision for the precautionary closure of the Medical Warehouse or the temporary suspension of its license until the violation is remedied, in any of the following cases:

   a. Transfer of Medical Warehouse's ownership to a third party without the consent of the Ministry or the Concerned Authority.

   b. If the Medical Warehouse shifts from the location to which a license was issued prior to obtaining the consent of the Ministry or the Concerned Authority.

   c. Commission of serious violations, which result in harm to the public health if the Medical Warehouse continues to be opened, according to the Implementing Regulations of this Law.

   d. Absence of full-time Pharmacist to manage the warehouse.

2. Decision of precautionary closure or temporary suspension of license may be issued based on an inspection report from the Competent Authority in the Ministry or the Concerned Authority, as the case may be. For the warehouse carrying on imports and exports, the Concerned Authority shall issue decision of precautionary closure or temporary suspension of license once a request from the Ministry is submitted.

3. In any event, the matter must be referred to the disciplinary committee stated in Article 102 hereof, within seven (7) working days from the date of license suspension or closure, to consider and decide on the disciplinary liability within a period not exceeding ten (10) working days from the date of referral of the matter to the committee. The Concerned Authority

shall inform the Ministry of the decision issued in respect of the Medical Warehouse carrying on exports and imports once it is issued.

Article (71)

Cancellation of Medical Warehouse License

1. The licensing entity shall, within the scope of its competence, issue a decision to cancel the license of a Medical Warehouse in any of the following cases:

    a. Circulation of Adulterated or unusable Medical Products.

    b. Conduct of an activity other than the licensed activity.

    c. If it is proved that the license to open the Medical Warehouse is obtained based on false documents or incorrect information.

    d. The Medical Warehouse is closed for three (3) consecutive months without reasonable justification.

    e. Non-commencement of work in the Medical Warehouse within six (6) months from the date of the license issuance without reasonable justification.

    f. Failure to remedy the violation within the grace period specified by the Ministry or the Concerned Authority according to Article 70 hereof.

    g. Commission of serious violations according to the Implementing Regulations of this Law.

2. The Concerned Authority shall inform the Ministry of the decision of cancellation of the license of the warehouse carrying on imports or exports once it is issued.

Article (72)

Maintaining General Record or Information System

The Pharmacist in Charge of the Medical Warehouse shall maintain a general record or information system, in which the type and quantity of Medical Products and chemicals stored in the warehouse, date of importation, dispensed volume and the recipient of such dispense. The Pharmacist must maintain a record for Controlled Products and Substances.

The owner and the Pharmacist in Charge of the Medical Warehouse shall be jointly liable for such records and the accuracy of information contained therein.

Article (73)

Placing Pricing Label

The Medical Warehouse must place a clear label of the price approved by the Ministry on the external cover of the Medical Product prior to sale and delivery of the product.

The Marketing Authorization Holder, Pharmacists in Charge and owners of Pharmaceutical Facilities shall be jointly liable for the pricing label approved by the Ministry on the external product packing.

Article (74)

Delivery or Sale Condition

A Medical Warehouse may not deliver or sell Pharmaceutical Products, Medical Devices or Raw Materials to any person other than the licensed Pharmacist in charge of Pharmaceutical Facility or the facility licensed to circulate such products.

Article (75)

Licensing Import and Export; Consent of Marketing Authorization Holder

A Medical Warehouse may not export or import any Medical Product unless it is licensed to carry on Import and Export activity by the Ministry. A Medical Warehouse may not undergo Import, Storage, Distribution or sale of any Medical Product without the consent of the Marketing Authorization Holder approved by the Ministry.

Chapter Six

Marketing Office Licensing

Article (76)

Licensing Conditions

Without prejudice to the conditions specified in Chapter 3 of this Title, a license to open a Marketing Office requires that the consent of the Ministry be obtained, and the manager of the Marketing Office be a qualified Healthcare Professional for its supervision.

Marketing Office must fulfill the conditions set forth decision of the Minister, without prejudice to any other licenses prescribed by the legislation in force in the State.

Article (77)

Prohibitions on Marketing Office

A Marketing Office may not import or store Medical Products for the purpose of sale and Distribution, but may keep free samples for product identification purposes, provided that each sample is sealed as Free Sample and Not for Sale.

Chapter Seven

Pharmaceutical Consulting Office Licensing

Article (78)

Office Opening Conditions

Without prejudice to the conditions specified in Chapter 3 of this Title, to open a Pharmaceutical Consulting Office, the consent of the Ministry must be obtained, and the manager of the office must be a full-time Pharmacist to directly supervise and manage the office and licensed to work in pharmaceutical consulting. The office and its staff must fulfill the conditions determined by decision of the Minister.

Article (79)

Prohibitions on Consulting Office

A Pharmaceutical Consulting Office may not import, export, distribute or store Medical Products. The Implementing Regulations of this Law shall prescribe the functions of the Pharmaceutical Consulting Office.

Chapter Eight

Pharmaceutical Laboratory and Research Center Licensing

Article (80)

Pharmaceutical Laboratory and Research Center Opening Conditions

Without prejudice to the conditions specified in Chapter 3 of this Title, to obtain a license to open a Pharmaceutical Laboratory or Research Center:

1. License must be issued from the Ministry.
2. Person in charge of the Pharmaceutical Laboratory or Research Center must be a full-time Qualified Person to supervise the Pharmaceutical Laboratory or Research Center and licensed according to the Implementing Regulations of this Law.
3. Pharmaceutical Laboratory or Research Center must be in compliance with the safety conditions and should provide the precautionary procedures to ensure containment of environmental pollutants.
4. Pharmaceutical Laboratory or Research Center must fulfill any other conditions determined by decision of the Minister.

Article (81)

Prohibitions on Pharmaceutical Laboratory or Research Center

Except for chemicals used in medical tests and products prepared for studies and research, a Pharmaceutical Laboratory or Research Center may not import, export or store Medical Products for the purpose of sale, Distribution or introduction.

Article (82)

Good Laboratory Practice

Licensed Pharmaceutical Laboratory or Research Center shall comply with the standards adopted by the Ministry for good laboratory practice.

Article (83)

Research and Tests on Human

A Pharmaceutical Laboratory shall not conduct any research or tests on humans for whatever reasons.

Article (84)

Laboratory Analysis Results

Person in charge of Pharmaceutical Laboratory shall issue accreditation certificates for the laboratory analysis results according to quality standards approved by the Ministry. The person in charge shall maintain test information records according to the regulations and procedures specified by the Ministry.

Chapter Nine

Medical Product Manufacturer Licensing

Article (85)

Medical Product Manufacturer Licensing Conditions

Without prejudice to the conditions specified in Chapter 3 of this Title, the opening a Medical Product Manufacturer requires a license from the Ministry according to the conditions and procedures set forth by decision of the Minister, provided that the owner has the nationality of the State.

Article (86)

Precautionary Closure or Suspension of License of the Manufacturer

1. The Ministry shall on its own and in coordination with the Concerned Authorities, or upon recommendation of the Concerned Authorities, issue a decision of precautionary closure or temporary suspension of license of a Manufacturer in any of the following cases:

a. Transfer of ownership of the Manufacturer to a third party without the consent of the Ministry;

b. If the Manufacturer moves from the location to which a license was issued prior to obtaining The consent of the Ministry.

c. Commission of serious violations, which result in harm to the public health if the Manufacturer continues to be opened, according to the Implementing Regulations of this Law.

d. Absence of Qualified Persons for direct supervision and management according to the common rules in this regard.

2. In any event, the matter must be referred to the disciplinary committee stated in Article 102 hereof, within seven (7) working days from the date of license suspension or closure to consider and decide on the disciplinary liability within a period not exceeding ten (10) working days from the date of referral of the matter to it.

Article (87)

Cancellation of License of the Manufacturer

The Ministry shall on its own and in coordination with the Concerned Authorities, or upon recommendation of the Concerned Authorities, issue a decision to cancel the license of the Manufacturer in any of the following cases:

1. Circulation of Adulterated or unusable Medical Products.

2. Conduct of an activity other than the activity for which license was obtained.

3. If it is proved that the license of the Manufacturer has been obtained based on false documents or incorrect information.

4. If the Manufacturer remains closed for three (3) consecutive months without reasonable justification.

5. Non-commencement of work in the Manufacturer within six (6) months from the date of the license issuance without reasonable justification.

Article (88)

Quality Management Standards and Good Manufacturing Controls

Medical Product Manufacturer must comply with the set quality management standards and good Manufacturing controls approved by the Ministry.

Article (89)

Re-Manufacturing using New Technical Specifications

A licensed Medical Product may not be remanufactured using new technical specifications, unless after the Manufacturer obtains the consent of the Ministry to the Manufacturing of the product under these specifications.

Chapter Ten

Controlled and Semi-controlled Substances and Products

Article (90)

Prohibitions and Instructions of Controlled Substances and Products

Subject to the provisions of any other law:

1. Compounding of any Medical Product not contained within the Medical Prescription, Import or re-export of, or compounding any Controlled Substances and Products contrary to the Medical Prescription may not be conducted without the consent of the Ministry.
2. Active Constituents used to manufacture any product referred to in paragraph (1) above may be used only in the Manufacturing of Medical Products authorized to be manufactured.
3. The Minister shall issue the necessary instructions that ensure protection from Controlled Substances and Products' risks and prevent their misuse or exposure to the effects thereof.

Article (91)

Storage and Circulation of Controlled Substances and Products

Controls of Storage and circulation of Controlled Substances and Products shall be specified by decision of the Minister.

Article (92)

Possession of Controlled Substances and Products

Subject to Article 93 of this Law, Controlled Substances and Products may not be possessed unless with permission issued by the Ministry or the

Concerned Authority, according to its competence, and exclusively for the following categories:

1. The Pharmacist in Charge of Medical Warehouse, through Import or purchase from another Medical Warehouse regulated by the Ministry.
2. The Pharmacist in Charge of the Pharmacy, who purchases from a licensed Medical Warehouse regulated by the Ministry and/or the Concerned Authority.
3. Licensed physician who uses them for the purposes of his profession. The Implementing Regulations of this Law shall set out the quantities of Controlled Products permitted to be possessed by the physician.
4. Drug Factories, provided that possession of Controlled Substances and Products and Raw Materials of their Active Constituents by Import or purchase is regulated by the Ministry according to this Law and its Implementing Regulations.
5. Scientific institute and research centres, provided that they are regulated by the Ministry or the Concerned Authority, within its competence.

In any event, possession by these categories of Controlled Substances and Products shall be restricted to places where they practice their profession.

Article (93)

Cases of Dispensing Controlled Substances and Products

Licensed Pharmacist in Charge of Pharmacy management may not dispense the Controlled Substances and Products, except in the following cases:

1. For patients according to a Medical Prescription issued by a licensed physician.
2. For Owners of sick animals according to a Medical Prescription issued by licensed veterinarian.
3. For Physicians pursuant to signed applications, including an acknowledgment that the requested quantities of Controlled or Hazardous Products are for use in their clinics according to the conditions set forth by decision of the Minister.

Article (94)

Circulation of Controlled Substances and Products

Circulation of Controlled Substances and Products among licensed Pharmaceutical Facilities and healthcare facilities requires the consent of the Ministry or the Concerned Authority, within the limits of its competence, according to this Law.

Article (95)

Procedures for Import of Controlled Substances and Products

Neither the Medical Warehouse nor the Medical Product Manufacturer shall be entitled to import Controlled Substances and Products or Raw Materials of their Active Constituents, unless after obtaining the Ministry's consent, by virtue of an application signed by the licensed Pharmacist in Charge of the Medical Warehouse, or the manager of the Manufacturer, including all details related to the Controlled Substances and Products to be imported, as well as the quantities, types, mode of shipment and clearance centre approved in the State.

The Implementing Regulations of this Law shall determine the customs clearance controls for these substances.

Article (96)

Periodic Inventory of Controlled Substances and Products

The person responsible for the custody of the Controlled Substances and Products in any of the categories specified in Article 92 of this Law, shall carry out a periodic inventory of this custody, and notify the Ministry or the Concerned Authority, as the case may be, of the result thereof. If any shortage is detected, the Ministry or the Concerned Authority, as the case may be, must be notified within a period not exceeding two (2) working days.

Article (97)

Hazardous or Toxic Substances and Products

Without prejudice to the provisions of international conventions to which the State is a party, Hazardous and Toxic Substances and Products may not be circulated except in accordance with the conditions issued by decision of the Minister.

Lists of Hazardous and Toxic Substances and Products shall be determined by decision of the Minister in coordination with the Concerned Authorities in the State.

Article (98)

Entity's Cessation of Activity

If an entity having a permit for possession of Controlled Substances and Products ceases business or its custody official abandons such custody for whatsoever reason, such entity shall conduct inventory and initiate the handover of these Substances and Products according to the conditions and procedures prescribed by the Implementing Regulations of this Law.

Article (99)

Semi-Controlled Substances and Products

List of Semi-Controlled Substances and Products and terms and conditions of their circulation shall be determined by decision of the Minister in coordination with the Concerned Authorities in the State.

Chapter Eleven

Circulation of Chemical Precursors

Article (100)

Lists of Chemical Precursors

1. Without prejudice to the provisions of the international conventions to which the State is a party, and to any other laws, two lists of Chemical Precursors used in the Manufacturing of Medical Products and Medicinal Products shall be annexed hereto.

2. the lists of Chemical Precursors annexed hereto may be modified by addition or deletion and other lists may be added thereto and modified by addition or deletion by virtue of a cabinet's resolution, based on a recommendation of a committee to be formed by the Minister and shall comprise among its members: representatives of the Ministry, Ministry of Interior, the Concerned Authority and any other competent authority.

Article (101)

Prohibitions on Chemical Precursors

Chemical Precursors may not be supplied, imported, exported, manufactured, derived, separated, produced, possessed, distributed, used or traded without the consent of the Ministry, according to the conditions and procedures determined by decision of the Minister, stating the method to maintain records and documents related to such substances and Chemical Precursors.

Customs clearance may not be made with respect to imported substances and Chemical Precursors, unless the Import permit is enclosed with the clearance transaction. The competent customs department must recover the Import permit after the end of the clearance transaction, and return it to the Ministry after having added a mention thereto stating that the imported Chemical Precursors have arrived and were handed to their holder.

Title Four

Administrative and Disciplinary Accountability; Criminal Penalties

Chapter One

Administrative and Disciplinary Accountability

Article (102)

Disciplinary Sanctions

1. Without prejudice to sanctions provided for herein or in any other laws, the licensing entity of Pharmaceutical Facility and its staff may inflict the following disciplinary sanctions:

    a. For violations committed by Pharmaceutical Facilities of the provisions of this Law or its Implementing Regulations or decisions issued in its implementation:

        1. Written notice.

        2. Written warning.

        3. A fine of no less than AED 1000 (Dirhams One Thousand) and not more than AED 1,000,000 (Dirhams One Million).

4. Temporary suspension of the license for a period not exceeding six (6) months.

5. Cancellation of license.

b. For violations committed by Pharmacy Profession Practitioners of the provisions of this Law or its Implementing Regulations or decisions issued in its implementation:

1. Written notice.

2. Written warning.

3. A fine of no less than AED 1000 (Dirhams One Thousand) and not more than AED 500,000 (Dirhams Five Hundred Thousand).

4. Temporary suspension of the license for a period not exceeding six (6) months.

5. Cancellation of license.

2. Violations mentioned in paragraph (1) above shall be considered by the disciplinary committee to be formed at the Ministry or the Concerned Authority.

Article (103)

Disciplinary Record

Every licensing entity shall maintain a record in which the sanctions imposed on licensees shall be noted. The disciplinary committees in the State shall exchange the information on sanctions inflicted on Pharmaceutical Facilities and Pharmacy Profession Practitioners according to the mandates of such committees.

Article (104)

Appeal against Sanctions

1. A person against whom a disciplinary decision is issued, pursuant to Article 102 hereof, may file an appeal against such decision to the appeal committee formed at the Health Authority within fifteen (15) days from the date of his notification of the decision.

2. The appeal shall be determined within thirty (30) days from the date of its submission by reasoned decision. If no reply regarding the appeal is received within this period, the appeal shall be deemed rejected.

3. Decision regarding the appeal shall be deemed final.

4. In any case, the sanction of suspension from work, cancellation of the license, or closure of the Pharmaceutical Facility, in other than precautionary closure events prescribed herein, may not be implemented prior to the expiry of the time set for the appeal or the time set for the determination thereof, as the case may be.

Article (105)

Non-Prejudice to Criminal or Civil Liability

Disciplinary accountability pursuant to the provisions of this Law shall not prejudice the criminal and civil liability, where applicable.

Article (106)

Exchange of Disciplinary Sanction's Notifications

The Ministry and the Concerned Authority shall notify each other with the issued disciplinary sanction, except for warning, notice and administrative penalties.

Chapter Two

Criminal Penalties

Article (107)

1. Shall be sentenced to detention for a period of no less than six (6) months and not more than two (2) years and/or to a fine of no less than AED 50,000 (Dirhams Fifty Thousand) and not more than AED 200,000 (Dirhams Two Hundred Thousand), whoever:

   a. submits false or untrue documents, makes untrue statements, or resorts to illegal methods to obtain a license in contradiction to the provisions of this Law and its Implementing Regulations and decisions issued in its implementation.

   b. violates any of the provisions of Articles (44), (56), (57) hereof.

   c. practices the Pharmacy Profession without obtaining a license.

2. Shall be sentenced to detention for a period of no less than one (1) year

and not more than five (5) years and/or to a fine of no less than AED 100,000 (Dirhams One Hundred Thousand) and not more than AED 500,000 (Dirhams Five Hundred Thousand), whoever:

a. circulates Hazardous or Toxic Medical Products or Substances contrary to the provisions hereof.

b. violates the conditions and controls of circulation of Semi-Controlled Medical Products or Substances prescribed by Article (99) hereof.

c. violates any provisions of Articles (3), (13), (14), (22), (26), (41), (90), (101) hereof.

Article (108)

1. Shall be sentenced to detention for a period of no less than six (6) months and not more than one (1) year, and/or to a fine of no less than AED 50,000 (Dirhams Fifty Thousand) and not more than AED 200,000 (Dirhams Two Hundred Thousand), whoever violates any of the provisions of Articles (7 paragraph 6), (9 paragraph 3 and 5), (19), (30), (33), (35), (36), (39), (46 paragraph 3), (48 paragraph 7), (50), (55), (58), (89), (93) hereof.

2. A criminal lawsuit for breach of provisions of articles (7 paragraph 6), (9 paragraph 3 and 5), (19), (35) and (46 paragraph 3) may be filed only at the written request of the Minister.

   The Minister may waive the request to initiate the criminal lawsuit if he finds justifiable reasons for this.

Article (109)

Shall be sentenced to a fine of not more than AED 100,000 (Dirhams One Hundred Thousand), whoever:

1. violates the pricing approved by the Ministry for Medical Products. Should the breach be repeated, the penalty shall be multiplied.

2. employs Pharmacist or Pharmacy Technician without a license, or while knowing that the license was obtained based on fraud or misrepresentation.

Article (110)

Shall be sentenced to a temporary imprisonment and to a fine of no less than AED 200,000 (Dirhams Two Hundred Thousand) and not more than AED

1,000,000 (Dirhams One Million), whoever:

1. falsifies, imitates, sells to third parties, illicitly imports or smuggles into the State a Medical Product, Raw Materials, chemicals, health foods or therapeutic cosmetics.
2. violates the provisions of paragraph (1), of Article (42) hereof.
3. violates the provisions of paragraphs (5) or (6), of Article (48) hereof.

Article (111)

Complementary Penalties

1. In any case, the court may, in addition to the prescribed penalties, order the closure of the facility for a period not exceeding three (3) months or the permanent closure and withdrawal of license.
2. In the event of conviction, confiscation of substances subject of breach must be ordered.
3. Offender shall bear the costs of disposal of harmful substances.

Article (112)

Non-Prejudice to Severer Penalty

Penalties provided for herein shall be without prejudice to any severer penalties prescribed by any other law.

Title Five

Final Provisions

Article (113)

Appeal against Decisions issued In Implementation of the Provisions of this Law

Subject to the provisions of Article 104 hereof, a person against whom one of the decisions issued in implementation of the provisions hereof, may file an appeal against such decision to the appeal committee formed by decision of the Minister or the chairman of the Concerned Authority, within fifteen (15) days from the date of his notification of the decision. The committee shall

decide on the appeal within thirty (30) days from the date of its submission with a reasoned decision. If no reply to the appeal is issued during this time, the appeal shall be deemed rejected. The decision on the appeal shall be deemed final.

Article (114)

Practice of the Pharmacy Profession among Government Bodies

Federal and local government entities may practice the Pharmacy Profession according to the regulations set forth in this Law and its Implementing Regulations. Other entities shall apply for obtainment of license to practice the Pharmacy Profession according to the regulations set forth in this Law and its Implementing Regulations.

Article (115)

Judicial Officers

A decision shall be issued by the Minister of Justice, in agreement with the Minister or chairman of the Concerned Authority, designating persons who shall have the status of judicial officers in establishing any violations of the provisions of this Law and its Implementing Regulations that fall within their respective competence.

Article (116)

Obtaining the Necessary Licenses

Obtaining the licenses provided for herein shall not exempt from obtaining the other necessary licenses required by the laws, regulations or orders in force in the State.

Article (117)

Exceptions

1. Those covered by the provisions of this Law in the free zones shall be exempted from holding the citizenship of the State.
2. A Pharmaceutical Facility owned by Non-nationals may be exempted from the requirement of holding the State citizenship by a cabinet's resolution.

Article (118)

Adjustment of Positions

Those covered by this Law at the time of its issuance shall adjust their positions in conformity with the provisions of the Law within a period not exceeding one (1) year from the date of its entry into force. This period may be extended by decision of the Minister for a period not exceeding in total five (5) years.

Article (119)

Implementing Regulations of this Law

1. The Implementing Regulations of this Law shall in particular set out the terms and conditions of the following:
    a. Provision of Medicinal Products and Medical Devices necessary for the needs of the community on a permanent basis.
    b. Circulation of donated Medical Products.
    c. Temporary licensing of visiting Pharmacists.
    d. Keeping Medical Products during maintenance of the Pharmacy.
2. The Implementing Regulations of this Law shall be issued by resolution of the Cabinet and based on the Minister's proposal within six (6) months from the date of its publication in the Official Gazette.
3. The Minister shall issue decisions necessary for the implementation of the provisions of this Law.

Article (120)

Delegation

The Cabinet may issue a decision to delegate some of the mandates of the Ministry stated herein to a Concerned Authority.

Article (121)

Repeals

The Federal Law no. (4) of 1983 and the Federal Law No. (20) of 1995 shall be abrogated. Regulations and decisions issued in implementation of the above

two Laws shall remain in force, to the extent they contradict this Law, until its implementing regulations and decisions are issued.

Article (122)

Repeal of Contrary or Conflicting Provisions

Any provision contrary to, or in conflict with the provisions of this Law shall be repealed.

Article (123)

Publication; Entry into Force

This Law shall be published in the Official Gazette, and shall come into force thirty (30) days after the date of its publication.

Khalifa bin Zayed Al Nahyan

President of the United Arab Emirates

Promulgated by Us at the Presidential Palace in Abu Dhabi

On: 22/Rabi Al Thani/1441 H

19/December/2019 G

Cabinet Resolution No. (90) of 2021 concerning the Implementing Regulations of Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Facilities*

The Cabinet:

- Having regard to the Constitution;
- Federal Law No. (1) of 1972 on the Mandates of Ministries and Powers of Ministers, as amended;
- Federal Law No. (14) of 1995 on Combating Narcotic Drugs and Psychotropic Substances; as amended;
- Federal Law No. (2) of 2019 on the Use of Information and Communication Technology (ICT) in Health Fields;
- Federal Law No. (8) of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Facilities;
- Federal Decree No. (9) of 1988 on the Approval of Accession to the Single Convention on Narcotic Drugs of 1961, as amended by 1972 Protocol, and Convention on Psychotropic Substances of 1971;
- Federal Decree No. (55) of 1990 on the Approval of Accession to the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Cabinet Resolution No. (39) of 2015 on Strategic Medical Stock;
- Cabinet Resolution No. (20) of 2017 Adopting the Unified Standards for Licensing Practitioners of Health Professions in the State, as amended;
- Cabinet Resolution No. (32) of 2020 concerning the Implementing Regulations of Federal Law No. (2) of 2019 on the Use of Information and Communication Technology (ICT) in Health Fields; and
- Based on the proposal of the Minister of Health and Prevention, and the approval of the Cabinet,

• **Resolves:**

* This translation from Arabic to English is provided for your convenience only. In case of any discrepancy, the Arabic version prevails

Article (1)

Definitions

Definitions set forth in the referenced Federal Law No. (8) of 2019 shall apply to this Resolution. Otherwise, the following words and expressions shall have the meanings ascribed to them, unless the context otherwise requires:

Health Authority	:	Any federal or local government entity in charge of health affairs in the State.
Product Suspension	:	Ceasing the circulation or use of the Product.
Healthcare Profession	:	A healthcare profession permitted to be practiced in the State, and determined by the referenced Cabinet Resolution No. (20) of 2017.
Narcotic Drug	:	A Medical Product containing any of the Active Constituents listed in Schedules 1, 2, 3 or 4 of the referenced Federal Law No. (14) of 1995, or listed in International Narcotics Control Board (INCB) Schedules 1, 2, 3 or 4 of the Convention on Narcotic Drugs of 1961, as amended by 1972 Protocol, and any amendments thereto.
Psychotropic Drug	:	A Medical Product containing any of the substances listed in Schedules 5, 6, 7 or 8 of the referenced Federal Law No. (14) of 1995, or listed in International Narcotics Control Board (INCB) Schedules 1, 2, 3 or 4 of the Convention on Psychotropic Substances of 1971, and its amendments.
Controlled Drug	:	Narcotic Drug and Psychotropic Drug.
Visiting Pharmacist	:	A Pharmacist licensed in a Pharmaceutical Facility or health facility in the State, and authorized to partially work at another Pharmaceutical Facility or health facility, or a Pharmacist coming from outside the State to practice the Pharmacy Profession in the State for a definite period, in accordance with the conditions and rules specified herein.

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

Article (2)

Medical Product Prices

1. No discount may be granted on prices specified by the Ministry, and special prices may be set within the scope of the application of a system for dispensing medicines from the Health Authority, as the case may be, or through government health insurance schemes.

2. Special prices may be set within the scope of the application of a system for the purchase of medicines by Health Authorities. In this case, drugs shall be dispensed to patients according to the value of the purchase price applied in respect of the health facility.

3. Without prejudice to paragraph (1) above, Pharmacies may be granted a quantity of Medical Products free of charge, without the granted quantity exceeding the percentage determined by decision of the Minister of the total quantity sold to the Pharmacy.

Article (3)

Medical Product Suspension

The Concerned Authority may suspend the Medical Product in government and Private health facilities within the jurisdiction of each of them, provided that it informs the Ministry within twenty-four (24) hours from the date of the suspension decision, in the form prepared for this purpose by it. The Ministry shall take the necessary decision in this regard accordingly.

Article (4)

Rules for Importation of Medical Product

Importation, acquisition or possession of the Medical Product with any person upon entering the State for personal use shall be subject to the conditions and rules set forth in Annex (1) hereto.

Article (5)

Obligations of Non-Pharmaceutical Facilities

The non-Pharmaceutical Facilities specified by decision of the Minister and which are permitted to sell, display, store and circulate non-prescribed Medical Products shall comply with the following:

1. Purchase the Medical Product from the warehouse licensed by the Ministry.
2. Comply with the types of non-prescribed Medical Products, according to the classification approved by the Ministry.
3. The facility obtains approval from the facility's licensing authority.
4. Approved storage controls for each product.
5. The price specified by the Ministry, if any.

Article (6)

Conditions for the Practice of Pharmacy Profession

No person may practice any activity in the Pharmacy Profession field or works as Pharmacy Technician, unless he is licensed to do so by the Health Authority as the case may be, in accordance with the conditions and controls stated in the referenced Cabinet Resolution No. (20) of 2017, as amended.

Article (7)

Profession Practitioner Registries

1. Whoever is registered in the national registry established in the Ministry and the special registry established in the Relevant Authority must be a Practitioner of Pharmacy Profession and Pharmacy Technician Profession, and licensed to practice the profession in the State.
2. Both the national registry and private registry must include a section for Pharmacists, and another section for Pharmacy Technicians.
3. The national registry and special registry must contain the following data:
    a. Personal identification details of the profession practitioner.
    b. Details of the license granted to the profession practitioner.
    c. The current status of the profession practitioner, i.e. (licensed and active, expired, etc.)

d. Any other data specified by the Health Authority, as applicable.

4. Both the national registry and special registry must be numbered, and may be in paper or electronic form.

5. It shall not be permissible to strike off, alter or erase in the national registry or in the special registry, except in accordance with the procedures set by the Health Authority, as the case may be.

6. The national registry and special registry shall be updated on periodic basis and at least once a year.

7. Information contained in the national registry and the special registry shall be subject to the information protection regulation determined 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 registry according to the following categories:

   a. Register of Pharmacists and Pharmacy Technicians working at Drug Factories.

   b. Register of Pharmacists and Pharmacy Technicians working at Pharmaceutical Laboratories.

   c. Register of Pharmacists and Pharmacy Technicians working at Pharmaceutical Consulting Offices.

   d. Register of Pharmacists and Pharmacy Technicians working at Marketing Offices.

   e. Register of Pharmacists and Pharmacy Technicians working at government and private facilities.

   f. Register of Clinical Pharmacists working at government and private hospitals.

   g. Register of Pharmacists and Pharmacy Technicians working at government and private health centres.

   h. Register of Pharmacists and Pharmacy Technicians working at Pharmacies and Medical Warehouses.

   i. Register of Pharmacists and Pharmacy Technicians working at Health Authorities.

Article (8)

Profession Practitioner Licensing and Renewal of License

The Health Authority, as the case may be, shall consider and decide on applications submitted for licensing or renewing licenses of persons to practice the Pharmacy Profession and the Pharmacy Technician Profession, in accordance with the controls and conditions set forth in the referenced Cabinet Resolution No. (20) of 2017, as amended.

Article (9)

Visiting Pharmacist Licensing Conditions

To issue a temporary license to practice the Profession by a Visiting Pharmacist, the following conditions and controls shall be met:

I. Conditions and Controls for Visiting Pharmacist from inside the State:

1. He/she must be licensed to practice the Pharmacy Profession in his/her original employer in the State under a valid license.
2. A copy of professional good conduct certificate issued by the Health Authority must be submitted, to prove his/her good behavior and that no judgment or disciplinary order has been issued against him/her which prevents him/her from the practice of Pharmacy Profession or restricts his/her practice thereof.
3. The approval of his/her employer.
4. Any other conditions set by the Health Authority, as the case may, without prejudice to the provisions of the Law and this Resolution.

Second: Conditions and Controls for Visiting Pharmacist from outside the State:

1. Submission of a certified copy of professional good conduct issued from the country of work, proving his/her good conduct and that no judgment or disciplinary order has been issued against him/her which prevents him/her from the practice of Pharmacy Profession or restricts his/her practice thereof.
2. Submission of proof of practice of Pharmacy Profession in the country of work.

3. Submission of copy of academic qualifications and degrees.

4. Any other conditions set by the Health Authority, as the case may, without prejudice to the provisions of the Law and this Resolution.

The Health Authority may exempt the Visiting Pharmacist from outside the State from any conditions and controls set out above, as it deems proper.

Article (10)

Observance of the Scope of Work and Area of Activity

The Pharmacist licensed to practice the Pharmacy Profession must observe the scope of work and area of activity as specified in the license granted to him/her to practice the Profession in the State, and shall perform his/her job duties in accurate and diligent manner as required by the scientific and technical recognized rules and responsibilities and principles stated in the Code of Conduct and Professional Ethics for the approved Healthcare Professionals.

Article (11)

Provision of First Aid

A Pharmacist may provide first aid, provided that he/she holds a certificate of training in first aid, issued by an accredited entity in this field.

Article (12)

Medical Prescription Conditions

In addition to the requirements set out in article 49 of the Law, the Medical Prescription shall:

1. be written in an indelible or unalterable material, if the prescription is in writing.
2. include the electronic signature and the electronic code, if it is electronic.
3. include the route of administration of the prescribed drug or preparation.
4. have been issued not later than sixty (60) days, unless it contains Controlled Substances or Products.
5. indicate the gender of the patient.

6. mention the duration of the treatment, with a limitation on the duration of the repetition, if necessary, even if it exceeds the period specified in paragraph (4) above. The drug may not be dispensed under repetition if a period of thirty (30) days elapses from the date specified by the physician for the entitlement to repeat the dispensing.

7. Include the license number of the Healthcare Profession Practitioner who discharged the Prescription, followed by the Health Facility seal, provided that the seal contains the name of the Emirate where the facility is situated.

Article (13)

Validity of Prescription of Controlled Substances and Products

Controlled Substances and Products may not be dispensed if a period of more than three (3) days has passed from the issuance of the Medical Prescription, which period can be extended for a similar period with the approval of the Health Authority, as the case may be.

Article (14)

Conditions for Replacement of a Medical Product

1. A Pharmacist may replace a Pharmaceutical Product with a Generic Pharmaceutical Product after providing advice to the patient in this regard, thus giving the patient the opportunity to choose the Pharmaceutical Product he/she prefers. The Pharmacist must indicate to the patient that the same composition of the prescribed or previously dispensed Pharmaceutical Product is contained in the Generic Pharmaceutical Product.

2. When replacing a Pharmaceutical Product with a Generic Pharmaceutical Product, the Pharmacist shall take into account the following:

    a. The agreement of the patient to switch product with another generic product.

    b. The prescribed Pharmaceutical Product must not be Narrow therapeutic index drug that requires careful monitoring and control of its concentration in blood.

    c. The prescribed Pharmaceutical Product must not be Narcotic Drug, Psychotropic Drug or other drug designated by the Ministry.

d. The Pharmaceutical Product must not be among therapeutic indication drugs.

e. The Pharmaceutical Product must not be a biological & biosimilar drug unless if the possibility of substitution is confirmed by the Ministry.

Article (15)

Conditions for 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 record the Medical Prescriptions that have been dispensed from these substances in the records determined by decision of the Minister, in accordance with the following controls and requirements:

   a. All Controlled and Semi-Controlled Substances and Products are recorded in a special record for each of these products, provided that the dispensing of each item is recorded in separate pages, taking into account the allocation of a sufficient number of pages for each item for paper records, and avoiding distributing the product on separate pages, and, when necessary, the Pharmacist must write the page number and the record as a source for the balance shown on the page.

   b. The generic and trade name, concentration and form of the product, which must be indicated at the top of each page for records.

   c. Data must be inserted in chronological order, provided that the date of each transaction is clear, and the entry is done on the same day of the transaction with a signature thereon.

   d. The ink used to insert the data on the pages of the paper record must be indelible.

   e. No modification, obliteration or cancellation of any of the data in the record is permitted. If any correction is required, a comment or note must be inserted in the “notes” field of the record and then the correct data is inserted in the next line available below.

   f. Custody official shall keep the record in a safe place within the facility, provided that it is available for inspection at any time. A separate record shall be kept for each facility.

2. Controls and requirements stipulated in paragraph (1) above for electronic records must be observed, in accordance with the requirements and characteristics of the electronic record type, provided that it includes in particular the back-up and tracking feature for any change or modification to the data, in addition to the conditions set forth in the referenced Federal Law No. (2) of 2019 and its Implementing Regulations.

3. The period for keeping the records referred to in this Article shall be determined by decision of the Minister.

Article (16)

Period of Validity of License of Pharmaceutical Facility

A license to open Pharmaceutical Facilities shall be valid for a minimum period of one (1) year and shall be renewable for a similar period based on an application submitted in this regard.

Article (17)

Transfer of Ownership of the Pharmaceutical Facility

Ownership of the Pharmaceutical Facility may be assigned to a third party with the consent of the Health Authority, as the case may be, as follows:

1. The conditions related to the transfer of ownership are verified.

2. Submission of duly approved assignment documents.

3. Evidence is provided of the settlement of any financial claims against the Pharmaceutical Facility with the licensing authority or insurance companies.

Article (18)

Serious Violations requiring the Closure of the Pharmacy

The following violations shall be deemed serious violations, and the Health Authority, as the case may be, shall issue the decision to close the Pharmacy temporarily for a period not exceeding one (1) month, if any of the following is committed:

1. Withdrawal and Suspension decisions issued by the Health Authority, as the case may be, for some Medical Products are not observed.

2. Circulation of Medical Products purchased from unlicensed entities.
3. The absence of the Pharmacist in Charge of the Pharmacy, and the practice of Pharmacy Profession by unlicensed persons.
4. Dispensing Controlled and Semi-controlled Drugs illegally.
5. Sale of expired, Adulterated or smuggled Medical Products, or for which the Marketing Authorization has not been obtained from the Ministry, if it is required, or if their expiry date or any of the data shown on the package has been tampered with.
6. Falsification of documents relating to Medical Products.
7. Failure to observe the health or technical conditions specified by the Health Authority, as the case may be, and repetition of violations.
8. Practice of activity before obtaining the final license.

Article (19)

Serious Violations requiring the Cancellation of the Pharmacy License

The following violations shall be deemed serious violations, and the Health Authority, as the case may be, shall issue the decision to cancel the Pharmacy license, if any of the following is committed:

1. Manipulation in the records of Controlled and Semi-Controlled Substances and Products and their circulation in violation of the legislation in force in the State.
2. Repeated tampering with the expiry date of Medical Products, with the precedent temporary closure of the facility because of that.
3. Continuing to practice the activity after the expiry of the period specified for renewing the license in accordance with the legislation in force in this regard.
4. Transfer of ownership of the Pharmacy for which the license is issued to another person without obtaining the consent of the Health Authority, as the case may be.
5. Failure to implement the directives of the Health Authority, as the case may be, to rectify its violations related to health and technical conditions.

Article (20)

Absence of the Pharmacist in Charge

If the Pharmacist in Charge of the Pharmacy is absent, the owner must entrust the Pharmacy and its supervision to another Pharmacist licensed to practice the Pharmacy Profession, such as another Pharmacist working in the same Pharmacy or in any other licensed Pharmacy, and within the limits of the same emirate. The owner may also entrust the Pharmacy to a Visiting Pharmacist, provided that the Pharmacy has a Pharmacist Technician. In any case, the period of absence should not exceed three (3) months, whether continuous or intermittent, during one (1) year.

Article (21)

Pharmacy Chain

The opening of more than one Pharmacy may be authorized under Pharmacy Chain system, provided that the following is complied with:

1. The number of Pharmacies in a Chain shall be within the limits permitted by the Health Authority, as the case may be.
2. The Pharmacies in the Chain belong to one natural or legal person.
3. All Pharmacies belonging to the Chain obtain a separate license for the facility and meet the necessary health and technical requirements and controls.
4. Where one or more Pharmacies owned by another person or persons are included in a Pharmacy Chain, the necessary procedures must be followed by the competent authorities of the State to transfer their ownership to the Chain owner before authorization for their inclusion is given.

Article (22)

Area of Activity of the Pharmacy

1. Without prejudice to Article 10 hereof, the Pharmacy may not be considered as medical clinic or for any other purpose, and its activity shall be restricted to:
    a. Storage, display, dispensing and sale of Medical Products, including infant and young child food and milk.

b. Formulation or preparation of Medical Products in accordance with the applicable legislation in this regard.

2. In addition to the activities listed in paragraph (1) above, the Pharmacy may perform the following subsidiary activities:

   a. Storage, display, dispensing, and selling of Medical Devices for personal use.

   b. The carrying out of weight, height, blood pressure, heat, or sugar tests, by acupuncture or any other tests, as determined by the Health Authority, as the case may be, for the purpose of counseling and guidance to the patient, without any diagnosis of the disease.

   c. Provision of awareness-raising and pharmaceutical education services to individuals inquiring on the use of Medical Products.

   d. Storage, supply, dispensing and sale of food supplements.

   e. Storage, supply, dispensing and sale of household insecticides.

   f. Selling cosmetics, personal decorations and perfumes.

   g. Any other activities determined by decision of the Minister.

Article (23)

Conditions for Licensing Some Pharmacies

The Health Authority, as the case may be, may license the opening of private Pharmacies affiliated with a non-health government entity, public establishments, public interest institutions or associations or hospitals and private medical centres, provided that the following is met:

1. A license application is submitted to the Health Authority, as the case may be.

2. The Pharmacy is managed by a licensed Pharmacist.

3. The Pharmacy must meet the technical and health conditions necessary for its operation, with the possibility of excluding any of these conditions as determined by the Health Authority, as the case may be.

4. The Pharmacy does not provide its services to the general public, and its area of activity is limited to the employees of the entity to which the Pharmacy belongs or the beneficiaries of the services of this entity.

The entity with which the Pharmacy is affiliated shall set the functioning rules of the Pharmacy, provided that they do not conflict with the provisions of the law and this Resolution.

Article (24)

Technical and Health Conditions of Medical Warehouse

The Medical Warehouse shall meet the technical and health conditions stated in Annex 2 hereto.

Article (25)

Serious violations requiring the Closure of the Medical Warehouse

The following violations shall be considered serious violations, and the licensing authority may, within the scope of its competence, issue a decision to temporarily close the Medical Warehouse or suspend its license, if any of the following is committed:

1. Practice of the activity before the license is obtained.
2. Trading in Adulterated or smuggled Products or products with a clear Manufacturing defect.
3. Non-compliance with the decisions issued for Withdrawal of some Medical Products or Suspension of their circulation.
4. Circulation of Medical Products purchased from unlicensed parties without the consent of the Ministry.
5. Absence of the Pharmacist in Charge of the warehouse and the practice of the Pharmacy Profession by unlicensed persons.
6. Non-compliance with the rules and controls related to the Circulation of Controlled and Semi-Controlled Substances and Products or Chemical Precursors or related to their records.
7. Circulation of Medical Products from companies not registered with the competent registration authority in the State without obtaining permission to do so from the Ministry.
8. Violation of the technical and health conditions for opening the Medical Warehouse.
9. Failure to implement the recommendations related to the violations committed by the warehouse.

10. Manipulation of documents or data inserted on the packaging of the Medical Product, such as the expiry date or otherwise.

Article (26)

Serious Violations requiring the Cancellation of the Medical Warehouse License

The following violations shall be considered serious violations, and the licensing authority may, within the scope of its competence, issue a decision to cancel the license of the Medical Warehouse, if any of the following is committed:

1. Manipulation in the records of Controlled and Semi-Controlled Substances and Products and Chemical Precursors.
2. Repeated tampering with the expiry date of Medical Products, with the precedent temporary closure of the warehouse because of that.
3. Continuing to practice the activity after the expiry of the period specified for renewal of the license in accordance with the legislation in force in this regard.
4. Repetition of any of the violations stated in subparagraphs b, c and d, paragraph 1, Article 70 of the Law for more than twice in a year.

Article (27)

Functions of Pharmaceutical Consulting Offices

The Pharmaceutical Consulting Offices shall:

1. provide strategic guidance to Pharmaceutical Facilities.
2. provide the good organizational advice in pharmaceutical field.
3. provide training and career development in Pharmaceutical field.
4. provide consultancy on the development of Medical Products.
5. provide consultancy on studies, research and management of pharmaceutical projects.
6. provide consultancy on pharmacovigilance and the safety of Pharmaceutical Products.

7. provide consultancy on quality of Pharmaceutical Facility and Pharmaceutical Product services.
8. provide consultancy on the fulfillment of the licensing conditions and applications for licenses necessary for Pharmaceutical Facilities.
9. provide advice on good Manufacturing practices for Manufacturers to help them obtain the required accreditation certificates.
10. provide consultancy on:
    a. Marketing and circulation of the Pharmaceutical Product.
    b. Studies related to the Medical Product prices and costs.
    c. Fulfillment of conditions and procedures for Marketing Authorization of the Medical Product.
    d. Any studies and advices for the good functioning of the Pharmaceutical Facilities.

Article (28)

Conditions of the Person in Charge of the Pharmaceutical Laboratory or Research Centre

Person in charge of the Pharmaceutical Laboratory or research centre shall be a Qualified Person who is dedicated for technical supervision of the Laboratory and licensed as per the following conditions:

1. He/she shall have an academic qualification from a university or centre accredited in the State in any of the following disciplines: Pharmacy, chemistry, microbiology or other related disciplines.
2. He/she must have a minimum experience of five (5) years in the field of specialty.

Article (29)

Serious Violations requiring the Closure of the Manufacturer

The following violations shall be considered serious violations. The Ministry, acting on its own initiative and in coordination with the Concerned Authorities or upon the recommendation of the Concerned Authorities, may issue a decision for the precautionary closure or temporary suspension of the license of the Manufacturer, in any of the following cases:

1. If it is proved that the Manufacturer does not apply the principles of good Manufacturing practice, which adversely affects the quality and safety of the Medical Product and public health, despite its warning.
2. Manufacturer's products are proved to be unsafe and unsecure.
3. Repeated failure of the product to comply with established quality standards while performing Laboratory Tests in a State-approved Laboratory despite being alerted.
4. Concealment of any information related to the quality of its products and failure to report it to the Ministry as soon as they become aware thereof.
5. Failure to comply with rules and controls relating to the Circulation of Controlled and Semi-Controlled Substances and Products or Chemical Precursors or their records.
6. Failure to observe good waste disposal practices, which poses threat to public health.

Article (30)

Possession of Controlled Substances and Products

The licensed physician (anesthesiologist or surgeon) may acquire Controlled Substances and Products for the purposes of his/her profession, to the following extent:

First: Health facilities without a boarding Pharmacy:

1. For Narcotics: based on the standard quota approved by the Health Authority in accordance with the number of patients treated and the standard dosage, provided that the quantity does not exceed the amount necessary to cover the usage needs for a maximum period of two (2) months.
2. The standard stock of Narcotic Drugs can be repackaged several times within one (1) month from the Medical Warehouse with a ratio between the standard stock and the expected monthly use (once to three times per month), and the standard quota is reviewed and adjusted for each facility as needed, based on two previous quarterly consumption reports of the facility.
3. For Psychotropic Substances: According to the quantity used, based on the number of patients treated with Controlled Drug, the quantity shall not

exceed the amount necessary to cover the usage needs for a maximum period of two (2) months.

4. In any case, the physician shall take into account the laws and decisions in force concerning the preservation of Controlled Substances and Products and shall record them in the approved official record, subject to the provisions of Article 15 of this Resolution.

Second: Health facilities with a boarding Pharmacy:

The physician in such establishments may not acquire Controlled Substances and Products.

Article (31)

Controls of Import of Certain Products

Customs clearance procedures for any Import shipment containing Controlled Substances and Products or Raw Materials used in manufacturing Controlled Substances and Products requires:

1. Existence of an Import authorization and an Import permit issued by the Ministry to private establishments. For government agencies, an Import authorization from the Ministry is sufficient.

2. Provision of a document proving that the imported materials match the shipment's documentation and labels.

3. The Ministry's inspector at border crossings approves the Import of Controlled Substances or Products in the shipment after ensuring that they meet the requirements and conform to the documents pertaining to the shipment.

4. The presence of the Pharmacist in Charge of the entity that submitted the Import request to receive the shipment, in addition to the presence of the Ministry's inspectors.

5. The presence of a representative having an official authorization in the event that the import request is submitted directly by government agencies, with the presence of a representative from the clearance company. If the import request is submitted by licensed Medical Warehouses, the Pharmacist in charge of the Controlled Substances and Products in the warehouse must be present, in addition to the Ministry's inspector.

Article (32)

Expiry of Possession and Custody of Controlled Substances and Products

In the event that the licensed entity ceases to keep in custody the Controlled Substances and Products or the custody official abandons their custody for any reason, the said entity shall make an inventory of them and take the handover procedures as follows:

1. If the entity for which a permit to possess Controlled Substances and Products ceases activity, the licensing authority shall be notified. If the Controlled Substances and Products are Narcotic Drugs, the Ministry shall be notified, along with the licensing authority. Inventory of Controlled Substances and Products shall be made by the custody official for their return to the Medical Warehouse concerned with the Controlled Substances and Products. Possession of Psychotropic Substances may be transferred to another branch of the same facility and the licensing authority shall be notified accordingly.

2. If the custody official abandons custody of Controlled Substances or Products, a clearance must be submitted together with a letter from the facility where he is employed to the licensing authority. If the Substances and Products are Narcotic Drugs, the Ministry shall be notified, together with the licensing authority. The notice must state the date of clearance, which must include the signature of the owner or the manager of the facility and the seal of the facility, together with the minutes of the custody handover to a new custody official licensed for the possession of the Controlled Substances and Products, along with a detailed account of the remaining quantities of those substances and products in the facility.

3. If the custody official abandons the custody of Controlled Substances and Products and there is no alternative officer, the manager of the facility shall keep them in custody and not allow their use, and shall notify the Ministry and the relevant Health Authority within two (2) working days to approve their return to the Medical Warehouses concerned with the Controlled Substances and Products, with the possibility of transferring Psychotropic Substances to a branch of the same facility.

4. The Ministry and the relevant Health Authority, or either of them, shall review the custody of the Controlled Substances and Products to approve their delivery to the new custody official or their return to the Medical Warehouses or local agents. In any case, the Ministry shall be notified thereof.

Article (33)

Provision of Medical Products

1. The Ministry shall, in coordination with the relevant Health Authority, prepare and periodically update the list of products for strategic medical stocks to ensure that the Medical Products needed by the community are provided on a permanent basis.

2. Pharmaceutical Facilities shall provide the products listed in the Strategic Medical Stock list in order to ensure the availability of essential or necessary Medical Products on a permanent basis in Medical Warehouses and in Pharmacies of public and private hospitals in quantities appropriate to the needs of patients. The Health Authority shall monitor the stocks of the products mentioned in the strategic medical stock list according to the appropriate mechanisms.

3. Marketing Authorization Holder or its representative in the State shall permanently provide the Medical Products that have been granted Marketing Authorization in the State, especially the life-saving products, whether innovative or generic, by maintaining a sufficient stock of them in the State's Medical Warehouses and by distributing the necessary quantities to the licensed Pharmacies in all the Emirates of the State according to the request of each Pharmacy.

4. Marketing Authorization Holder or its representative in the State shall provide Medicinal Products and Medical Devices falling within the scope of their work by means of an undertaking attached to each application for the Product Marketing Authorization and upon each request for its renewal.

5. Marketing Authorization Holder or its representative in the State shall take all necessary precautionary measures to ensure the continued availability in the State of the Medical Products referred to in this Article.

6. If a Medical Product could not be imported for a reason beyond the control of the Marketing Authorization Holder or its representative in the State, either of them shall immediately notify the Ministry and take the necessary

measures to manage the remaining stock in their warehouses in the State in the best way to serve the largest number of patients, and shall work to provide the product in the State as soon as the reasons for the impossibility of Import ceases to exist.

7. If the representative of the Marketing Authorization Holder is unable to provide the products referred to in this Article, he shall notify the Ministry thereof. The Ministry may allow any licensed Medical Warehouse or official government agency to import the same product by another licensed Importer, provided that the product is sold to the public at the same price on the market or at a specified price under a mechanism adopted by the Ministry or an alternative is provided.

8. The Ministry may allow the Import of drugs that have obtained Marketing Authorization from any Medical Warehouse to guarantee the drug security for the State.

9. The Ministry reserves the right to cancel the Marketing Authorization of the Medical Products referred to in this article in the event that they are not provided within the State without indicating the necessary justifications, in coordination with the Ministry of the Economy for Medical Products covered by exclusive agencies from the Ministry of the Economy.

Article (34)

Donation of Medical Products

Donation of Medical Products shall be subject to the following conditions and controls:

1. Donation should be for the benefit of charities, government agencies, public establishments or public interest institutions, or directly to people who have a health need to use these products and who have a valid Medical Prescription, but who lack sufficient financial resources to purchase them.

2. The relevant permit must be obtained from the Health Authority, as the case may be.

3. Donation process must meet the conditions and standards necessary to maintain the quality and validity of the Medical Product during all stages of its circulation, from its transfer from the donor until it reaches the recipient.

4. If the donation recipient is not a person to whom the drug is dispensed as an end user, he must have the conditions of preservation and Storage that guarantee the safety of the Medical Product until it is disbursed to the end user.

5. Donation involving Controlled Substances or Products requires the approval of the Ministry.

6. Donated Medical Products shall be usable, and shall have a shelf life of no less than six (6) months.

7. No donations shall be accepted from individuals unless after drugs are assessed by the Competent Department or the Concerned Authority, as the case may be.

8. No drugs that have been opened or used in part may be donated.

9. Medical Products that are accepted from individual donors must have Marketing Authorization in the State. The Batch to be donated must be imported with the official permit of the Ministry, provided that it is stored in the temperatures on the outer packaging and does not fall into the category of Controlled Substances and Products.

10. If the donation is to charities or public interest associations, their Storage conditions must be checked in advance to ensure that the quality and safety of the donated product is maintained.

11. Any other controls determined by decision of the Minister in coordination with the Concerned Authorities.

Article (35)

Conditions and Controls for Pharmacy Maintenance

The following conditions and controls must be met during the maintenance of the Pharmacy in order to preserve the quality and safety of the Medical Products:

1. Medical Products shall not be exposed to any factors that would adversely affect their quality and safety for use; otherwise, the Medical Products in the Pharmacy shall be transferred to another place that meets the requirements for the preservation of their quality and safety, provided that the Health Authority, as the case may be, approves the mode of transport and the place of Storage before the start of transport.

   If the Pharmacy contains Controlled Substances and Products, the Health Authority, as the case may be, shall be notified thereof, and these products shall be permitted to be returned to the concerned Medical Warehouse after the approval of the Ministry is obtained.

2. Upon completion of maintenance works, the Health Authority, as the case may be, shall be notified thereof and the Medical Products may not be returned to the Pharmacy after its maintenance unless after the Pharmacy is inspected again to ensure that the conditions necessary for its re-operation are met.

3. Any other controls specified by decision of the Minister.

Article (36)

Amendment of Annexes to the Resolution

Provisions of Annex 1 and Annex 2 hereto may be amended by decision of the Minister, in coordination with the other Health Authorities.

Article (37)

Adjustment of Positions

Those covered by the provisions of this Resolution shall adjust their positions according to the provisions of this Resolution within no later than six (6) months of the date of its issuance.

Article (38)

Executive Decisions

The Minister shall issue any other decisions necessary for the implementation of the provisions of this Resolution.

Article (39)

Repeals

Any provision contrary to, or in conflict with the provisions of this Resolution shall be repealed.

Article (40)

Publication; Entry into Force

This Resolution shall be published in the Official Gazette, and shall come into force as from the day following the date of its publication.

Mohammed bin Rashid Al Maktoum

Prime Minister

Issued by us:

On: 21/Safar/1443 H

28/September/2021 G

Annex (1)

To the Cabinet Resolution No. (90) of 2021 Conditions and Controls of Importation, Acquisition or Possession of Medical Product with Individuals upon Entry into the State for Personal Use

Clause (1)

Provisions stated in Clauses 2 to 7 hereof shall apply to arrivals to, or departures from the State in case any of the following Controlled Drugs are traveled with:

1. Narcotic Drugs.
2. Psychotropic Drugs.

Clause (2)

Controlled Drugs (N-Narcotic) and Psychotropic Drugs) shall include the Medicinal Products that contain any of the Active Constituents listed in the following Schedules:

1. International Narcotics Control Board (INCB) Schedules 1, 2, 3 or 4 of the Convention on Narcotic Drugs of 1961, as amended by 1972 Protocol, and its amendments.
2. International Narcotics Control Board (INCB) Schedules 1, 2, 3 or 4 of the Convention on Psychotropic Substances of 1971, and its amendments.
3. Schedules 1, 2, 3, 4, 5, 6, 7 or 8 of the referenced Federal Law No. (14) of 1995.

Clause (3)

Arrivals to the State shall, when bringing Controlled Drugs:

1. Obtain prior permission from the Ministry to bring drugs with them through its website and disclose them at the official entry points of the State. To obtain permission, the following documents must be submitted in Arabic or English:
    a. A medical report issued no later than one (1) year by the health facility in which the patient is treated, authenticated by the health authority

in the country in which he received treatment, or by the embassy of the State therein, or from any approved authentication entity in that country.

b. The medical report must include the patient's personal data and information (the patient's full name), the medical diagnosis, the trade or generic name of the drug, the prescribed quantity, the treatment plan and its duration, the date of the report, the doctor's name and specialization, the license number with the address and the stamp of the health facility.

c. A copy of a Medical Prescription in the name of the patient issued no later than three (3) months, provided that it includes the patient's full name, the trade and generic name of the drug, as the case may be, the Pharmaceutical Form, the prescribed dose, the date of prescription issue, the duration of treatment, the doctor's name and stamp and the seal of the treatment authority. The Prescription must be certified by the health authority in the country where he received the treatment, or from the embassy of the State therein, or from any approved authentication entity in that country.

d. Copy of the passport or ID.

2. In the absence of prior permission, the customs authorities will coordinate with the Ministry to take the necessary measures based on the documents available with the traveller.

3. Without prejudice to the provisions of paragraphs (1) and (2) above, if the drugs are in possession of a patient's relative or delegate, an official power of attorney from the patient must be authenticated by an approved authentication authority in that country for such person, containing a copy of proof of identity, must be attached.

4. The consent of the Ministry in respect of the travel with Controlled Drugs to the state within the quantity appropriate to the treatment period, provided that it does not exceed the patient's need for a maximum period of three (3) months.

Clause (4)

With regard to diplomatic missions, official government agencies, and delegations participating in sports and other activities, when travelling with Controlled Drugs, the conditions and controls stipulated in this Annex shall be

applied when coming to or leaving the State. In any case, coordination with the Ministry must be made to complete the necessary procedures in this regard.

Clause (5)

1. The patient who leaves the State and needs to take Narcotic Drugs with him shall obtain the consent of the Ministry based on a valid Medical Prescription and the treating physician's report, up to the quantity appropriate to the treatment period.

2. If the patient who leaves the State needs injection with Narcotic Drugs during his travel, he must be accompanied by a Healthcare Professional, and shall be permitted to take the Narcotic Drugs within an appropriate quantity with approval of the Ministry based on a valid Medical Prescription and the treating physician's report.

3. If the patient who leaves the State needs Psychotropic (Non-narcotic) Drugs for treatment abroad, he may apply for the consent of the Ministry to take the quantity specified in the Medical Prescription. If the Medical Prescription contains re-dispensing, then the patient may take the necessary quantity up to a maximum period of three (3) months.

Clause (6)

1. In the event that the transiting traveler brings Controlled Drugs to the State, he shall be allowed to enter the quantity that is sufficient for his transit period in the State, and the excess quantities shall be seized, and returned to him upon his departure from the State.

2. In the event that the traveler coming to the State brings Controlled Drugs, the quantities that are in excess of the permitted quantity or that exceed the appropriate quantity for the duration of his treatment as determined by the Medical Prescription or the medical report shall be confiscated by the Competent Authorities, and shall be destroyed in accordance with the established procedures in this regard.

3. When the permissible quantity of drugs runs out, the patient must consult a licensed physician in any of the health facilities licensed in the State and approved by the Health Authority to ascertain his need to continue using the same drug, or alternative drugs registered in the State, and in case the drug is not available in the State, the health facility has the right to provide medication according to the applicable procedures.

4. If a traveler coming to the State travels with Medical Devices containing Controlled Substances, they shall be subject to the provisions of this Resolution, and he shall not be allowed to travel with these devices except for the purpose of personal use according to his sick need and treatment requirements.

Clause (7)

It shall be prohibited to bring the following Controlled Drugs when entering the State:

1. Drugs that do not contain the data of the Active Constituents in Arabic or English.
2. Expired drugs for personal use.
3. Drugs whose constituents are unknown or without a label showing the constituents.
4. Drugs that are prohibited from being circulated in the State in accordance with the lists specified by decision of the Minister, or his authorized representative, and listed on the Ministry's website.

Clause (8)

Provisions of Clause (9) and seq. shall apply to the arrivals to, or departures from the State in case any of the following Drugs or Medical Devices are travelled with for human use:

1. Semi-controlled Drugs.
2. POM Non-controlled Drugs for human use (other than Controlled Drugs).
3. Non-prescription (OTC) non-controlled drugs for Human use.
4. Preventive medicine drugs.
5. Biological drugs.
6. Herbal or supplementary drugs.
7. Medical Devices for personal - human use.

Clause (9)

Travelling to the State with Semi-controlled Drugs and Non-controlled Drugs and Medical Devices shall be subject to the following:

1. **For POM Drugs:**

   A traveler coming to the State may travel with POM non-Controlled Drugs for human use, up to the quantity that is proportional to his period of stay in the State, provided that the quantity necessary for personal use does not exceed six (6) months at the most, and the traveler must have a medical report or any other medical document showing the type of disease and required treatment or copy of Medical Prescription containing the patient's data.

2. **For OTC Drugs:**

   A traveler coming to the State shall bring OTC Drugs for human use, in a quantity that is proportional to his period of stay in the State and the amount required for personal use shall not exceed six (6) months at the most.

3. **For herbal or supplementary drugs:**

   A person coming to the State is prohibited from bringing prohibited drugs, complementary substances, or herbal substances within the State according to the lists specified by decision of the Minister, or his authorized representative, provided that they are listed on the Ministry's website.

4. **For Medical Devices:**

   A traveller coming to the State may bring Medical Devices for personal human use. If these devices contain any of the Controlled Drugs, they shall be subject to the procedures contained in this Resolution in respect of traveling with the Controlled Drugs upon entering or leaving the State. If they contain any of the drugs mentioned in paragraph (2) of this Annex, the required steps must be taken into account according to the classification of the Active Constituent.

Clause (10)

With regard to diplomatic missions, official government agencies, and delegations participating in sports and other activities, when traveling with Controlled Drugs, the conditions and controls stipulated in this Annex shall be

applied when coming to or leaving the State. In any case, coordination with the Ministry must be made to complete the necessary procedures in this regard.

Clause (11)

The following provisions shall apply to the travel with the preventive medicine drugs:

1. A traveler coming to the State must attach a medical report or a medical document explaining the type of disease and the required treatment, or a copy of a Medical Prescription containing the patient's data.

2. A traveler coming to the State may bring preventive medicine drugs within the limits of the quantity necessary for his personal use in proportion to the period of his stay in the state and up to the quantity necessary for his personal use for a period not exceeding six (6) months, provided that the excess quantity is delivered to the Preventive Medicine Centre at his place of residence to complete treatment, and the remaining amount is delivered to the traveler in the event of his departure, provided that he provides evidence of departure date.

3. If the traveler is coming to the State for the purpose of residency, he shall not be allowed to bring preventive medicine drugs except in a quantity sufficient for a period of six (6) months, while the excess quantity shall be transferred to the preventive medicine centre at his place of residence to complete his treatment. The same rules and procedures apply to the citizen traveler coming to the State.

Clause (12)

A traveller departing from the State may take Semi-controlled or uncontrolled personal drugs or Medical Devices with him within the limits of personal use, and the Ministry shall grant him permit or authorization if he so requests.

Clause (13)

The following conditions shall apply to drugs subject to the provisions of this Resolution and referred to in this Annex:

1. They should be in their original and tightly closed packages, or in packages with a label issued by the health facility or Pharmacy indicating the content of the drug, the name of the patient and the storage temperature to ensure the safety of the patient.

2. Controlled Drugs are included in the Ministry's lists listed on its website, or have an Import permit from the Ministry.

3. The technical conditions for transporting medicines that need refrigeration must be observed.

4. Quantities in excess of the quantity permitted by the competent authorities shall be confiscated and shall be seized and returned to the traveler when he leaves the State with the approval of the Ministry, if the traveler is transiting the State or not residing in it. If he resides in the State, the excess quantity shall be destroyed in accordance with the established procedures in this regard.

5. In the event that the permitted quantity of medicines runs out, the patient must consult a licensed doctor in any of the health facilities licensed in the state and approved by the Health Authority to ascertain his need to continue using the same medicine, or to use alternative medicines registered in the state, and if the medicine is not available in the state, the facility may provide the medicine through one of the approved Distributors and take the approval according to the applicable procedures.

6. A person coming to the State may, if he is not allowed to bring in uncontrolled drugs, Medical Devices, or Healthcare Products, re-export them within a period specified by the Ministry in coordination with the Competent Authority.

7. In exceptional cases and with the approval of the Ministry, a quantity of drugs may be brought in for a period exceeding the quantity specified in accordance with this Annex, for the purpose of personal use by individuals who return to the State after a treatment trip abroad.

Clause (14)

First. The following drugs may not be travelled with to the State:

1. Drugs that do not contain the Active Constituent data in Arabic or English.

2. Radioactive drugs.

3. Expired drugs for personal use.

4. Drugs with unknown constituents or without a label indicating the constituents.

5. Alternative medicine drugs and medicinal herbs with unknown constituents.

6. Drugs prohibited from being circulated in the State in accordance with the lists specified by decision of the Minister, or his authorized representative, provided that they are listed on the Ministry's website.

Second. The Ministry’s inspectors are responsible for providing technical support to the employees in charge of monitoring passengers and goods at the State’s border crossings whenever requested.

Annex (2)

To the Cabinet Resolution No. (90) of 2021 Health and Technical Conditions that should be met in Medical Warehouses

I. Public Safety and Security Requirements

1. The Medical Warehouse shall have public safety and security facilities, such as: the presence of valid and ready-to-use fire extinguishers, installation of the fire-fighting system, determination of emergency exits and other officially approved security and safety requirements (Civil Defense certificate).
2. Every warehouse must have a backup generator for emergency use.
3. A first aid box or kit containing Medical Products and first aid kits shall be provided and marked with an "ambulance" or the standard logo.
4. Electrical wires must be unexposed, so that they do not endanger warehouse workers.
5. Flammable substances, chemicals, expired drugs and any other Hazardous Substances shall not be discharged into public sewers or other disposal routes, and the means for their discharge and disposal shall be provided in accordance with the relevant regulations and legislation. Contracts shall be signed with the municipality or a company specialized in the medical waste disposal.
6. In the event of the presence of chemicals or Hazardous Substances, spill kit must be provided, and the means to discharge and destroy them must be provided in accordance with the relevant regulations and legislation.
7. The storage area should be well secure, separated from the office, with a mechanism for counting only those personnel who are cleared to enter, similar to the electronic access mechanism.
8. All workers must wear work-hazard uniforms, be hygienic, and have to wear ID badges at all times.
9. Posters with emergency numbers and no-smoking posters should be provided in visible places.

II. Infrastructure Requirements:

1. The location and internal layout of the Medical Warehouse must be in accordance with the latest layout approved by the municipality or any government licensing entity.

2. The site intended to be the location of the Medical Warehouse to be licensed must be located away from the residential areas and on the ground floor, and must not have an exit connected to a medical clinic, residence, Pharmacy or any other place of activity not related to its activity.

3. External walls and ceilings must be built of bricks or reinforced concrete, and false ceilings and walls made of (gypsum board) are allowed to be used only for the design and fitting out of facilities and not in storage areas.

4. The height of the ceilings must not be less than 270 cm (two hundred and seventy centimetres). If the Medical Warehouse consists of two floors or more, the height of each floor must not be less than 270 cm (two hundred and seventy centimetres).

5. All surfaces, including walls, ceilings, doors and others, should be coated with a material that is resistant to bacteria, is easy to wash and clean, is not flammable or water leakage, and heat and water-insulated.

6. The storage area in the Medical Warehouse must not be less than 50 m2 (fifty square metres) without the offices designated for the administration, and the storage space must be commensurate with the size of the stock. If the Medical Warehouse consists of two floors or more, the floors must be directly connected with stairs or elevator from inside, and the floor area must be within the area of the Medical Warehouse, provided that the storage area on the ground floor is not less than 35 m2 (thirty-five square metres), without prejudice to any other conditions listed in this paragraph, provided that the storage space in all floors is not less than 50 m2 (fifty square metres).

7. The floor of the Medical Warehouse shall not be lower than the general road level, and shall be covered by ceramics or the like (non-combustible and clean).

8. The doors must be wide (at least 120 cm wide (one hundred and twenty centimetres) to allow the passage of shipments of materials to be stored.

9. The floor, walls, and ceiling should be cohesive, smooth, porous, and clean.

10. Windows in the Medical Warehouse for ventilation and lighting should be covered with narrow wire fabric to prevent the entry of flies and other insects.

11. All wood must be painted with an oil dye or its substitute, and repainted whenever necessary.

12. The Medical Warehouse must have a toilet and hand washbasins for workers. Water connected to the Medical Warehouse must be from the public source, and toilets should not be open to storage sites. It is permitted to have a toilet outside the warehouse, provided that it is in the same building or warehouse complex, and is intended for the licensed Medical Warehouse workers only, provided that it is part of the plan approved by the licensing department.

13. Regular waste of the Medical Warehouse must be disposed of according to the system followed in the municipality of each emirate, with the need for contracts with competent authorities for the safe disposal of liquid, solid and medical waste. Sewer openings must be covered with tight iron covers.

14. The name of the Medical Warehouse must be written in Arabic and English on a visible board and in large letters, and the working hours must be displayed.

III. Interior fit-out and design requirements

1. When fitting out the Medical Warehouse for licensing purpose, consideration must be given to the general technical appearance, the flow of movement, and the availability of spaces to accommodate the stored materials, and commensurate with the volume of work and the quality of the materials to be stored.

2. The facility shall have a sufficient number of strong, durable and rust-resistant metal shelves and cabinets suitable for storing Medical Products.

3. A distance of at least 90 cm (ninety centimetres) must be maintained in the aisles between the shelves to facilitate the movement of workers or cranes.

4. Wooden pallets and platforms shall be insect-treated, or made of suitable synthetic material, and shall be maintained and clean.

5. Lighting shall be good and proportionate to the scope and extent of the activities or services provided.

6. The following sections should be specified in the warehouse: receipt and delivery area, storage areas, practical area for distribution and transportation, quarantine area as well as personnel and administration offices.

7. Specific and separate places should be allocated for storing the following items:

    a. Chemicals.

    b. Radioactive materials (after obtaining the approval of the Concerned Authorities)

    c. Narcotic Drugs.

    d. Psychotropic Substances.

    e. Expired drugs.

    f. Rejected or unusable products.

    g. Medical Devices, equipment and supplies.

    h. Flammable or explosive materials such as medical gases (after obtaining the approval of the Concerned Authorities).

8. A place must be allocated for double-locked safe box(es) to keep the Controlled Substances and Products and their records in a separate place with surveillance cameras, or in an electronically double-locked secured room whose outer walls are built of reinforced concrete, cement or bricks and monitored by cameras.

9. A place must be allocated for expired products or those for which a recall or circulation and use suspension circular has been issued, and (Products unfit for use and not for sale) must be written thereon from the outside in red, provided that the permitted period of their retention in the warehouse does not exceed six (6) months.

10. In the event that there are free medical samples, they must be kept in places completely separate from the rest of the products. If these

samples are Controlled Drugs, they must be kept in the Controlled Drug cabinet in the warehouse, and the incoming and outgoing ones should be recorded in special pages of the Controlled Drug register.

11. The Medical Warehouse must have the following devices and equipment: (a warehouse management office, a landline phone, fax, computer, internet service, and an email address for the warehouse).

12. A place must be allocated for the archive (paper or electronic) to save the relevant documents, papers, laws and scientific references, in addition to a file for keeping the circulars and decisions issued by the Ministry, and the retention period shall be as specified by the legislation in force in this regard.

13. Both the warehouse license and the Pharmacists licenses should be displayed at a visible and prominent place.

14. The warehouse must adopt an effective mechanism for inventory management (receipt and delivery), provided that it includes inventory management information (generic name of the product, trade name, company name, expiry date, Batch numbers, storage conditions, invoice numbers, etc.).

IV. Temperature and Humidity in the Warehouse:

1. A warehouse intended to house a medical warehouse required to be licensed shall contain a sufficient number of air conditioners as necessary to maintain the temperature within the warehouse between 15°C and 25°C and the humidity below 60% permanently. It is preferable to provide means at the doors to prevent leak of cold during loading and unloading.

2. Solar-exposed glass interfaces must be protected by adequate curtains to protect products from heat and sunlight.

3. The Medical Warehouse shall have refrigerators, freezers, refrigeration or freezing rooms intended for the preservation of Medical Products requiring refrigeration or freezing. Refrigerators or rooms must contain more than one thermometer, and a temp-mapping must be taken to capture the heating and coldness points of refrigerators or rooms, without being used for any other purpose.

4. The Medical Warehouse shall have numerical calibrated mechanisms for continuous temperature and humidity measurement such as data

loggers, which shall be distributed in the warehouse in proportion to the area and size.

5. All devices must be calibrated on periodic basis and calibration must be based on global standards.

V. Hygiene Requirements:

1. The Medical Warehouse building and its equipment, flooring, shelves, cabinets, etc. must be in good condition and clean at all times, and a schedule should be available to record the completion of daily cleaning.

2. The Medical Warehouse must have a contract with a cleaning company, or provide standard means for insect and rodent control.

3. The Medical Warehouse must contain pest repellers and their number shall be determined depending on the size of the warehouse.

VI. Requirements for Receipt and Transport of Medical Products

1. The Medical Warehouse shall provide a safe and appropriate means of transport for Medical Products, meeting the necessary requirements in this regard, and shall abide by the following:

   a. To maintain the safety, quality and prevention of damage during the transport of a Medical Product.

   b. The existence of controls necessary to maintain storage conditions during transport, such as temperature and relative humidity.

   c. During the transportation of refrigerated or frozen Medical Products, the temperature and coldness of each item must be monitored according to the required criteria during the shifting, and recorded at intervals. The Medical Warehouse must have a complete record of temperatures during transportation, and it is preferable to put in place temperature loggers for electronic recording of temperatures.

   d. Verification of the maintenance and safety of refrigerated vehicles and means of transport on a monthly basis.

2. The facility shall use refrigerated transport vehicles licensed by the Health Authority, as the case may be, within the limits of its competence, in accordance with the necessary requirements determined by the Health Authority.

3. Unloading the Medical Products from cargo vehicles and their dispatch to the warehouse should take place as soon as possible to avoid their presence in the receiving area.

4. The shipping record must be available, and shall include the following:

    a. Description of goods received (Pharmaceutical Form, form and size of unit, number of units in a package, and any other important details).

    b. Quantities.

    c. The Batch number given by the supplying Manufacturer.

    d. Invoice date.

    e. Expiry date.

    f. The method by which it is placed during the transport process.

5. All documents and records relating to the transportation of products, as well as a record of each shipment received, shall be kept for a period of one (1) calendar year after the expiration period.

6. No means of transport of Medical Products shall be permitted if they do not meet the requirements of maintaining the safety and quality of the products transported in accordance with the instructions provided by the Health Authority.

7. The warehouse must take additional precautions when transporting vaccines, Biological Drugs, Controlled Substances and Products, chemicals, or radioactive materials.

VII. Requirements for Good Storage and Distribution of Medical Products:

1. If the Medical Warehouse wishes to store Controlled Drugs, it must provide a separate sealed area with the necessary security equipment, such as protective fences, surveillance cameras, entry and exit control, alarm systems, and round-the-clock security guards, in addition to obtaining the approval of the Concerned Authorities.

2. Medical Products must be arranged on shelves, in cabinets or on pallets in an orderly manner and Medical Product boxes must not be in direct contact with the ground.

3. Medical Products shall be organised and arranged in alphabetical order according to the generic name, and for drugs per Pharmaceutical Form, and specific and separate places shall be designated for the storage of drugs of different Pharmaceutical Forms.

4. There should be enough distance between products, and between the place of storage of each Pharmaceutical Form and other for drugs.

5. Medical Products must be stored according to the Manufacturer's instructions, and storage information and requirements mentioned on the label must be followed. Storage conditions for products usually include the following:

    a. Products that need cooling from (2-8°C).

    b. Products that need to be frozen (-18°C or less).

    c. Products that need to be stored at room temperature (between 15°C and 25°C).

    d. Products that should not be exposed to light.

    e. Flammable products.

6. In addition to electronic records that continuously document temperatures under the mechanisms referred to in section IV (4) of this Annex, "Temperature and Humidity in the Warehouse", the temperature should be measured and recorded manually (temperature profile) at least twice a day for drugs kept below 25°C and three times a day for drugs kept in refrigerators.

7. Boxes should be aligned such that the date of production, expiration and label can be clearly seen and, if this is not possible, a label should be placed clearly on the box.

8. Liquid and heavy products must be placed on the lower shelves or at the bottom of the pallets.

9. Expired and spoilt products or products for which a recall or circulation and use suspension circular has been issued shall be separated and stored in their designated places until they are destroyed or disposed of, provided that the period of retention does not exceed six (6) months.

10. To recycle and monitor the inventory, First Expired, First Out (FEFO) principle must apply.

11. The warehouse must have a contract with a waste recycling company to destroy, dispose of and process spoilt and expired products.

VIII. Requirements for Qualified Professionals and Medical Warehouse Personnel:

1. If the Medical Warehouse is a warehouse for storing, importing, exporting, or distributing drugs, it must be under the management and supervision of a full-time Pharmacist who must be licensed by the concerned licensing authority and must cover all the working hours of the warehouse. The person in charge may be a Qualified Person (such as medical equipment engineer) in case of Storage, Import, Export or Distribution of Medical Devices and supplies other than drugs.

2. The Pharmacist in Charge of the Medical Warehouse shall be responsible for registering Controlled Drugs (if any) in their records in accordance with the rules, regulations and procedures followed for Controlled Drugs. Other procedures shall be followed with regard to the conditions, functions and obligations of the Pharmacist in Charge of the warehouse.

3. Medical Warehouse personnel must comply with relevant laws, regulations, decisions and guides.

4. Medical Warehouse personnel must adhere to the Code of Conduct and Ethics for the respective Healthcare Professions.

5. Medical Warehouse personnel must adhere to the principles of good Storage and Distribution practices.

IX. Requirements for Documents, Publications and Records to be kept in the Medical Warehouse (or their electronic alternative):

1. Documentation for the Medical Warehouse and its Personnel:

   a. Valid Medical Warehouse opening license (annual renewal receipt).

   b. Valid municipal license.

   c. Valid trade license.

   d. Licenses for Pharmacists and technicians (annual renewal receipt).

e. Record of the Medical Warehouse personnel stating their data.

f. Job description of all Medical Warehouse personnel, Pharmacists, and certified technicians.

g. Record of the continuing pharmaceutical development and education of each licensed Pharmacist and assistant Pharmacist.

h. List of the names, specializations and training of personnel.

i. Training files for each core worker, bearing in mind that all workers must be qualified to work in their respective capacities.

2. Contact Details:

a. Contact numbers and details of the relevant departments and sections at the Health Authority for reporting or inquiring on any related matters.

b. Contact numbers and details of pharmacovigilance units at the Health Authority.

c. Contact numbers and details of medical and toxic information centres in the State.

3. Records, Documents and Reports

a. Dispensing and distribution records, including: information stated in the dispensing records (orders), at a minimum, the following details:

1) Dispensing date.

2) Name and address of buyer or customer.

3) Product description (Name, Pharmaceutical Form, Concentration, packaging & Quantity).

4) Batch number.

5) Storage conditions.

b. Record for a daily registration of the temperature and humidity for both the warehouse and the refrigerator, so that the data are kept for the last twenty-four (24) months.

c. Records of Controlled Drugs numbered and stamped with the Ministry's seal or electronically archived.

d. A file containing the monthly and periodic reports on the Controlled Drugs.

e. A file containing reports on drug or medical product-related issues.

f. A file containing all the irregularities recorded against the warehouse and its workers.

Conclusion

With God's blessings, the third issue of the Encyclopedia of Health Legislation of the Department of Health - Abu Dhabi has been released to be launched in 2023.

On behalf of myself and all the members of the team working on the Health Legislation Encyclopedia project, I would like to extend my thanks for the precious trust placed by His Excellency the Chairman of the Department of Health - Abu Dhabi, and for the interest and follow-up of His Excellency the Undersecretary of the Department, by providing all means of support and motivation throughout the stages of work until the release of the third issue of the Encyclopedia.

I also pay tribute to the outstanding efforts and hard work made by my fellow team members for the release of this Encyclopedia in its current issue.

To conclude, we look forward to working together with our partners towards further initiatives that achieve the Department's promising vision that "the Emirate of Abu Dhabi be a place where everyone is at his healthiest" by providing a distinguished and sustainable healthcare and services that achieve the well-being and happiness of the community.

Saqr Al Marzooqi

Manager, Legal Affairs Office

Abu Dhabi - February 2023

Index

دائـــــرة الـصـــحـــة

DEPARTMENT OF HEALTH

www.doh.gov.ae | DoHSocial | Department of Health Abu Dhabi

Third Issue 2023