Federal Decree-Law No. (38) of 2024
Governing Medical Products, Pharmacists and Pharmaceutical Establishments

We, Mohammed Bin Zayed Al Nahyan, President of the United Arab Emirates;

- Upon reviewing the Constitution;
- Federal Law No. (1) of 1972 Concerning the Competences of Ministries and the Powers of Ministers, as amended;
- Federal Law No. (4) of 2015 Concerning Private Health Establishments, and as amended;
- Federal Decree-Law No. (4) of 2016 Concerning Medical Liability, as amended;
- Federal Law No. (9) of 2017 Concerning Veterinary Preparations;
- Federal Law No. (8) of 2019 Concerning Medical Products, Pharmacists and Pharmaceutical Establishments, as amended;
- Federal Law No. (11) of 2021 Regulating and Protecting the Industrial Property Rights;
- Federal Law No. (30) of 2021 Combating Narcotics and Psychotropic Substances, as amended;
- Federal Decree-Law No. (32) of 2021 Concerning Commercial Companies;
- Federal Law No. (3) of 2022 Regulating the Commercial Agencies;
- Federal Decree-Law No. (28) of 2023 Establishing the Emirates Drug Establishment (EDE);
- Federal Decree-Law No. (49) of 2023 Regulating the Use of the Human Genome,
- Based on the proposal of His Highness, Chairman of the UAE Space EDE, and the approval of the Cabinet,

Have promulgated the following Decree-Law:

Part One

General Provisions

Article (1)

Definitions

In application of the provisions of this Decree-Law, the following words and phrases shall have the meanings assigned to each of them, unless the context otherwise requires:

State	:	The United Arab Emirates.
The Ministry	:	Ministry of Health & Prevention.
The EDE	:	The Emirates Drug Establishment (EDE)
Minister	:	Minister of Health & Prevention.
Board of Directors (BOD)	:	The Emirates Drug Establishment Board of Directors.
Chairman	:	EDE Chairman BOD.
Competent Health Entity	:	Any local government body concerned with health affairs, each within their jurisdiction.
Medical Product	:	The product described in Article (2) herein.
Pharmaceutical Product	:	Any product that contains an active substance or group of active substances that achieves the intended purpose of use thereof in or on the human or animal body through a biological effect, and which is manufactured, sold, or offered for use in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of a disease. 2. Restoring, renewing, modifying, or correcting the physiological functions. The following shall also be included in Pharmaceutical Products: 1. BioPharmaceutical Products; 2. Food Supplements; 3. Cosmetics.
Biopharmaceutical Products	:	Pharmaceutical Products obtained by biotechnology from a living organism, and are divided into several categories such as

		vaccines, monoclonal antibodies, growth factors, blood derivatives, plasma derivatives, advanced medical therapy products, and allergy detection products.
Advanced Medical Treatment Products	:	Pharmaceutical Products based on modern and innovative technologies such as gene and cell therapy, stem cell therapy, genetic engineering, and engineered tissues, which are designed to treat, prevent, or diagnose complex and genetic diseases and injuries by modifying genes or replacing abnormal cells and tissues.
Local Product	:	It is a Pharmaceutical Product that has obtained Marketing Approval from the Marketing Rights holder within the State and is manufactured in local factories at manufacturing rates determined by the EDE.
Food Supplements	:	Products taken orally that support the human diet and do not treat, diagnose, or prevent diseases. They consist of natural or partially manufactured products, or both, and do not require a prescription or direct medical supervision when used.
Cosmetics	:	Products with a medical effect that are used on the human body to produce a desired local effect on the skin, hair or nails and do not require a prescription or direct medical supervision for their sale when used.
Innovative Product	:	A Pharmaceutical Product that is the first of its kind in its category, either because it contains new components or formulations that have not been used before to treat a specific condition or is used in new ways, or it was developed and marketed for the first time by the developing company and has not previously obtained Marketing Approvals in the State, and the Marketing Approval for the product was submitted to the EDE by the company that invented it or through someone it authorized for this purpose, while the product enjoyed valid patents at the time of submission.

Orphan Pharmaceutical Product	:	A Medical Product intended to treat, diagnose, or prevent a rare disease or condition.
Alternative Product	:	A Pharmaceutical Product that is similar to another Pharmaceutical Product, having the same qualitative and quantitative composition of active ingredients, the same Pharmaceutical Form, and being bioequivalent thereto. It may have the status of pioneer, so it will be the first generic Pharmaceutical Product to obtain Marketing Approval in the State, similar to the innovative product that has not obtained Marketing Approval in the State in terms of indication, Pharmaceutical Form, active ingredients, and Bioequivalence, without prejudice to the intellectual property laws in force in the State.
Compassionate Use	:	Use of a Medical Product for a patient with a serious illness or life-threatening condition outside of Clinical Trials when no alternative treatment options are available.
Medical Equipment	:	A Medical Product that contains a substance, device, instrument, engine, implant, detector, or system, including accessories, and operating software thereof. It shall include wearable devices and products based on AI technology, which shall achieve the intended purpose of its use in or on the human or animal body without a pharmaceutical, immune, or metabolic effect. In addition, it is manufactured, sold, or offered for use in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of a disease, an injury, or a disability; 2. Detection, modification, or replacement of anatomical position. 3. Birth Control.

Health Care Product	:	Any Medical Product that is used for the general health care of humans or is not intended for the diagnosis, treatment, cure, or prevention of any disease, and does not require a prescription or direct medical supervision when used.
Pharmaceutical Product	:	A Medical Product manufactured in a specific Pharmaceutical Form and has specific uses in humans or animals.
Veterinary Product	:	A substance, a composition of substances, or a material intended for the treatment, prevention, or diagnosis of medical conditions in animals, or for the repair or modification of physiological functions in animals.
Personalized Medicine	:	A personalized or precision medicine model that considers variation in genes, environment, and lifestyle to determine treatment and prevention of disease and more accurately predict which product treatment and prevention strategies will work best for each individual patient.
Defective Product	:	Any Medical Product that does not meet the quality requirements and does not meet the requirements specified in this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.
Counterfeit Product	:	A Medical Product that has been deliberately prepared with the intent to deceive or mislead, including: 1. Providing its packaging, packaging, identification card or internal leaflet with false or incorrect information concerning its identity or source, in a manner that does not correspond to reality. 2. Imitating another Medical Product using the same artistic shapes and colours of the original product packaging, package, and label. 3. Adding or deleting one or more active or inactive ingredients from the composition stated on its packaging, package,

identification card or internal leaflet without the approval of the EDE.

4. Changing the quantity or size of one or more of its active and inactive components without the approval of the EDE.

Preliminary Materials	:	Materials used in the composition or manufacture of a Medical Product or any other products.
Pharmaceutical Raw Materials	:	The basic components used in the pharmaceutical industry that aim to achieve the desired therapeutic effect when manufactured in a suitable Pharmaceutical Form. These materials include the chemical elements and active compounds that form the effective basis of the drug, in addition to inactive materials used to improve the form and properties of the drug, such as solvents and excipients of all kinds.
Excipients and Solvents	:	Inactive ingredients used to improve the form and properties of a medicine
Active ingredient	:	Any one or more substances responsible for the primary effects of a Medical Product, and which may be obtained from humans, animals, plants, microorganisms, chemicals, or other sources.
Marketing Approval	:	The approval granted by the EDE to a legal entity licensed in the State to market a specific Medical Product. This legal entity shall be responsible for all aspects of marketing, promotion, and follow-up of the product in the State.
Annex to the Marketing Approval	:	Attached to the Marketing Approval is a document containing all details related to the Medical Product, its description, the composition of the active and inactive ingredients and their quantities, uses, dosages, methods of use, side effects and any other details specified by the Decree-Law, its Executive Regulations and the decisions issued in implementation thereof.
Product Brochure	:	A paper or electronic leaflet containing important and concise information for the Marketing Approval supplement intended for users of the Medical Product.

The Main Effects of the Medical Product	:	The effects on the user of the Medical Product that are positive for its uses included in its Marketing Approval.
New Use	:	A newly added use to the list of previously authorized uses of a Medical Product that has previously been approved for marketing in the State, provided that the new use results from effects separate from those basic effects of its previous uses.
Approved Pharmacopoeia	:	A set of documents and standards that define the basic requirements for the quality of pharmaceutical and Pharmaceutical Products in the State and are concerned with providing precise guidelines for pharmaceutical manufacturing Establishments to ensure that Pharmaceutical Products produced in the State comply with strict standards of safety, effectiveness and quality.
Pharmaceutical Form	:	The form of a Medical Product that is prepared or manufactured into its final form and taken by the patient.
New Way to Use	:	A new method of administration of a Medical Product for which there is no previous Marketing Approval in the State in order to obtain the product main effects.
Side View	:	The sum of the indications and symptoms documented in the product internal leaflet and expected to occur in some patients, which may appear in the patient while using the Medical Product in accordance with the uses, doses and methods of use stated on the packaging or card of the Medical Product or in its internal leaflet and specified in the Marketing Approval.
Reverse Reaction	:	Any unintended or unwanted effect or symptom that appears in the user of the Medical Product within the doses documented in the internal leaflet and the uses authorized in the Marketing Approval and which occurs as a result of effects separate from those of the primary effects of the Medical Product.

Opposite Event : An undesirable medical event that occurs to a user of a Medical Product or to a person exposed to a specific health intervention and which does not necessarily have a causal relationship with taking the product. It is also called an adverse effect if the Medical Product is a medical device.

Adverse Reaction : Adverse reactions that are not expected to occur during the use of the Medical Product and whose nature or severity exceeds those documented in the Marketing authorization annex.

Serious Side Effect or Serious Adverse Event : An undesirable medical event not intended for treatment that leads the user of the Medical Product or an adverse event, at any dose or by any method, to one or more of the following results:

1. Death.
2. Serious, life-threatening illness or injury.
3. Permanent or substantial impairment of body structure, body function, or organs.
4. Causing an abnormality, birth defect, disability or permanent impairment.
5. Chronic Disease.
6. Causing a life-threatening condition that requires hospitalization or prolonged hospitalization.
7. A medical or surgical intervention to prevent life-threatening disease or injury or permanent impairment of body structure, function, or organs.
8. Fetal distress, fetal death, congenital or organic malformation, or any negative effects on the fetus.

Non Clinical Research : Pharmaceutical research and toxicity research to evaluate the safety of a Medical Product and its readiness for the Clinical Research stage that is not conducted on humans. This research yields preliminary information about the effectiveness, toxicity, effect of the drug in the body and its level of safety. It is conducted through laboratory experiments (test tube or cell

culture In Vitro) or experiments on animals (in vivo experiments), or using computer models of interactions between the drug or the targeted treatment (In Silico).

Clinical Research : It is research conducted on groups of people or the study of their data, samples, or tissues for understanding health and disease, for the most important reasons:

1. Explore the cause of a disease or group of symptoms.
2. Test effectiveness, efficiency and quality on a specific Medical Product that are conducted on groups of humans to determine how it is absorbed, metabolized, distributed, and eliminated from the body, to identify basic effects, side effects, and adverse interactions thereof. With the aim of confirming the effectiveness, efficiency, quality, and safety of using the Medical Product within the approved uses in accordance with the Marketing Approval granted to the Medical Product, or for new uses or drugs under research and development
3. Testing the effectiveness of a therapeutic procedure in treating symptoms or conditions.
4. Learn how a particular intervention or factor affects people health.

Clinical Research consists of two basic types of research:

1. Clinical Trial.
2. Other Clinical Research: Any Research Projects that do not fall within Clinical Trials and include:
    a. Research Projects on humans that involve procedures for taking samples of biological material or collecting personal health data on individuals, such as health survey projects of various types.
    b. Research Projects involving the further use of biological materials or personal health data of individuals.

c. Research Projects carried out on deceased persons.
d. Research Projects carried out on stillbirth.

Bioavailability : The speed, extent and availability of the active ingredient of a Medical Product or any of its active metabolites in the blood or at its site of action in the body.

Bioequivalence : There is no statistically significant difference in the bioavailability of the active ingredient in a Pharmaceutical Product compared to another product with the same active ingredient.

Research Information : Any information obtained as a result of research in chemistry, manufacturing, controls, Non-Clinical and Clinical Research to support the safety, efficacy and quality of a new Medical Product for Marketing Approval.

Equivalent Alternative : A Pharmaceutical Product that is an alternative to another product and is therapeutically equivalent to it and provides the same therapeutic effect, benefits and drug safety limits for the patient in accordance with its approved uses.

Stability studies : Tests conducted under conditions similar to approved storage conditions or under conditions that are more severe than those used to increase the rate of chemical or physical degradation of the Medical Product in order to detect degradation reactions or any indications of unsuitability of the product in order to estimate the shelf life of the product under approved storage conditions.

Batches : A specific quantity of a Medical Product that has been manufactured in a single batch and carries a unique identification number as well as a manufacturing date after passing the necessary inspection and testing stages.

Product Withdrawal : The process of withdrawing a Medical Product in its entirety or a batch thereof due to a defect in the product or to confirm the validity of a complaint about an adverse reaction, a serious adverse event, or a serious side effect, or any other reasons

explained by the party requesting the withdrawal. The withdrawal process is initiated by the producing factory, distributor, or importer or by order of the EDE.

Reference Manuals : The State whose Marketing Approval of the Medical Product is relied upon to grant approval for its marketing in the State.

Practitioner : A person who is scientifically and technically qualified and licensed to practice one of the health professions in the State, in accordance with what is specified in the Executive Regulations of this Decree-Law.

Pharmacy Profession : One of the health professions that aims to improve the health level of users of Medical Products through their correct and rational use, based on specialized scientific knowledge. The pharmacy profession includes a number of licensed activities, which are manufacturing, compounding, dispensing, giving, selling or storing any Medical Product or providing pharmaceutical consultations, in addition to any other activities specified by a resolution of the Minister. It also includes providing a group of health care services to the patient directly or through supporting other licensed health care practitioners through communication and providing clinical advice (technical and scientific).

Clinical Pharmacy : One of the Applications of the pharmacy profession based on specialized scientific knowledge to ensure that the patient benefits from the drug Treatment Plan to the maximum extent possible in his recovery, improving his health, or preventing him from diseases or complications, in order to practice the rational use of medicines.

Qualified Person : A natural person who is scientifically and technically qualified and licensed to practice a specific activity within the field of the pharmacy profession or the medical profession in accordance

with the provisions of this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.

Pharmacist : A person who holds an academic qualification of no less than a Bachelor degree in Pharmacy or its equivalent from a higher institute, college or university recognized in the State and who is licensed to practice the profession of pharmacy in the State in accordance with the provisions of this Decree-Law, its Executive Regulations and the decisions issued in implementation thereof.

Pharmacist in Charge : The licensed Pharmacist in the licensed Pharmaceutical Establishment, who shall be responsible for implementing the provisions of this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof, within the scope of the tasks assigned to him.

Precautionary Closure : A precautionary measure taken by the Inspector of a Pharmaceutical Establishment or Biobank in the event of a serious violation that may harm public health.

Clinical Pharmacist : A person who holds accredited scientific degrees in clinical pharmacology and has extensive experience in this field and specializes in developing Treatment Plans for patients, including the use of Medical Products based on scientific analysis of the patient condition and reports on the diagnosis of his condition. He is also committed to providing specialized professional advice on the patient drug Treatment Plan and the optimal use of Medical Products to all healthcare professionals who are members of the health team responsible for the patient and to the patient himself.

Medical Equipment Engineer : A person who holds an academic qualification of no less than a Bachelor degree in Medical Engineering or Medical Technology Engineering.

Prescription : A document transmitted in writing or electronically and issued by a practitioner of a health profession who is legally licensed to

prescribe to a practitioner of a health profession who is authorized to dispense or handle in accordance with what is specified in the Executive Regulations of this Decree-Law and the decisions, regulations and instructions issued in this regard. The verbal order issued by a practitioner of a health profession shall be considered a medical prescription, provided that it is subsequently documented in accordance with a resolution of the Minister.

Treatment Plan : The plan for the use of Medical Products designed based on a careful analysis of the patient medical condition and the patient situation to obtain the best possible results for his treatment and includes the schedule for taking the products specified by name, type, Pharmaceutical Form, strength, method of use, single dose amount, number of doses per day, term of treatment and any other instructions such as the sequence of use of the products or gradual dose adjustment and the like.

Medical Product Use (Protocol) : The law approved by the Health Establishment or the treating physician, which specifies the medical conditions in which the Medical Product may be used, the warnings concerning the prohibition of its use, and the conditions for determining the sequence of use of the product, the dosage, the term of treatment, and the method of use.

Patient Treatment Guide : The system that governs how to proceed with the treatment of a specific medical condition in accordance with precise instructions describing the diagnostic conditions for the medical condition and specifying the Medical Products and other therapeutic procedures for each condition and the sequence of their use or employment.

Direct Supervision and Control : Full knowledge and complete monitoring at all times of all activities carried out by the employees of the Pharmaceutical Establishment or Biobank.

Establishment : Establishment licensed to work in any of the fields of pharmacy and Medical Products in the State, including:

1. General pharmacies and Pharmacy Chains.
2. Non-Clinical and Clinical Research entities
3. Bioequivalence centers
4. Pharmaceutical labs.
5. Factories and Contracting Companies to manufacture medical products.
6. Contractual Company for Research and Development
7. Marketing Offices.
8. Pharmaceutical Consulting Offices.
9. Compound Pharmacies.
10. Medical Warehouses and Medical Stores.

General Pharmacy : A Pharmaceutical Establishment licensed to store, prepare, dispense, display or sell Medical Products directly to the public, through a fixed or mobile, permanent or temporary Establishment, or through a health Establishment.

Pharmacy Chain : A group of pharmacies owned by one natural or legal person and bearing the same name.

Compound Pharmacy : A Pharmaceutical Establishment licensed to prepare medical preparations based on medical prescriptions or to meet the needs of Health Establishments for the necessary synthetic products.

Medical Warehouse : The Pharmaceutical Establishment licensed to store and possess the Medical Product or pharmaceutical raw materials and supplies. The warehouse may be licensed for import, distribution, re-export, or any other activities in accordance with the geographical location of the Establishment, as determined by the Executive Regulations of this Decree-Law.

Medical Store : A Pharmaceutical Establishment licensed to store Medical Products without the right to possess or dispose of them and

provide logistical services, and does not have the right to trade or distribute for sale.

Marketing Office : A Pharmaceutical Establishment licensed to practice the activity of introducing Medical Products to healthcare professionals and monitoring their circulation in the State.

Pharmaceutical Consulting Office : A Pharmaceutical Establishment licensed to practice the activity of providing specialized and practical consultations in the field of pharmacy profession applications, in accordance with what is specified in the Executive Regulations of this Decree-Law.

Medical Products Factory : A Pharmaceutical Establishment intended to manufacture Medical Products, in whole or in part.

Pharmaceutical Laboratory : A Pharmaceutical Establishment licensed to carry out various laboratory analysis operations for Medical Products, including stability studies and quality tests, in accordance with the specifications and controls specified for them by the requesting party.

Contractual Company for Research and Development	:	Companies contracted to outsource and accelerate the processes of innovation, development, and manufacturing of Medical Products. Including: 1. Contract Research Organizations: A person or company that is contracted to carry out one or more of the obligations of a Clinical Trial sponsor. 2. Contract Site Management Organizations: A person or company that is contracted to provide administrative services related to the management of Clinical Trial sites, and shall not bear any of the regulatory obligations of the Clinical Trial sponsor. It may have a network of Clinical Research sites managed thereby, and its services include: identifying or managing principal and secondary researchers, recruiting study staff, preparing submissions to institutional review committees and boards, assisting in project feasibility, patient recruitment, study site launch and close-out, or any other study-related activities at the study site.
Contract Manufacturing Company	:	A company that is contracted by major pharmaceutical companies to outsource and accelerate medical product manufacturing processes and provide end-to-end services from development to manufacturing of the medical product, which can aid in scalability or can allow the major company to focus on drug discovery and drug marketing. The services shall include: Pre-product development services, technical studies related to the product, materials, manufacturing methods, registration, and commercial production.
Biobank	:	An establishment licensed to collect, preserve, store and distribute biological samples such as, but not limited to, blood, tissues and cells, and related information for future use, including but not limited to independent and mobile blood banks, umbilical cord blood banks and stem cell storage centers.

Biological Sample	:	Any type of sample of biological material taken from a living organism - such as blood, serum, urine, skin, muscle, and organ tissue samples, as well as cell cultures and DNA samples.
Bioequivalence Centre	:	A licensed Pharmaceutical Establishment where comparative research and studies are conducted to determine the Bioequivalence of a generic drug compared to an innovative drug.
Storage	:	The process of keeping a Medical Product at any time during its life cycle in manufacturing and distribution channels.
Manufacturing	:	A set of activities related to the manufacture of a Medical Product, from purchasing raw materials and products in its manufacture, to its production processes, such as preparation, composition, derivation, packaging, repackaging, quality control, approval, etc.
Distribution	:	Transporting or moving the Medical Product from the premises of the producing factory or any other central point to the end user or to any intermediate center between them, using equipped means of transport.
Import	:	Importing Medical Products in their final form or raw materials from outside the State or its free zones to the mainland or within the State through customs ports and after obtaining permit or approval from the EDE for each shipment.
Export	:	Exporting locally manufactured medical products or their raw materials from the State through customs ports and after obtaining permit or approval from the EDE for each shipment.
Re-export	:	Exporting medical products or pharmaceutical raw materials that were previously officially imported through customs ports and after obtaining permit or approval from the EDE for each shipment.
Import or Export Permit	:	The permit issued by the EDE to the Medical Warehouse licensed to import and export Medical Products or to the licensed medical

		factory after fulfilling the conditions stipulated in accordance with the provisions of this Decree-Law, its Executive Regulations and the decisions issued in implementation thereof.
Import or Export Approval	:	The approval granted by the EDE to a specific Establishment or entity to import or export specific or essential Medical Products required to perform its duties, and not for commercial purposes, in cases specified by a decision from the President.
Importer	:	A legal person licensed to import any quantity of Medical Products from outside the State for possessing, storing, distributing or selling them in bulk.
Distributor	:	A legal person licensed to practice any activity related to the circulation of a Medical Product, except for import and direct sale to the public.
Marketing Rights Holder	:	The holder of a license to market one or more Medical Products in the State, in accordance with the provisions of this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof, and shall be responsible for the aspects of its marketing, promotion, and follow-up in the State.
Lab Study	:	The study and research conducted on one or more Medical Products or their components within the scope of the laboratory and laboratory tests to determine their toxic, chemical, physical, microbiological, biological or technical properties, which do not include experiments on humans and can be tested on animals.
Controlled Materials and Products	:	Products and materials for which medical and commercial circulation require special control procedures are: 1. Toxic substances and plants. 2. Prohibited veterinary substances. 3. Narcotic and psychotropic substances, whether in the form of raw materials or in a Medical Product. 4. Hazardous Medical Products.

Toxic Substances and Plants	:	Materials and plants specified in accordance with the legislation regulating this type of materials and plants.
Prohibited Veterinary Substances	:	Materials specified in accordance with the legislation regulating this type of materials.
Narcotics and Psychotropic Substances	:	Medical, pharmaceutical and other products containing any of the active ingredients in accordance with Federal Law No. (30) of 2021 on Psychotropic Substances referred to, and its amendments.
Semi-Controlled Products	:	Substances or drugs that are not classified as narcotic or psychotropic substances, but circulation thereof in the State shall be controlled because their misuse may lead to harm to public health.
Hazardous Medical Products	:	Products whose definition and prohibited uses are determined by a decision issued by the President or his delegate.
Chemical Precursors	:	A chemical substance that is used in any stage of the manufacturing or production of narcotic or psychotropic substances, Hazardous substances, psychoactive substances, or toxic substances, In accordance with the two lists attached to this Decree-Law and any subsequent amendments thereto.
Exclusive Marketing	:	Approval to market specific Medical Products to specific entities within the State, without the need to issue a Marketing Approval.
Pharmacovigilance	:	It is the science that accompanies activities related to identifying side effects, adverse reactions or toxicity of Medical Products and the potential risks of their use, methods of monitoring and controlling them, and collecting these reports for evaluating, analyzing, treating and preventing them, and determining ways to prevent their occurrence.
Grey Market	:	Circulation Medical Products through distribution channels that are not recognized by the original manufacturer, or are not licensed.

Article (2)

Decree-Law Scope of Application

The provisions of this Decree-Law shall apply to the following products, professions, and establishments:

1. Hazardous Medical Products:
    a. Pharmaceutical Products.
    b. Medical Equipment.
    c. All Pharmaceutical Products.
    d. Health Care Products;
    e. Biopharmaceutical Products;
    f. Food Supplements;
    g. Cosmetics.
    h. Genetically modified organism products intended for medical use.
2. Chemical precursors, controlled, semi-controlled, hazardous and toxic products and substances, whether for human or veterinary use.
3. Pharmacy profession for state employees including free zones.
4. Pharmaceutical Establishments and Biobanks operating in the State, including those operating in free zones.
5. Any other Pharmaceutical Establishments for which a decision is issued by the Cabinet.

Part Two

Regulation and Circulation of Medical Products

Article (3)

Approved Pharmacopoeia

The EDE, in coordination with the Competent Health Authority, shall prepare, publish and update the State Pharmacopoeia. The EDE shall also approve reference Pharmacopoeia.

Article (4)

Exclusive Marketing Approval

1. The EDE may grant approval for the exclusive marketing of a Medical Product in accordance with the controls and conditions specified in a decision issued by the BOD.
2. The Medical Product subject to exclusive marketing may not be manufactured, imported, distributed, possessed, sold or used in the State unless the approval for exclusive marketing has been obtained from the EDE.

Article (5)

Marketing Approval

1. Without prejudice to the applicable legislation concerning veterinary preparations, it is not permitted to import, distribute, possess, sell, display, re-market, use, or manufacture any Medical Product in the State for circulation therein, except after obtaining Marketing Approval of any type from the EDE.
2. As an exception to Clause (1) of this Article, all categories of Medical Products that are compounded in licensed compounding pharmacies are exempt from the requirement to obtain Marketing Approval.
3. The Cabinet may, upon the proposal of the President, decide to exempt any other Medical Products from the requirement to obtain Marketing Approval for their circulation.

Article (6)

Terms and Conditions for Granting Marketing Approval

1. The Marketing Approval for the Medical Product is issued by the EDE in accordance with the following conditions:
   a. The Applicant shall be a Pharmaceutical Establishment licensed as a Marketing Office, a Medical Products Manufacturer, a contracted Medical Products manufacturing company, or a Medical Warehouse designated by the Marketing Rights holder.
   b. The Applicant shall implement a quality assurance and product traceability system, a pharmacovigilance system and post-marketing follow-up.

c. Assessing the Medical Product compliance with the Marketing Approvals issued for it by the reference countries or its compliance with research information that proves its effectiveness, safety of use, and conformity with approved quality specifications, including the results of clinical assessment or Bioequivalence and post-marketing results to prove the safety and effectiveness of the Medical Product.
d. The presence of a certificate of analysis for Medical Products in Pharmaceutical Form or a quality certificate for their batches proving their quality or safety from a laboratory licensed by the EDE or approved by it.
e. The Applicant has the right to market it in accordance with the established rules for intellectual property and trademarks. If the Medical Product is similar, the Applicant shall ensure compliance with the applicable laws and regulations concerning the protection of intellectual property and trademarks and provide evidence of the use of information and data for innovative products.
f. Submit a valid Good Manufacturing Practice Certificate from the EDE and/or from the Competent Authority in the State of origin and/or any of the reference bodies accredited by the EDE.
g. All information and data on the Medical Product and how to use it are provided on the internal and external card and the paper or electronic leaflet for the Medical Product, and the product meets the labelling guidelines issued by the EDE.
h. Any other conditions determined by the Executive Regulation of this Decree-Law.

2. Without prejudice to the provisions of international agreements to which the State is a party, and to the provisions of the intellectual property legislation in force in this regard, the EDE may grant Marketing Approval for a similar product, based on its biological and qualitative equivalence with a Pharmaceutical Product for which the legal protection granted has ceased, and for which Marketing Approval has previously been issued in accordance with the provisions of this Decree-Law.
3. The EDE shall record the Medical Product for which Marketing Approval has been issued in the database referred to in Article (66) of this Decree-Law.
4. The Executive Regulations of this Decree-Law shall specify the conditions, requirements and other controls for granting Marketing Approval, classified in accordance with the type

of Medical Product and whether it is a similar, innovative, pioneering or orphan Pharmaceutical Product.

Article (7)

Marketing Approval Validity and Renewal Term

1. The Marketing Approval shall be valid for a period of (5) five years, and shall be renewed for similar periods in accordance with the terms and rules governing this in the Executive Regulations of this Decree-Law.
2. The request to renew the Marketing Approval shall be submitted ninety (90) days before its expiration date.
3. The Marketing Right Holder may not continue the activity permitted in the Marketing Approval issued for the specific Medical Product after the expiry date of the Marketing Approval and until its renewal, unless the EDE deems otherwise. The EDE may authorize the Marketing Right Holder to continue the activities related to some Medical Products if necessary.
4. The EDE may grant Marketing Approval for a period less than the period referred to in Clause (1) of this Article, in accordance with the controls specified in the Executive Regulations of this Decree-Law.

Article (8)

Conditional Marketing Approval

Without prejudice to the applicable legislation concerning intellectual property, the EDE may issue conditional Marketing Approval for the following Medical Products:

1. Orphan medical or biological products for the treatment of rare diseases that have been provisionally approved globally by some reference Health Authorities.
2. Medical Products for the treatment of life-threatening and serious diseases, the use of which results in significant therapeutic benefit, and no alternative, equivalent or authorized Medical Product is available in the State.
3. Medical Products that are not available in the State and for which there is no equivalent alternative.

4. Any other products determined by the Executive Regulations of this Decree-Law.

Article (9)

Terms and Controls of Conditional Marketing Approval

1. The Conditional Marketing Approval for the Medical Product is issued by the EDE in accordance with the following conditions:
   a. Fulfilling the conditions referred to in paragraphs (a, b, d, g) of Clause (1) of Article (6) of this Decree-Law.
   b. Assessing the Medical Product compliance with the Marketing Approvals issued to it by the reference countries, or providing complete information and data concerning the reasons and justifications for the Medical Product obtaining conditional Marketing Approval from the reference country or one of the global reference Health Authorities for assessment.
   c. Submitting an undertaking stating that the Application for the Marketing Approval referred to in Article (5) of this Decree-Law will be submitted immediately after the reasons and justifications that called for the request for conditional Marketing Approval have expired, and in the event that the Marketing Right Holder wishes to continue circulation the Medical Product after the expiry of these reasons and justifications.
   d. Any other conditions determined by the Executive Regulation of this Decree-Law.
2. The Conditional Marketing Approval for the Medical Product is issued by the EDE in accordance with the following controls:
   a. The use of Medical Products that have received conditional Marketing Approval on specific persons or groups of persons without the need to conduct Clinical Trials.
   b. Marketing Medical Products that have been granted conditional approval to fill the temporary shortage of a similar Medical Product licensed in the State, provided that the Medical Product is licensed in another country that has similar control over Medical Products, and there is no identical, licensed and available Medical Product in the State.
   c. Any other controls determined by the Executive Regulation of this Decree-Law.

3. The EDE shall record the Medical Product for which Marketing Approval has been issued in the database referred to in Article (66) of this Decree-Law.

Article (10)

Conditional Marketing Approval Validity and Renewal Term

1. Conditional Marketing Approval shall be valid for one year and is renewable for similar periods if the reasons and justifications for requesting conditional Marketing Approval continue.
2. The request to renew the conditional Marketing Approval shall be submitted ninety (90) days before its expiration date. The renewal shall be made in accordance with the same terms and conditions specified for its first issuance, if the reasons and justifications for requesting the conditional Marketing Approval continue.
3. The Entity submitting the conditional Marketing Approval request may not continue to practice the activity mentioned in the conditional Marketing Approval after its expiry date and until its renewal.
4. The EDE may grant Conditional Marketing Approval for a period less than the period referred to in Clause (1) of this Article, in accordance with the controls specified in the Executive Regulations of this Decree-Law.
5. If the Marketing Right Holder desires to continue trading the Medical Product after the expiry of the conditional marketing approval period and the expiration of the reasons and justifications calling for its submission, he shall submit a request to obtain the Marketing Approval referred to in Article (5) of this Decree-Law.

Article (11)

Emergency Use Approval

Without prejudice to the applicable legislation on intellectual property and as an exception to the terms and conditions for granting Marketing Approval, the EDE may issue Emergency Use approval for some Medical Products required by the State in the event of a health emergency, epidemic or health pandemic that is announced in accordance with the applicable legislation in this regard.

Article (12)

Controls and Conditions of Emergency Use Approval

1. Approval for Emergency Use of a Medical Product shall be issued in accordance with the following conditions:
   a. There is evidence of the effectiveness of the Medical Product in diagnosing, treating or preventing the diseases involved in the emergency health condition.
   b. Providing evidence that the known and potential benefits of the Medical Product outweigh its risks.
   c. The lack of adequate, approved and available alternatives to the Medical Product for the diagnosis, prevention or treatment of the diseases involved in the emergency health condition.
   d. The presence of data from Clinical Research, Clinical Trials or any other reference sources that prove the safety and effectiveness of the Medical Product.
   e. Having a plan in place to monitor the use of the Medical Product and manage any risks associated with its use.
   f. Any other conditions determined by the Executive Regulation of this Decree-Law.
2. Approval for Emergency Use of a Medical Product shall be issued in accordance with the following controls:
   a. Pharmaceutical and Health Establishments in the State that handle the Medical Product that has received Emergency Use approval shall comply with the instructions issued by the EDE concerning uses and dosages.
   b. Any other controls determined by the Executive Regulation of this Decree-Law.
3. As an exception to Clause (2) of Article (6), and in the event that the State is exposed to a health pandemic that is declared in accordance with the legislation in force in this regard, the EDE may grant approval for Emergency Use and a permit to import the similar product before the expiration of the legal protection period for the reference innovative product.

Article (13)

Term of Emergency Use Approval and Renewal

1. The approval for Emergency Use of the Medical Product shall be valid for the term of the State of health emergency declared by the State, and until it issues another declaration stating the end of the State of emergency, unless another period is specified by the EDE.
2. The EDE may review its Emergency Use authorization and consider revoking it based on new evidence or changes in the health emergency situation.
3. The EDE may extend the validity period of the Emergency Use approval issued by it or renew it for periods determined by it if the health emergency continues and the Medical Product continues to meet the necessary standards.
4. The Entity submitting the Emergency Use approval request may not continue to practice the activity mentioned in the Emergency Use approval after its expiration date.
5. Submit an undertaking stating that the Application for the Marketing Approval referred to in Article (5) of this Decree-Law will be submitted immediately after the reasons and justifications that called for the request for conditional Marketing Approval have expired, and in the event that the Marketing Right Holder wishes to continue circulation the Medical Product after the expiry of these reasons and justifications.

Article (14)

Fast Track Marketing Approval

1. The EDE establishes a fast track with simplified procedures in line with quality, safety, efficacy requirements and international agreements, to grant Marketing Approvals for innovative Medical Products of therapeutic importance.
2. The Executive Regulations of this Decree-Law shall specify other Medical Products permitted to be included in the fast track and the terms, controls and requirements for submitting a request for Marketing Approval within this track.

Article (15)

Resubmission of Marketing Approval and Conditional Marketing Approval

The Marketing Approval or conditional Marketing Approval issued by the EDE is considered invalid and the Marketing Right Holder may not use it. He shall reapply for a new Marketing Approval or conditional Marketing Approval for the same Medical Product, in any of the following cases:

1. Substantial changes in the composition or formulation of a Medical Product.
2. Significant changes in dosage form or concentration.
3. Changes in the classification of the Medical Product type or its route of administration, which were not included in the current Marketing Approval or conditional Marketing Approval.
4. Significant changes in the manufacturing and production process that may affect the quality, safety or effectiveness of the Medical Product.
5. Fundamental changes in medical device design.
6. Voluntarily withdraw a Medical Product from the market for later re-introduction with significant changes.
7. Results of pharmacovigilance operations, whether due to new safety concerns or reports of adverse reactions or medical events that require withdrawal or re-assessment and significant changes to the Medical Product.
8. Any other cases determined by the Executive Regulation of this Decree-Law.

Article (16)

Approval of Minor Changes to the Medical Product

The Marketing Right Holder shall submit a request for minor changes to the Medical Product to the EDE without the need to submit a new request for Marketing Approval of all types as referred to in Article (15) of this Decree-Law, in any of the following cases:

1. Any minor changes in the composition of the Medical Product or in the event of new uses for the Medical Product, whether as new indications for use or suitability for a new category of patients.
2. Any change in the appearance of the Medical Product or its internal leaflet.

3. Any change in the location of the Medical Product manufacture or in the Marketing Rights holder, or minor changes in the method of its manufacture.
4. Any other cases determined by the Executive Regulation of this Decree-Law.

Article (17)

Cancellation of All Types of Marketing Approval or Cancellation of Emergency Use Approval and Transfer of Ownership Thereof

1. The EDE may issue a decision to cancel the Marketing Approval, conditional Marketing Approval, or approval for Emergency Use of a Medical Product in the State in any of the following cases:
   a. The locally manufactured Medical Product has not been put on the market within (2) years from the date of granting Marketing Approval without an excuse acceptable to the EDE.
   b. The locally manufactured Medical Product has not been put on the market within one year from the date of granting Marketing Approval without an excuse acceptable to the EDE.
   c. The Medical Product that has obtained Emergency Use approval or conditional Marketing Approval has not been placed on the market within (3) three months from the date of granting it without an excuse acceptable to the EDE.
   d. The unavailability or absence of the Medical Product in the market for (2) consecutive years after its introduction to the market without an excuse acceptable to the EDE.
   e. If it is proven that Marketing Approval of any kind or Emergency Use approval was obtained based on incorrect documents.
   f. If a decision is issued requiring a ban on the manufacture, distribution or circulation of the Medical Product in the State, the State of origin or any of the reference bodies approved by the EDE.
   g. If it is proven that the Medical Product Manufacturer or the contracted company for manufacturing Medical Products has repeatedly failed to apply the principles of good manufacturing practice or the principles of good storage and distribution, which affects the quality of the Medical Product.

h. If the Medical Product is proven to be unsafe or unsafe, or repeatedly fails to comply with approved quality standards, when laboratory tests are conducted in the EDE quality control laboratory.

i. If the Medical Product is proven to be unsafe due to new safety concerns or reports of adverse medical reactions or events that may require the Medical Product to be withdrawn.

j. If a decision is issued requiring the prohibition of the activity of a Medical Products Manufacturer, a contracted company for the manufacture of Medical Products, a Medical Warehouse in the State, the Entity represented by the Marketing Office in the State of origin, or any of the reference bodies approved by the EDE.

k. The Executive Regulations of this Decree-Law shall specify any other cases that require the cancellation of Marketing Approval of all types or approval for Emergency Use.

2. With the approval of the EDE, Ownership of the Marketing Approval or conditional Marketing Approval for a Medical Product may be transferred to other parties, in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.

Article (18)

Protect Intellectual Property

Without prejudice to the applicable legislation concerning intellectual property, documents and data related to an innovative Medical Product and a Medical Product with at least one new active ingredient, whether developed in the State or imported, are subject to a protection period. The Executive Regulations of this Decree-Law shall specify the period, mechanism and system related to regulatory protection.

Article (19)

Scientific Fraud

Pharmaceutical Establishments licensed to manufacture, market or distribute the Medical Product or provide pharmaceutical consultations shall refrain from any distortion, fraud, theft or scientific plagiarism of published studies and research, in a manner that affects the legal rights established for the Owners of these studies and research.

Article (20)

Product Pricing

The Marketing of a Medical Product that has obtained Marketing Approval requires the existence of a specific price for this product, which is determined in accordance with the general rules issued by a decision of the BOD.

Article (21)

Marketing Rights Holder Obligations

The Applicant for Marketing Rights or his representative for marketing Medical Products shall undertake the following:

1. Appoint one or more qualified persons residing in the State, in accordance with the controls specified in the Executive Regulations of this Decree-Law.
2. Fulfil the conditions mentioned in Article (22) of this Decree-Law
3. Monitor the movement of the Medical Product in the distribution channels.
4. Provide the required capabilities and systems to follow up on the requirements for obtaining Marketing Approval, conditional Marketing Approval, Emergency Use approval, or exclusive Marketing Approval for the Medical Product.
5. Monitor the performance of the Medical Product licensed for marketing, and receiving reports from Health Establishments concerning the effectiveness, safety and quality of the product.
6. Comply with the guides and standards issued by the EDE concerning pharmacovigilance, and to implementing the provisions of Clause (3) of Article (68) of this Decree-Law.
7. Follow up on the procedures for withdrawing the Medical Product.

8. Follow up on patent protection and manufacturing rights issues for the product.

Article (22)

Appointment of Pharmaceutical Establishments

1. The Marketing Right Holder shall appoint at least two Pharmaceutical Establishments licensed by the EDE to import Medical Products into the State as importers of the Medical Product for which he has obtained the Marketing Right, and shall appoint one or more Pharmaceutical Establishments licensed in the State to distribute the Medical Product for which he has obtained the Marketing Right, in accordance with the following controls:
   a. The Marketing Right Holder shall inform the EDE of the designation of one main Pharmaceutical Establishment from the Pharmaceutical Establishments designated by the Marketing Right Holder to undertake all product licensing work, pharmacovigilance activities and management of the entire life cycle of the Medical Product.
   b. One application shall be submitted by the Pharmaceutical Establishment specified in paragraph (A) of item (1) of this Article, to obtain Marketing Approval of all types for each Medical Product, regardless of the number of designated Pharmaceutical Establishments.
   c. All designated Pharmaceutical Establishments are required to carry out import operations of Medical Products during the calendar year.
2. The holder of the local Marketing Right for locally manufactured Medical Products shall appoint one or more Pharmaceutical Establishments licensed in the State to store and distribute the Medical Product for which he has obtained the Marketing Right, either by establishing Establishments dedicated to this purpose at the local factory licensed by the EDE or by appointing one or more Pharmaceutical Establishments to carry out these tasks.
3. Any other controls or conditions determined by the Executive Regulation of this Decree-Law.
4. The Cabinet may exempt the Marketing Right Holder from the Application of the provisions of this Article based on the proposal of the President, and in accordance with the controls that it determines.

Article (23)

Obligations of the Appointed by the Marketing Rights Holder

The qualified person appointed by the Marketing Right Holder shall undertake the following:

1. Providing pharmaceutical or scientific information about the marketed Medical Product to Health Establishments, ensuring its accuracy and conformity with the information approved by the EDE.
2. Inform the EDE of any change or update in the manufacturing or composition methods, the source of the active ingredients, the form, packaging, or qualitative testing methods of the Medical Product, or any new use of the Medical Product or any change, update, addition, or deletion of the uses specified within the Marketing Approval to obtain its approval, and the EDE is obligated to make available data and information about the changes after their approval in accordance with the mechanisms approved by it.
3. Comply with the provisions of the guides and standards issued by the EDE concerning pharmacovigilance, and implementation of the provisions of Clause (3) of Article (68) of this Decree-Law.
4. Follow up on post-marketing reports on the Medical Product, reports on its effectiveness, safety of use and quality during its circulation in Health Establishments in the State.

Article (24)

Civil Liability

The qualified person shall be responsible, together with the Marketing Right Holder, for any violations of the provisions of this Decree-Law, especially with regard to maintaining all records and records related to the activity of circulation the Medical Product.

Article (25)

Non-Clinical and Clinical Research

1. Non-Clinical Research on humans is prohibited, and the Executive Regulations of this Decree-Law shall specify the controls for conducting non-Clinical Research.
2. It is prohibited to conduct any Clinical Trials before conducting non-clinical studies to initially confirm the degree of safety and effectiveness of the intended medical

intervention from the clinical studies, with the exception of the compassionate use of the Medical Product in accordance with the controls specified in the Executive Regulations of this Decree-Law.

3. Clinical Research may be conducted in accordance with the terms, controls and procedures issued by the Cabinet.

Article (26)

Accredited or Licensed Laboratory

A laboratory study, product analysis certificate or quality certificate for a batch or batches of a Medical Product may not be accepted as a document authorizing its quality, stability or safety unless it has been conducted and approved by a laboratory accredited or licensed by the EDE, and in accordance with the standards of good practice prepared or approved by the EDE for good laboratory practices.

Article (27)

Medical Product Manufacturing Conditions

No Medical Product may be manufactured in the State for marketing therein, except after obtaining Marketing Approval from the EDE, provided that it is manufactured in a factory licensed in the State, in accordance with the controls and standards contained in Article (126) of this Decree-Law. The Executive Regulations of this Decree-Law shall specify the conditions and controls for licensing a locally manufactured product designated for export purposes without marketing it within the State.

Article (28)

Good Practice

The BOD shall issue, by decision, rules, guidelines and standards of good practice that are consistent with internationally recognized guidelines and standards, in order to ensure the quality, efficiency and safety of Pharmaceutical Establishments. The decision shall also determine the mechanism for issuing good practice certificates in accordance with the activity and category of the Establishment.

Article (29)

Loan of Manufacturing Materials

1. Excipients and solvents may not be loaned or transferred between licensed factories in the State except with the approval of the EDE and in the cases it permits, provided that this does not prejudice the specifications of the Medical Product to be manufactured.
2. The Executive Regulations of this law shall specify the cases, conditions and controls for obtaining the approval referred to in Clause (1) of this Article.

Article (30)

Promoting Investment in the Medical Industries Sector

A system of incentives and benefits to attract investment and support innovation and development in the medical industries sector shall be issued by a resolution of the Cabinet, based on the proposal of the President and after coordination with the Competent Health Authorities and other concerned parties.

Article (31)

Approval or Permit to Import and Export Medical Product and Raw Materials

1. It is not permitted to import, export or re-export any Medical Product or any raw materials or pharmaceutical raw materials used in its manufacture except after obtaining approval or permit from the EDE.
2. The cases specified by a resolution of the Cabinet based on the proposal of the President, after coordination with the Competent Health Authority, and in accordance with the controls and conditions included in this resolution, are excluded from Clause (1) of this Article.

Article (32)

Conditions for Issuing Import or Export Approval or Permit

1. The approval or permit to import, export or re-export Medical Products, raw materials or pharmaceutical raw materials shall be issued by the EDE in accordance with the following conditions:
   a. The existence of any type of Marketing Approval or Emergency Use approval valid from the EDE for the Medical Product to be imported or exported. Products exempted from obtaining Marketing Approval in accordance with the provisions of Article (5) of this Decree-Law are exempt from this condition.
   b. The Applicant shall be a Biobank, Pharmaceutical Laboratory, Non-Clinical and Clinical Research entity, Bioequivalence center, Medical Warehouse, Medical Products factory or contracted Medical Products manufacturing company licensed to carry out the activity specified in accordance with the provisions of this Decree-Law, its Executive Regulations and the decisions issued in implementation thereof.
   c. Fulfilling the technical and operational conditions and any other conditions, controls or requirements and the validity periods of the approval or import, export or re-export permit in accordance with the type of application submitted, which are determined by the Executive Regulations of this Decree-Law.
2. The EDE shall confirm that the conditions and requirements referred to in Clause (1) of this Article, including shipping conditions, are met by inspecting the shipments.
3. The EDE may restrict or prohibit the import, export or re-export of some Medical Products if their use poses a risk to public health or if circumstances indicate that they may be intended for illegal purposes. A list of Medical Products, raw materials or pharmaceutical raw materials whose import, export or re-export is restricted or prohibited shall be issued by a decision of the BOD.
4. Without prejudice to the laws and provisions in force concerning controlled and semi-controlled substances, narcotic drugs and psychotropic substances, the BOD shall issue a decision to regulate the procedures related to shipments of Medical Products in temporary transit using the State ports or crossing the State territory and not actually passing through it.

Article (33)

Cancellation of Approval or Permit Issued for Import or Export or Transfer of Ownership

1. The EDE shall issue a decision to cancel the approval or permit issued by it to import, export or re-export the Medical Product, raw materials or pharmaceutical raw materials, in any of the following cases:
   a. If it is proven that obtaining approval or permit from the EDE was a result of submitting forged documents or incorrect information.
   b. New clinical data or new data resulting from post-marketing surveillance activities, including an increase in the number of medical events or serious adverse reactions associated with the Medical Product, which demonstrate the unsafety of the Medical Product to be imported or exported.
   c. Reasons for cancelling or resubmitting the Marketing Approval of all types or the Emergency Use approval issued for the Medical Product to be imported or exported in the State, as stated in Article (15) and Article (17) of this Decree-Law.
   d. Withdrawal or suspension of the Marketing Approval issued for the Medical Product to be imported in the State of origin, or the State of origin revoking the authorization for international export.
   e. Receive data proving the unsafety of the raw materials or pharmaceutical raw materials to be imported or exported.
2. The Ownership of the approval or import, export or re-export permit issued by the EDE may not be transferred to another party. In the event that the Marketing Right Holder or the importing or exporting Establishment changes, a new approval or permit for import, export or re-export shall be applied for.

Article (34)

Operation Disclosure Certificate

1. A clearance certificate shall be obtained from the EDE for each batch of certain vital products that require compliance with safety, quality and efficacy standards, either after

they are manufactured in the State or for the purposes of obtaining the EDE approval to import and distribute them.

2. The Executive Regulations of this Decree-Law shall specify the types of other Medical Products subject to Clause (1) of this Article, any exceptions thereto, and the requirements that shall be met to obtain the certificate.

Article (35)

Personal Use of the Medical Product

The Executive Regulations of this Decree-Law shall specify the conditions, rules and controls for bringing, possessing or obtaining a Medical Product with any person upon entering or leaving the State for personal use, or bringing or sending the Medical Product through express shipping institutions.

Article (36)

Drug Policy Committee

Pursuant to this Decree-Law, a committee called the "Pharmaceutical Policy Committee" shall be established, reporting to the President, and shall be responsible for proposing policies related to the circulation, pricing, and monitoring of Medical Products in the State. A decision shall be issued by the Cabinet concerning its formation, jurisdiction, and the determination of its work system, based on a proposal from the Chairman.

Article (37)

Providing Medical Product

1. None of the following categories may refuse to provide a Medical Product that has obtained Marketing Approval in accordance with the provisions of this Decree-Law, in an illegal manner or with the intent to monopolize:
   a. Marketing Rights Holder
   b. The qualified person appointed by the Marketing Right Holder.
   c. The licensed Pharmaceutical Establishment designated by the Marketing Right Holder to import and market Medical Products.

2. The categories referred to in Clause (1) of this Article shall be obligated to provide a sufficient stock of the Medical Product in the State, in order to ensure the availability of the Medical Product for use within the State.
3. The categories referred to in Clause (1) of this Article shall inform the EDE, the Ministry and the Competent Health Authority of any potential or actual shortage in the stock of Medical Products, in accordance with the mechanism established by the EDE in coordination with the Ministry and the Competent Health Authorities.

Article (38)

Medical Product Information

1. No Medical Product may be traded or marketed unless the information and data recorded on the internal and external card and the paper or electronic leaflet for the Medical Product are identical to the information and data for the package included in the Annex to the Marketing Approval issued for it or similar to the details approved in the State of origin if the Medical Product is exempt from obtaining Marketing Approval. The EDE shall determine the data that shall be recorded on both the internal and external card and the information leaflet for the Medical Product.
2. At least Arabic and English shall be used in the internal leaflet, whether printed or electronic, for the Medical Product, except in cases where a decision is issued by the Chairman or his delegate.

Article (39)

Prohibitions on Circulation and Selling

1. It is prohibited to trade in counterfeit, defective or expired Medical Products.
2. The sale of free advertising samples of Medical Products is prohibited, and the outer and inner cards of these samples shall be clearly stamped, in indelible ink, with the phrase "Free Medical Sample Not for Sale" in both Arabic and English.

Article (40)

Prescription Medical Product Circulation

Non-Pharmaceutical Establishments are prohibited from importing, marketing, selling, displaying, storing or circulation any Medical Product that requires a prescription for dispensing.

Article (41)

Circulation of Medical Product Without Prescription

The Executive Regulations of this Decree-Law shall specify the types of establishments other than pharmaceuticals that are permitted to market, sell, display, store or trade Medical Products that are dispensed without a prescription, a list of these Medical Products, and the procedures, controls and conditions for regulating their sale, display, storage and trade.

Article (42)

Description or Sale of a Medical Product

1. Physicians may not prescribe a Medical Product for new uses not specified in the internal leaflet or electronic leaflet, or prescribe a Medical Product that has not been submitted for Marketing Approval, except when necessary, provided that there is no equivalent alternative available and with the patient approval. The compassionate use of the Medical Product is excluded from the provisions of this Clause.
2. It is prohibited for any licensed Healthcare Practitioner to advise, prescribe or dispense any Medical Product unless he is authorized to do so in accordance with the provisions of this Decree-Law, its Executive Regulations and the decisions issued in implementation thereof.
3. Healthcare professionals are prohibited from prescribing or advising any Medical Product for personal gain.
4. Free samples of Medical Products may not be provided to anyone other than licensed health professionals authorized to prescribe, for prescribing them to patients.

5. Licensed health professionals other than Pharmacists are prohibited from selling any Medical Product directly or indirectly except after obtaining the approval of the Ministry or the Competent Health Authority in coordination with the EDE.
6. The Executive Regulations of this Decree-Law shall specify the terms and conditions for the compassionate use of Medical Products.

Article (43)

National Policy for Strategic Stock of Medical Products

The EDE shall issue the National Policy for the Strategic Stock of Medical Products after its approval by the Cabinet. The EDE shall be responsible for its management and follow-up of its implementation at the federal and local levels in coordination with the National Emergency, Crisis and Disaster Management Authority and other Competent Health Authorities and concerned parties at the federal and local levels.

Article (44)

Medical Product Promotion and Advertising

1. It is prohibited to advertise, publicize or promote Medical Products by any means, whether visual, written, audible or on social media, unless approved by the EDE.
2. Advertising, publicity or promotion to the public of controlled, semi-controlled, hazardous or toxic chemical precursors, products or substances, whether for human or veterinary use, is prohibited.
3. The EDE may prohibit advertising, publicity or promotion of some Medical Products or restrict their advertising to targeted groups of individuals. The Executive Regulations of this Decree-Law shall specify the Medical Products whose advertising is prohibited or restricted, as well as the relevant controls and conditions.

Article (45)

Conditions for Issuing Approval to Advertise a Medical Product

The approval for advertising, publicity or promotion of Medical Products shall be issued by the EDE in accordance with the following conditions:

1. Valid Marketing Approval from the EDE for the Medical Product to be advertised. Products exempted from obtaining Marketing Approval in accordance with the provisions of Clause (3) of Article (5) of this Decree-Law are exempt from this condition.
2. The Applicant shall be a licensed pharmaceutical or healthcare Establishment.
3. The advertising material shall be truthful, not misleading, and supported by evidence reflecting the information and approved uses of the Medical Product.
4. The advertising material shall clearly disclose any risks or side effects associated with the Medical Product.
5. Fulfilling other conditions and controls for promotional advertisements in accordance with the target group, whether for health professionals or the public, in accordance with what is specified in the Executive Regulations of this Decree-Law.

Article (46)

Validity Term of Approval for Advertising a Medical Product

The approval to advertise the Medical Product issued by the EDE shall be valid for a period ranging from (30) thirty days to one year, depending on the Applicant desire. The Applicant shall obtain a new approval for each Medical Product he wishes to advertise.

Article (47)

Cancellation of Approval to Advertise or Transfer Ownership of a Medical Product

1. The EDE shall issue a decision to cancel the approval issued by it to advertise the Medical Product during its validity period (the advertisement through all means in which it was published, whether visual, written, audio, or on social media), in any of the following cases:

a. If it is proven that obtaining approval from the EDE was a result of submitting forged documents or incorrect information.
b. If it is proven that the advertising materials submitted to the EDE do not match the published advertisement.
c. If, after publication of the announcement, any new clinical data or new data resulting from post-marketing surveillance activities not previously reported indicate an increase in the number of medical events or serious adverse reactions associated with the medicinal product, which proves that the advertised medicinal product is unsafe.
d. The absence of any of the conditions for issuing approval to advertise the Medical Product mentioned in Clause (1) of Article (45) of this Decree-Law, after publishing the advertisement.
e. Withdrawal or suspension of the Marketing Approval issued for the imported Medical Product to be advertised in the State of origin, or the State of origin revoking the authorization for international export.
f. Any other cases determined by the Executive Regulation of this Decree-Law.

2. The Ownership of the approval to advertise the Medical Product issued by the EDE may not be transferred to another party, and a new application shall be submitted to obtain approval to advertise the Medical Product.

Article (48)

Approval for Safe Disposal of Medical Products

It is prohibited to destroy or safely dispose of Medical Products, except after obtaining approval from the Competent Health Establishment or Authority, each within the limits of their jurisdiction.

Article (49)

Conditions for Issuing Approval of Safe Disposal from a Medical Product

1. Approval for the destruction or safe disposal of Medical Products shall be issued by the Competent Health Establishment or Authority, each within the limits of its jurisdiction in accordance with the following conditions:

a. The Applicant shall be a Establishment licensed by the EDE, Ministry, or Competent Health Authority, or any other Establishment that has been issued approval by the EDE to import Medical Products.
b. The Application meets the requirements of the environmental legislation in force in this regard.
c. The Application shall include a specification of the licensed entity inside or outside the State that will carry out the process of destroying and safely disposing of the products in accordance with medical conditions.
d. The Application shall be accompanied by the necessary documents to ensure that the destruction or disposal process is tracked and that it is consistent with the general rules issued by the EDE in this regard, including records of the quantities of the Medical Product to be disposed of and the method of its safe disposal.
e. Obtaining any other necessary approvals from the relevant authorities in the State if the materials or products to be destroyed or disposed of are chemical precursors or controlled, semi-controlled, hazardous or toxic products and materials, whether intended for human or veterinary use.
f. Fulfilling other conditions and controls for disposing of Medical Products in accordance with their type, in accordance with what is specified in the Executive Regulations of this Decree-Law.

2. The Entity referred to in paragraph (C) of Clause (1) of this Article shall be obligated to ensure that the disposal methods followed by it comply with the applicable legislation and general rules issued by the EDE in this regard, and in a manner that ensures that they do not harm the environment and public health.
3. The Competent Health Authorities may add any other conditions related to their specializations.
4. If the approval for destruction is issued by the Competent Health Authority, a periodic report shall be submitted to the EDE, including the reasons, mechanism, and date of destruction, and the quantity and type of destroyed materials.

Article (50)

Conditions for Approval Validity Term for Safe Disposal of a Medical Product

1. The approval for the safe destruction and disposal of the Medical Product shall be valid for the period determined by the Competent Health Establishment or Authority, each within the limits of their jurisdiction.
2. The Applicant shall obtain a new approval for each batch of a Medical Product that he wishes to destroy or dispose of.

Article (51)

Cancellation of Approval of Safe Disposal of a Medical Product or Transfer of Ownership

1. The Competent Health Establishment or Authority, each within the limits of their jurisdiction, shall issue a decision to cancel the approval issued by it for the safe disposal or destruction of the Medical Product and inform the Entity referred to in paragraph (c) of Clause (1) of Article (49) of this Decree-Law of that, in any of the following cases:
   a. If it is proven that obtaining approval was a result of submitting forged documents or incorrect information.
   b. The absence of any of the conditions for issuing approval to advertise the Medical Product mentioned in Clause (1) of Article (49) of this Decree-Law, after publishing the advertisement.
   c. Any other cases determined by the Executive Regulation of this Decree-Law.
2. The Ownership of the approval for safe disposal or destruction of the Medical Product may not be transferred to another party, and a new application for approval for safe disposal or destruction of the Medical Product shall be submitted.

Part Three

Controlled and Semi-Controlled Substances, Products and Chemical Precursors

Article (52)

Prohibited Substances and Controlled Products and the Necessary Instructions Concerning Them

Subject to the provisions of any other legislation:

1. It is not permitted to install any Medical Product that is not included in a medical prescription that meets the conditions specified in this Decree-Law.
2. It is not permitted to import, export or re-export any controlled material or product without the approval issued by the EDE, and it is not permitted to install any of these products without a medical prescription that meets the conditions specified in this Decree-Law.
3. The active ingredients used in the manufacture of any of the products referred to in Clause (2) of this Article may only be used in the manufacture of Medical Products licensed for manufacture or analysis.
4. Without prejudice to the powers assigned to any relevant authority, the Chairman or his delegate shall issue the necessary instructions that ensure protection from the risks of controlled materials and products or exposure to their harmful effects, as well as instructions that prevent the misuse of materials approved for use.

Article (53)

Preservation and Circulation of Controlled Materials and Products

The controls related to the storage and circulation of controlled materials and products shall be determined by a decision of the Chairman or his delegate, in coordination with the Ministry, the Competent Health Authorities, and other relevant authorities.

Article (54)

Controlled Materials and Products

Subject to the provisions of Article (55) of this Decree-Law, it is prohibited to possess controlled materials and products except by virtue of a license issued by the competent institution, Ministry or Health Authority for Health Establishments in the State within the limits of their jurisdiction, and for the following categories exclusively:

1. The Pharmacist Responsible for controlled materials and products in the Medical Warehouse, through import, export, re-export, sale or purchase.
2. The Pharmacist Responsible for controlled materials and products in the General Pharmacy, through purchasing from the Medical Warehouse.
3. A physician licensed in accordance with the legislation in force in the State, to use it for the purposes of his profession. The Executive Regulations of this Decree-Law shall specify the specializations of the authorized physicians and the quantities of the controlled products that the physician has the right to possess.
4. Medical Product factories or contracting companies for the manufacture of Medical Products, provided that they possess controlled materials and products or raw materials for their active ingredients through import, purchase or sale in accordance with the provisions of this Decree-Law, its Executive Regulations and the decisions issued in implementation thereof.
5. Scientific institutes, research centers, Non-Clinical and Clinical Research entities, and contracting Research and Development Companies.
6. In all cases, the possession of controlled materials and products by these categories shall be limited to the places where they practice their profession.

Article (55)

Cases for Controlled Materials and Products

The Pharmacist Responsible for controlled substances and products in the pharmacy may not dispense controlled substances or products for medical use except in any of the following cases:

1. For patients, by prescription issued by a licensed human physician in accordance with the laws in force in the State.
2. For Owners of sick animals, by prescription issued by a licensed veterinarian in accordance with the laws in force in the State. The veterinarian is prohibited from issuing a prescription for any other use.
3. For doctors, by virtue of signed requests from them that include a pledge that the quantities they request of these controlled or Hazardous products are for use in their clinics, in accordance with the conditions specified by a decision issued by the President or his delegate.

Article (56)

Circulation of Controlled Materials and Products

The circulation of controlled materials and products between licensed Pharmaceutical or Health Establishments requires obtaining the approval of the Competent Authority, Ministry or Health Authority. in accordance with the competencies assigned to each of them in accordance with this Decree-Law, provided that the procedures for tracking the controlled Medical Product in force in the State are taken.

Article (57)

Import Procedures of Controlled Materials and Products

1. Pharmaceutical Establishments may not import controlled materials and products or their raw materials or pharmaceutical raw materials for their active ingredients except after the approval of the EDE based on a request submitted to it and signed by the licensed Pharmacist Responsible for managing the Pharmaceutical Establishment, which includes all details related to the controlled materials and products to be imported, their quantities and types, the State of export, as well as the method of shipping them, and the approved clearance center in the State.
2. The Executive Regulations of this Decree-Law shall determine the controls for customs clearance of these materials.

Article (58)

Periodic Inventory of Controlled Materials and Products

The person responsible for the custody of controlled materials and products in any of the categories specified in Article (54) of this Decree-Law shall conduct a periodic inventory of this custody and inform the EDE, Ministry or Competent Health Authority, each within the limits of their jurisdiction, of its results, and in the event that any is discovered. If there is a deficiency in it, the EDE, Ministry or Competent Health Authority shall be informed within a period not exceeding (2) working days. The Executive Regulations shall specify the procedures to be taken by the EDE, Ministry or Competent Health Authority in this case.

Article (59)

Hazardous or Toxic Medical Products and Materials

1. Without prejudice to the provisions of international agreements to which the State is a party, hazardous or toxic medical materials and products may not be traded except in accordance with the controls issued by a decision of the Chairman or his delegate.
2. Lists of hazardous or toxic medical materials and products shall be determined by a decision of the Chairman or his delegate, in coordination with the Competent Authorities in the State.

Article (60)

The Establishment has Suspended Working

If the Establishment that has been issued a permit to possess controlled materials and products stops working or the person responsible for it relinquishes custody of it for any reason, the person responsible for the Establishment shall inventory it and take measures to hand it over in accordance with the controls and procedures specified in the Executive Regulations of this Decree-Law, provided that the Ministry or the Competent Health Authority is informed of this.

Article (61)

Semi-Controlled Materials and Products

The list of semi-controlled medical materials and products and the terms and conditions for their circulation shall be determined by a decision of the Chairman or his delegate, in coordination with the Ministry, the Competent Health Authorities and other concerned parties, provided that their movement within the State is monitored through the electronic system stipulated under the provisions of Federal Decree-Law No. (30) of 2021 referred to.

Article (62)

Lists of Chemical Precursors

1. Without prejudice to international agreements to which the State is a party or any other law, two lists of chemical precursors used in the manufacture of Medical Products are attached to this Decree-Law.
2. The two lists of chemical precursors attached to this Decree-Law may be amended by addition or deletion, and other lists of chemical precursors may be added and amended by addition or deletion, by a decision of the Chairman or his delegate after the approval of a committee formed by a resolution of the Cabinet.

Article (63)

Prohibitions on Precursor Chemicals Used for Medical Purposes

1. It is prohibited to bring, import, export, manufacture, extract, separate, produce, possess, distribute, use in the manufacture or trade of chemical precursors without obtaining permit from the EDE.
2. The Cabinet shall issue a decision regarding the controls and conditions for circulation in chemical precursors used for medical purposes and the procedures for obtaining the EDE permit, based on the Chairman proposal.

Article (64)

Prohibitions on Precursor Chemicals Used for Medical Purposes

1. It is prohibited to bring, import, export, manufacture, extract, separate, produce, possess, distribute, use or trade in chemical precursors used for non-medical purposes without the permit of the Ministry of Interior.
2. The Cabinet shall issue a resolution concerning the controls and conditions for circulation in chemical precursors used for non-medical purposes and the procedures for obtaining permit from the Ministry of Interior, provided that this decision includes the method of circulation, keeping records, and clearing customs procedures related to these materials and chemical precursors, based on the proposal of the Minister of Interior.

Part Four

National Databases

Article (65)

National System for Tracking and Coding of Medical Products

1. The EDE, in coordination with the Competent Health Authority, shall establish a National System for the circulation, tracking and coding of Medical Products from the factory to the end user. The EDE shall manage this system in a manner that achieves the following objectives:
   a. Ensuring the validity, safety and authenticity of the Medical Product circulating in the State.
   b. Reducing and reporting grey market, counterfeit, expired or illegal Medical Products.
   c. Ensuring adequate supplies of Medical Products and strengthening emergency response capacity.
   d. Protecting investments made by Pharmaceutical Establishments in the State and protecting their intellectual property in the State, including protecting pharmaceutical trademarks and their Owners.
2. The EDE makes the system available for use and reporting by the following categories in the State:
   a. The Ministry and the relevant Health Authorities.

b. Pharmaceutical Establishments and Biobanks.
c. Health Establishments.
d. Practicing health professions.
e. The federal and local authorities concerned with customs inspection.
f. The judicial police officers mentioned in this Decree-Law. G. Patients and community members.

3. The mechanism of the system operation, data sources, controls and procedures for recording, storing, managing, using, circulating and exchanging it, making it available, and the mechanisms for linking it with the Ministry, the Competent Health Authorities, pharmaceutical and Health Establishments, Biobanks, and the relevant customs inspection authorities, and the obligations of these authorities to feed the system with any relevant data and information available to them or to their affiliated Establishments, shall be issued by a resolution of the Cabinet based on the Chairman proposal.

Article (66)

Medical Products Database and Pricing

1. A national database for Medical Products shall be established in the EDE, in which all data and information related to Medical Products, their technical specifications, pricing and other data shall be recorded and stored.
2. Determined by a decision of the BOD. The sources of this data and information, and the controls and procedures for recording, storing, managing, using, circulating, exchanging and making it available to the Ministry, the Competent Health Authorities, the public, health professionals, health and Pharmaceutical Establishments, and biobanks, and the mechanisms for linking them to the relevant databases in all health and relevant authorities, and the obligations of these authorities to provide the EDE with any relevant data and information available to them or to the Establishments affiliated with them.

Article (67)

Database of Pharmaceutical Establishments, Biobanks and Other Databases

The mechanism of the system operation, data sources, controls and procedures for recording, storing, managing, using, circulating and exchanging it, making it available, and the mechanisms for linking it with the Ministry, the Competent Health Authorities, pharmaceutical and Health Establishments, Biobanks, and the relevant customs inspection authorities, and the obligations of these authorities to feed the system with any relevant data and information available to them or to their affiliated Establishments, shall be issued by a resolution of the Cabinet based on the Chairman proposal.

Part Five

Pharmacovigilance

Article (68)

Reporting and Interested Parties

1. The BOD shall issue a decision on the controls, conditions and good vigilance practices that shall be adhered to by the Marketing Rights holder, licensed Pharmaceutical Establishments and Biobanks. The EDE shall be committed to updating them periodically in accordance with new information and educating the EDEs mentioned in this Clause about them.
2. Pharmaceutical Establishments, Biobanks and Health Establishments shall operate a system for reporting the cases mentioned in Clause (3) of this Article, and issue periodic safety reports related thereto to the EDE in accordance with the controls, conditions and good vigilance practices issued by the EDE.
3. Pharmaceutical Establishments, Biobanks, Health Establishments, the Ministry, the Competent Health Authorities, their employees, and health professionals shall inform the EDE of the following:
    a. Any serious side effects, serious adverse events, or serious adverse reactions, whether expected or unexpected, of the Medical Product, during its circulation or through local and international Clinical Research conducted on it, as soon as possible from the date of knowledge thereof, and shall not be delayed for more than (5) five days. Reporting

may be in the form of initial reports, provided that follow-up reports are submitted within a maximum of (15) fifteen days, including re-assessment of the case and after completion of the data.

b. Any side effects, adverse events, or non-serious adverse reactions of the Medical Product during its circulation or through local and international Clinical Research conducted on it, within (90) ninety days of receiving the related reports, provided that the reporting is in the form of complete reports.

c. Any complaint or report to withdraw a batch of the Medical Product or the entire Medical Product inside or outside the State within a period not exceeding (15) fifteen days from the date of knowledge of the complaint or report.

d. Any suspicion of fraud or counterfeiting of the Medical Product or suspicion of illegal trade in Medical Products by third parties immediately from the date of knowledge thereof.

e. Any defects in the quality of the Medical Product within (15) fifteen days of receiving the full reports related thereto.

4. Users of Medical Products, patients, their affiliates, and members of society as a whole shall inform the EDE directly, or inform Pharmaceutical Establishments, Health Establishments, the Ministry, or the Competent Health Authority, of any of the cases mentioned in Clause (3) of this Article, immediately from the date of becoming aware of them.

5. The EDE shall establish and manage the national electronic system to receive and document reports of the cases referred to in Clause (3) of this Article, and the related data and information received from the categories mentioned in Clauses (3-4) of this Article, and shall be committed to educating these categories about the reporting mechanism and use of the system.

6. The EDE shall determine a mechanism for documenting reports in the system referred to in Clause (5) of this Article, which may be received through the system referred to in Article (65) of this Decree-Law, or verbally or in writing outside the system by the categories mentioned in Clauses (3-4) of this Article.

7. The EDE shall investigate the reports received by it concerning the cases referred to in Clause (3) of this Article, and confirm their validity and accuracy in consultation and

coordination with the relevant pharmaceutical and Health Establishments or Biobanks. To this end, it may conduct announced and unannounced inspections, take samples, and request relevant information and documents. Based on the results of the investigation, the EDE shall suspend or withdraw the Medical Product in question or take any other necessary measures or procedures to ensure that the report is not repeated.

Article (69)

Awareness and Education on Safety Information Related to Medical Products

1. Without prejudice to the legislation in force in this regard and in cases that require ensuring the public health of individuals, the EDE is committed to educating health professionals, patients and members of society about safety information related to Medical Products, and the following information:
   a. Serious side effects, serious adverse events or serious adverse reactions, whether expected or not, for Medical Products and appropriate recommendations.
   b. Professional information on all active ingredients and excipients in the Medical Product provided that publication does not conflict with any confidential interests that deserve protection.
   c. Correct use of Medical Products for protecting health and combating their misuse.
   d. Important information about the Medical Products sector, including authorization and revocation decisions and post-marketing surveillance results.
2. The Ministry or the Competent Health Authority may educate and inform its health professionals of safety information related to Medical Products and the information referred to in Clause (1) of this Article, in accordance with good pharmacovigilance practices and any guidelines issued by the EDE related to the Medical Products in question.
3. The Ministry or the Competent Health Authority may educate and inform members of the community about the correct use of Medical Products for protecting health and combating their misuse, in accordance with good pharmacovigilance practices and any guidelines issued by the EDE and related to the Medical Products in question.

Article (70)

Suspension and Withdrawal of Medical Product

1. The EDE may suspend the circulation of the Medical Product if it is necessary to confirm information indicating its lack of quality, safety or effectiveness. The EDE shall issue a decision to withdraw the entire Medical Product or batches thereof within (30) thirty days from the date of suspension, in any of the following cases:
   a. If the Medical Product is proven to be adulterated or does not conform to the quality, safety of use or effectiveness specifications approved by the EDE.
   b. If the Medical Product is proven to be toxic or harmful under the conditions of use recommended by the manufacturer or marketer.
   c. If an unexpected or serious side effect or an unexpected or serious adverse reaction to the Medical Product is proven to have occurred after its use under the conditions of use recommended by the manufacturer or marketer.
   d. If the Marketing Approval for the Medical Product is cancelled in accordance with the provisions of Article (17) of this Decree-Law, or its production is stopped in the reference country for reasons related to the quality of the product.
   e. If it is proven that the Marketing Approval for the Medical Product was granted on the basis of incorrect documents or data or on the basis of the use of illegal methods.
   f. If any of the cases mentioned in Article (15) of this Decree-Law arise, without a new Marketing Approval or a new conditional Marketing Approval issued by the EDE.
   g. If any of the cases mentioned in Article (16) of this Decree-Law arise without the approval issued by the EDE and it is proven after the EDE assessment that it is necessary to withdraw the Medical Product.
   h. If he violates any of the conditions specified in this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.
2. The EDE shall confirm the existence of the cases referred to in Clause (1) of this Article, by investigating and confirming their validity and accuracy with the relevant pharmaceutical or Health Establishments, conducting announced and unannounced inspections, taking samples, and requesting relevant information and documents.

3. In all cases, the EDE, the Ministry, the Competent Health Authority and health professionals shall coordinate with each other concerning any measures taken in accordance with this Article. The Ministry or the Competent Health Authority also has the right to suspend the Medical Product in Pharmaceutical Establishments, Biobanks, and government and private Health Establishments licensed by it, while committing to informing the EDE in the manner specified in the Executive Regulations of this Decree-Law.

Part Six

Regulating the Practice of Pharmacy

Article (71)

Terms and Conditions for Practicing the Profession of Pharmacy and Registration Records

1. The Ministry shall be responsible for licensing the practice of the pharmacy profession in Pharmaceutical Establishments and Biobanks that are subject to the EDE license.
2. The Ministry or the Competent Health Authority shall license the practice of the pharmacy profession in Pharmaceutical Establishments and Biobanks licensed by it, each within the limits of their jurisdiction.
3. No person may practice any activity in the field of pharmacy without the License referred to in Clauses (1) or (2) of this Article.
4. A national record shall be established in the Ministry, in which data shall be recorded of those licensed to practice any activity in the field of the pharmacy profession.
5. A national record shall be established in the Competent Health Authority, in which data shall be recorded of those licensed to practice any activity in the field of the pharmacy profession.
6. Pharmacists recorded in the records mentioned in this Article are classified into categories in accordance with their academic qualifications and experience.
7. The Executive Regulations of this Decree-Law shall specify the conditions, procedures and updating of registration in the aforementioned records.

Article (72)

License Applications and License Renewals

1. The Ministry or the Competent Health Authority, each within the limits of their jurisdiction, shall consider and approve applications submitted to license or renew licenses of persons to practice the profession of pharmacy, in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.
2. The Ministry or the Competent Health Authority shall decide on the License application within (30) thirty days from the date of submission of the Application, and the decision issued to reject the License or reject its renewal shall be reasoned.
3. A grievance may be filed with the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, against the decision issued to reject the License within (15) fifteen days from the date on which the grievant becomes aware of the decision, and in accordance with the procedures in effect for each of them. The grievance shall be decided within (30) thirty days, and the decision issued to decide on the grievance shall be final.

Article (73)

Duties

A Pharmacist licensed to practice any activity in the field of the pharmacy profession shall perform his work in accordance with the principles and customs of practicing the profession, and shall preserve its honour and keep its secrets in accordance with the guide to the principles of professional conduct and the ethics of practicing the pharmacy profession in the State. He shall, in particular, do the following:

1. To practice work in the Pharmaceutical Establishment or Biobank in which he has been licensed to work, and within the limits of the activity for which he has been licensed to practice, in accordance with the terms and rules contained in the Executive Regulations of this Decree-Law.
2. To be accurate and honest in performing his work.
3. To comply with the provisions of Clause (3) of Article (68) of this Decree-Law.
4. To maintain the confidentiality of patient information that reaches him or that he becomes aware of by virtue of his work.

5. To report communicable diseases in accordance with the applicable legislation in this regard.

Article (74)

Clinical Pharmacy

Subject to the provisions of Article (72) of this Decree-Law, the Clinical Pharmacist may provide his specialized services and practice clinical pharmacy, provided that the practice is in a health Establishment licensed to provide treatment services to patients, and in partnership with the licensed treating physician supervising the patient. He may practice, in particular, the following:

1. Determining and describing the patient drug Treatment Plan or modifying it, including replacing one Medical Product with another, unless written or electronic instructions have been issued by the treating physician to prevent any modification. The Clinical Pharmacist is prohibited from performing any procedure for the patient before he is diagnosed by the licensed treating physician.
2. The specific or modified drug Treatment Plan shall be consistent with the drug product use protocol and guidelines for the treatment of the disease.
3. The Clinical Pharmacist shall share with the treating physician the records and data of the patients he cares for.
4. The treating physician shall be informed of the implementation or amendment of the plan in writing by recording the data related to the plan or the amendment thereto in the patient record prepared for the review of the treating physician and the Clinical Pharmacist together, within (24) twenty-four hours following the start of the implementation of the plan.
5. Comply with guiding patients and providing them with specialized information, including: information about the medical condition, the use of Medical Products, and the drug Treatment Plan. He shall also provide consultations concerning this information to health professionals who are members of the health team treating the patient.

6. Any of the following tasks, provided that they are consistent with the general instructions of the health Establishment in which he works, and the regulations for using Medical Products (protocols)
    a. Requesting routine tests to assess the patient condition in relation to choosing and determining a drug Treatment Plan, which include measuring pulse, temperature, blood pressure, and respiratory rate.
    b. Requesting laboratory tests related to the selection and determination of the drug Treatment Plan.
    c. Giving the patient the dose of treatment in accordance with the doctor instructions, such as injections and various vaccinations.

Article (75)

Prohibitions

A person licensed to practice the profession of pharmacy may not commit an act that violates the duties of the profession or violates the requirements of honesty or honour. He is specifically prohibited from the following:

1. Doing any act that undermines the dignity of the profession, such as unfair competition, indecent appearance, or smoking in the workplace.
2. To inform anyone of the diseases revealed by the medical prescription submitted to him or of the medicines included in this prescription that have come to his knowledge in any other way due to his practice of his profession, except in accordance with what is required by the laws in force in the State.
3. Using illegal methods to induce patients to purchase Medical Products from the Establishment in which he works.
4. Preventing Medical Products from being traded, hidden or sold at a price different from the price set by the EDE.
5. Changing the quantity, type and form of the Medical Products in his possession, in violation of the provisions stipulated in this Decree-Law.

6. Selling Medical Products that are unfit for consumption, defective, expired, or have not obtained Marketing Approval from the EDE, or that are known to be adulterated or smuggled and have been brought into the State illegally.
7. Practicing medical or healthcare activities that he is not licensed to practice, such as nursing or diagnosing diseases, except for those related to first aid as specified in the Executive Regulations of this Decree-Law.
8. Dispensing Medical Products that require a prescription without a prescription.
9. Dispensing prescriptions with a symbol or sign that is not scientifically agreed upon.
10. Agreement with a physician or Healthcare Practitioner authorized to prescribe Medical Products to write prescriptions in a special manner or with other marks agreed upon between them.
11. Insulting or criticizing any health professional in front of others.

Article (76)

Prescription

1. A licensed Pharmacist may not dispense Medical Products without a prescription, if the dispensing requires it. In all cases, the prescription shall be:
   a. Documented in clear handwriting or printed electronically and in an understandable language.
   b. Issued by a Healthcare Practitioner licensed to issue a prescription.
   c. It shows the name of the Healthcare Practitioner who issued the prescription, his seal, signature, and the date the prescription was issued.
   d. Containing the scientific name, trade name, or both, its Pharmaceutical Form, standard, method of administration, and term of use.
   e. It shows the patient full name, age, weight, and phone number.
   f. Containing information about the patient possible allergic reactions, if any.
   g. In agreement with any other requirements determined by the Executive Regulations of this Decree-Law.
2. The Executive Regulations of this decree shall specify the terms and conditions for repeating the dispensing of a medical prescription.

Article (77)

Narcotics and Psychotropic Substances

1. The Pharmacist may not dispense prescriptions that include Pharmaceutical Products containing narcotic substances or psychotropic substances in accordance with Federal Decree-Law No. (30) of 2021 referred to, unless they meet the following conditions:
   a. The prescription shall be issued from the electronic system stipulated in accordance with the provisions of Federal Decree-Law No. (30) of 2021 referred to.
   b. The prescription shall include the name of the commercial Pharmaceutical Product, the scientific name of the active ingredient, the amount of the Pharmaceutical Product, the dose in numbers and letters, the method and term of its use, the patient full name, age, address, and any other requirements required for registration on the Narcotic and Psychotropic Substances Tracking Platform.
   c. The prescribed dose shall not exceed what is stated in the scientific references used in the EDE.
2. A prescription for controlled Medical Products may not be dispensed if a period of time has elapsed since it was issued exceeding the period specified in the Executive Regulations of this Decree-Law.

Article (78)

Change or Alter What Is Stated in the Prescription

The Pharmacist may not change or alter anything contained in the medical prescription except after obtaining the written opinion of the person who issued it. An exception to this is the Pharmacist replacing a Pharmaceutical Product with a similar Pharmaceutical Product in accordance with the controls specified in the Executive Regulations of this Decree-Law.

Article (79)

Duplicate Prescription Dispensing

The Pharmacist may not repeat the dispensing of a medical prescription that contains controlled or semi-controlled substances that have the property of accumulating in the body, or that lead to habituation to their use or addiction, unless the issuing party indicates that the

prescription has been repeated, within the limits of the types of products for which a decision is issued by the BOD.

Article (80)

Prescription Mistake

The Pharmacist is obligated to contact the treating physician if he suspects or finds that there is a fundamental error in the prescription to clarify and request correction if necessary.

Article (81)

Prescription Registration

The Pharmacist shall record the prescriptions for controlled and semi-controlled substances and products that have been dispensed on the Narcotic and Psychotropic Substances Tracking Platform in force in the State.

Article (82)

Prohibition of Prescription for Self or a Relative

A Healthcare Practitioner licensed to issue a prescription may not issue a prescription for himself, his spouse, or his relatives up to the second degree for controlled substances and products.

Part Seven

License of Pharmaceutical Establishments and Biobanks

Chapter One

General Pharmacies and Pharmacy Chains

Article (83)

License Conditions

1. No person may open a General Pharmacy unless he has obtained a license from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. The following conditions shall be met to obtain a license to open a General Pharmacy:

a. To entrust its technical management to a licensed Pharmacist who is responsible and dedicated to working in it.
b. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.

3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of General Pharmacies or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a General Pharmacy shall be issued in accordance with the commercial license issued by that authority.
4. General Pharmacies operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other General Pharmacies specified by a resolution issued by the Cabinet.
5. The Owner of a General Pharmacy shall appoint citizens in the professions required by the activity of this pharmacy in accordance with the percentages specified in the legislation in force in this regard.
6. The Competent Health Authority may add any technical and health conditions and other controls for licensing General Pharmacies within their jurisdiction.
7. The Ministry and the Competent Health Authority shall inform the EDE of the Licenses issued by it to General Pharmacies and Pharmacy Chains and any other information related to General Pharmacies and Pharmacy Chains, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.

Article (84)

License Term and Renewal

1. The License to open a General Pharmacy shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.

2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed media activity from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (180) one hundred eighty days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (85)

Transfer or Assignment of Ownership of a General Pharmacy

1. Subject to the legislation in force in the State, no General Pharmacy may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, with the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, the Ownership of the General Pharmacy may be transferred to a third party in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law. The Competent Health Authority may add any other terms and conditions for transferring Ownership to a third party.

Article (86)

Prohibitions

The General Pharmacy may not:

1. Practicing any activity not licensed.
2. Practicing the activity before obtaining the final license from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

3. Circulation in Medical Products obtained from unlicensed sources, or expired, adulterated, or smuggled products, or products that were brought into the State without obtaining an official import permit from the EDE, or Marketing Approval was not obtained from the EDE if necessary, or their expiration date or data shown on the packaging was tampered with.
4. Dispensing controlled and semi-controlled medicines in an illegal manner that violates the provisions of this Decree-Law, its Executive Regulations, or the decisions issued in implementation thereof.
5. Selling a priced Medical Product at a price higher than that set by the EDE.
6. Granting discounts from the prices set by the EDE, and special prices may be set within the scope of implementing a system for dispensing Medical Products in accordance with what is specified in the Executive Regulations of this Decree-Law.
7. Dealing with other unlicensed Pharmaceutical Establishments.
8. Any other prohibitions contained in the Executive Regulations of this Decree-Law or in the local legislation in force in this regard.
9. The Owner of the General Pharmacy and the Pharmacist in charge shall be responsible for violating the provisions of this Article.

Article (87)

Temporary Closure of the General Pharmacy

1. With the exception of General Pharmacies affiliated with Government Health Establishments, the Ministry or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily close the General Pharmacy, in any of the following cases:
   a. Transferring Ownership of a General Pharmacy to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   b. Receiving a request for voluntary closure from the Owner of the General Pharmacy in the event of maintenance of the General Pharmacy or absence of the responsible person.

c. The absence of a responsible, licensed, and full-time Pharmacist to work in the General Pharmacy, or the failure to appoint licensed Pharmacists to manage it in the required number in accordance with what is specified in the decisions, regulations, and instructions issued by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

d. Committing a violation that requires the Temporary Closure of the General Pharmacy, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

2. In all cases, the matter shall be referred to the committee referred to in Clause (2) of Article (160) of this Decree-Law, within (7) seven working days from the date of the Temporary Closure of the General Pharmacy, to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date of referring the matter to it.

Article (88)

General Pharmacy License Cancellation

With the exception of General Pharmacies affiliated with Government Health Establishments, the Ministry or the Competent Health Authority, each within their jurisdiction, may issue a decision to cancel the license of the General Pharmacy, in any of the following cases:

1. The General Pharmacy is practicing an activity for which it is not licensed.
2. If it is proven that obtaining the license to open a General Pharmacy was the result of submitting forged documents or incorrect data or information.
3. The General Pharmacy remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
4. Failure to start work in the General Pharmacy within (6) six months from the date of licensing to open it without an acceptable excuse from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

5. Any other cases requiring the cancellation of the General Pharmacy license, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

Article (89)

Absence of Pharmacist in Charge

If the Pharmacist Responsible for the General Pharmacy is absent, the Owner shall entrust its responsibility to a licensed Pharmacist, after the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction. In this case, the License may be granted for a specific period in accordance with the conditions specified in the Executive Regulations of this Decree-Law.

Article (90)

General and E-Pharmacies Chain

1. It is permitted to license the opening of more than one General Pharmacy in accordance with the Pharmacy Chain System specified in the Executive Regulations of this Decree-Law.
2. The General Pharmacy and the Pharmacy Chain may provide their services electronically in accordance with a system issued by a resolution of the Minister or the head of the Competent Health Authority, each within the limits of their jurisdiction.

Article (91)

Affiliated Pharmacies

1. Government Health Authorities and Establishments may open a pharmacy or pharmacies affiliated with them after obtaining a license to do so from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, in accordance with the terms and conditions specified in this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.
2. The Ministry or the Competent Health Authority, each within the limits of their jurisdiction, may issue a license to open pharmacies affiliated with a non-health

government entity, public establishment, association, public benefit institution, or private hospital or medical Center, provided that these pharmacies are under the management of a licensed Pharmacist. The Executive Regulations of this Decree-Law shall specify the conditions for opening these pharmacies and their operating system.

Chapter Two

License to Open a Compound Pharmacy

Article (92)

License Conditions

1. No person may open a Compound Pharmacy unless he has obtained a license from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. The following conditions shall be met to obtain a license to open a Compound Pharmacy:
   a. Obtain a valid Good Installation Practice Certificate from the EDE.
   b. Its technical management shall be entrusted to a licensed, responsible Pharmacist who is dedicated to working there as a Pharmacist specializing in pharmaceutical preparations, in accordance with the conditions specified in the Executive Regulations of this Decree-Law.
   c. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.
3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Synthetic Pharmacies or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a Compound Pharmacy shall be issued in accordance with the commercial license issued by that authority.
4. Synthetic Pharmacies operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Synthetic Pharmacies specified by a resolution issued by the Cabinet.

5. The Owner of a Compound Pharmacy shall appoint citizens in the professions required by the activity of this pharmacy in accordance with the percentages specified in the legislation in force in this regard.
6. The Competent Health Authority may add any technical and health conditions and other controls for licensing Synthetic Pharmacies within their jurisdiction.
7. The Ministry and the Competent Health Authority shall inform the EDE of the Licenses issued by it to Synthetic Pharmacies and Pharmacy Chains and any other information related to Synthetic Pharmacies and Pharmacy Chains, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.

Article (93)

License Term and Renewal

1. The License to open a Compound Pharmacy shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the activity from the date the License expires until its renewal.
4. As an exception to Clause (3) of this Article, the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, may grant the Compound Pharmacy an additional period of (30) thirty days after the expiration date of the License to practice its activity in accordance with the following conditions:
   a. Obtain a valid Good Installation Practice Certificate from the EDE.
   b. There is a request to renew the License submitted in advance and under process with the competent Ministry or Health Authority, each within their jurisdiction.
5. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine

specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (94)

Transfer or Assignment of Ownership of a Compound Pharmacy

1. Subject to the legislation in force in the State, no Compound Pharmacy may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, with the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, the Ownership of the Compound Pharmacy may be transferred to a third party in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law. The Competent Health Authority may add any other terms and conditions for transferring Ownership to a third party.

Article (95)

Prohibitions

The Compound Pharmacy is prohibited from the following:

1. Practicing any activity not licensed.
2. Dealing with other unlicensed Pharmaceutical Establishments.
3. The installation of Medical Products shall not commence until after obtaining the certificate referred to in Paragraph (a) of Clause (2) of Article (92) of this Decree-Law.
4. Commencing the installation of Medical Products that are essentially copies of Medical Products that have a valid Marketing Approval from the EDE, unless there is no commercially available Medical Product that can achieve the expected direct benefit to the patient health, and similar results could not be obtained by other means.
5. Compounding Pharmacies may not conduct any activities related to improvised, unstudied formulations or the extraction process of medicines and preparations derived

from natural sources, and it is not permitted to formulate a Medical Product prepared for research, development or experimentation.

6. Any other prohibitions contained in the Executive Regulations of this Decree-Law or in the local legislation in force in this regard.

The Owner of the Compound Pharmacy and the Pharmacist in charge shall be responsible for violating the provisions of this Article.

Article (96)

License Suspension and Precautionary Closure

1. The Ministry or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily suspend the License of the Compound Pharmacy for a period not exceeding one month, in any of the following cases:
   a. Withdraw, cancel or non-renew a Compound Practice Certificate.
   b. Transfer Ownership of a Compound Pharmacy to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   c. Moving a Compound Pharmacy to another place without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   d. The absence of a responsible, licensed, and full-time Pharmacist to work in the Compound Pharmacy, or the failure to appoint licensed Pharmacists to manage it in the required number in accordance with what is specified in the decisions, regulations, and instructions issued by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   e. Proof that the Compound Pharmacy used forged documents and papers while practicing their licensed activities.
   f. Commit the prohibitions mentioned in Clauses (2-5) of Article (95) of this Decree-Law.
   g. Commit a violation that requires the Temporary Closure of the Compound Pharmacy, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

2. The Ministry or the Competent Health Authority, each within their jurisdiction, shall issue an immediate decision to close the Compound Pharmacy as precaution if its continued operation poses a risk to public health or results from its commission of violations that require precautionary closure, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.
3. In all cases, the matter shall be referred to the committee referred to in Clause (2) of Article (160) of this Decree-Law, within (7) seven working days from the date of the Temporary suspension, to consider it and decide on Temporary Closure and disciplinary responsibility, within a period not exceeding (10) ten working days from the date of referring the matter to it.

Article (97)

Compound Pharmacy License Cancellation

With the exception of General Pharmacies affiliated with Government Health Establishments, the Ministry or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily close the Compound Pharmacy, in any of the following cases:

1. The Compound Pharmacy is practicing an activity for which it is not licensed.
2. If it is proven that obtaining a license to open a Compound Pharmacy was the result of submitting forged documents or incorrect data or information.
3. The Compound Pharmacy remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
4. Failure to start work in the Compound Pharmacy within (6) six months from the date of licensing to open it without an acceptable excuse from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
5. Repeatedly performing the activity in a manner that contravenes the standards and instructions of good installation practice.
6. Repeating or not removing the violations mentioned in Article (96) of this Law within the period specified by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

7. Any other cases that require cancellation of the Compound Pharmacy License, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

Chapter Three

Medical Warehouses and Medical Stores License

Article (98)

License Conditions

1. No person may open a Medical Warehouse or Medical Store unless he has obtained a license from the EDE.
2. The following conditions shall be met to obtain a license to open a Medical Warehouse or store:
   a. Obtain a valid Good Storage and Distribution Practice Certificate from the EDE.
   b. To entrust its technical management to a Licensed Pharmacist who is responsible and dedicated to working in it.
   c. As an exception to the requirement of a full-time Pharmacist to manage the Medical Warehouse or Medical Store referred to in the previous Clause, if the activity of the Medical Warehouse or Medical Store is limited to medical equipment, it may be managed by a medical equipment engineer or a specialist in one of the health professions who is licensed and dedicated to working in it.
   d. In the event of practicing the activity of importing or exporting Medical Products in the State, it is required to obtain a license for that from the EDE, and the Executive Regulations of this Decree-Law shall specify any other activities that the Medical Warehouse or Medical Store is permitted to practice in accordance with its geographical location.
   e. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.
3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the

activity of General Pharmacies or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a General Pharmacy shall be issued in accordance with the commercial license issued by that authority.

4. Medical Warehouses and Medical Stores operating in free zones are excluded in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other General Pharmacies specified by a resolution issued by the Cabinet.
5. The Owner of Medical Warehouses and Medical Stores shall appoint citizens in the professions required by the activity of this pharmacy in accordance with the percentages specified in the legislation in force in this regard.
6. The EDE shall inform the Competent Health Authority of the Licenses issued by it to Medical Warehouse or Medical Store and any other information related to Medical Warehouse or Medical Store, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.
7. The Medical Warehouse or Medical Store may provide its services electronically in accordance with a system issued by a decision of the Chairman or his delegate.
8. The provisions of this chapter exclude Medical Stores affiliated with Government Health Establishments or in private Health Establishments, which are licensed in accordance with the terms and conditions contained in the legislation in force for licensing Health Establishments by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

Article (99)

License Term and Renewal

1. The License to open Medical Warehouses and Medical Stores shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.

3. The License Holder may not continue to practice the Medical Warehouses and Medical Stores activity from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (180) one hundred eighty days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (100)

Transfer or Assignment of Ownership of a Medical Warehouse or Medical Store

1. Subject to the legislation in force in the State, no Medical Warehouses and Medical Stores may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, the Ownership of the Medical Warehouse or Medical Store may be transferred to a third party with the approval of the EDE in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.

Article (101)

Prohibitions

The Medical Warehouse or Medical Store may not:

1. Practicing any activity not licensed.
2. Delivering or selling Medical Products or raw materials to parties other than those licensed to trade in these products.
3. Import, export, store, distribute or sell any Medical Product unless licensed to practice these activities. It is also prohibited to practice these activities without the approval of the Marketing Right Holder.
4. Dealing with other unlicensed Pharmaceutical Establishments.
5. Selling a priced Medical Product at a price higher than that set by the EDE.

6. Granting discounts from the prices set by the EDE, and special prices may be set within the scope of implementing a system for dispensing Medical Products in accordance with what is specified in the Executive Regulations of this Decree-Law.
7. Any other prohibitions specified by the Executive Regulations of this Decree-Law. The Owner of the Medical Warehouse or Medical Store and the person responsible shall be liable for violating the provisions of this Article.

Article (102)

License Suspension and Precautionary Closure

1. The EDE shall issue a decision to temporarily suspend the License of the Medical Warehouse or Medical Store, in any of the following cases:
   a. Withdraw, cancel or non-renew Certificate of Good Practice for Warehousing and Distribution.
   b. Transfer of Ownership of the Medical Warehouse or Medical Store to another person without the approval of the EDE.
   c. Move the Medical Warehouse or Medical Store from the licensed location before obtaining the EDE approval.
   d. The absence of a responsible, licensed and dedicated person or Pharmacist to work in the Medical Warehouse or Medical Store.
   e. Proof that the Medical Warehouse or Medical Store has used forged documents and papers while practicing their licensed activities.
   f. Commit the prohibitions mentioned in Clauses (6-4) of Article (101) of this Decree-Law.
   g. Any other cases that require the temporary suspension of the Medical Warehouse or Medical Store license, as determined by the Executive Regulations of this Decree-Law.
2. The EDE shall issue an immediate decision to close the Medical Warehouse or Medical Store as precaution if continuing its operation poses a threat to public health or as a result of committing violations requiring precautionary closure as determined by the Executive Regulations of this Decree-Law.

3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee within (7) seven working days from the date of the Temporary License Suspension or Precautionary Closure to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date refer the matter to it.

Article (103)

License Cancellation

The EDE shall issue a decision to cancel the License of the Medical Warehouse or Medical Store, in any of the following cases:

1. The Medical Warehouse or Medical Store is practicing an activity for which it is not licensed.
2. If it is proven that obtaining a license to open a Medical Warehouse or Medical Store or obtaining marketing approval for Medical Products was the result of submitting forged documents or incorrect data or information.
3. Circulation in counterfeit or unusable products.
4. The Medical Warehouse or Medical Store shall remain closed for a period exceeding (3) three consecutive months without an excuse acceptable to the EDE.
5. Failure to commence work in the Medical Warehouse or Medical Store within (6) six months from the date of the License to open it without an excuse acceptable to the EDE.
6. Repeatedly performing the activity in a manner that contravenes the standards and instructions of Good storage and distribution practice.
7. Repeating or not removing the violations mentioned in Article (102) of this Law within the period specified by the EDE.
8. Committing the prohibitions mentioned in Clauses (2-3) of Article (101) of this Decree-Law.
9. Any other cases that require cancellation of the license of the Medical Warehouse or Medical Store, as determined by the Executive Regulations of this Decree-Law.

Article (104)

Maintain a Public Record or Information System

1. The Pharmacist in charge or the person in charge of the Medical Warehouse or Medical Store shall maintain a general record or information system, in which the type and quantity of Medical Products received by the warehouse, the date of their supply, the quantities dispensed from the Medical Warehouse, and the parties to whom they were dispensed are regularly recorded. He shall also maintain a special record for controlled materials and products.
2. Both the Owner and the person responsible for managing the Medical Warehouse or Medical Store shall be jointly and severally responsible for these records and the accuracy of the data recorded therein.

Article (105)

Setting the Price of the Medical Product

1. The Medical Warehouse shall place the selling price to the public on the outer packaging of the Medical Product subject to pricing and approved by the EDE in a clear and easy-to-read manner before selling and delivering it. It is also obligated to place a sign to identify the Medical Warehouse mentioned in the Marketing Approval issued by the EDE as an importer in the State.
2. The Marketing Rights holder, the Pharmacists responsible in General Pharmacies or Medical Warehouses and their Owners shall be jointly liable for failure to place the public selling price approved by the EDE on the product outer packaging.

Chapter Four

Marketing Offices License

Article (106)

License Conditions

1. No person may open a Marketing Office unless he has obtained a license from the EDE.
2. The following conditions shall be met to obtain a license to open a Marketing Office:
   a. Providing evidence that the Applicant for a Marketing Office license represents the Owner of the Marketing Rights for the Medical Product to be marketed in the State.
   b. Having a valid commercial license for the activity within the field of the pharmacy profession.
   c. Its management shall be entrusted to a qualified person licensed to practice one of the health professions or the activity specified within the field of the pharmacy profession, and he shall be appointed to be responsible for managing the office and dedicated to working in it.
   d. Fulfil Any other conditions determined by the Executive Regulation of this Decree-Law. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Marketing Offices or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a General Pharmacy shall be issued in accordance with the commercial license issued by that authority.
4. Marketing Offices operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Marketing Offices specified by a resolution issued by the Cabinet.
5. The Owner of a Marketing Offices shall appoint citizens in the professions required by the activity of this pharmacy in accordance with the percentages specified in the legislation in force in this regard.

6. The Marketing Offices may provide its services electronically in accordance with a system issued by a decision of the Chairman or his delegate.
7. The Ministry and the Competent Health Authority shall inform the EDE of the Licenses issued by it to Marketing Offices and any other information related to Marketing Offices, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.

Article (107)

License Term and Renewal

1. The License to open a Marketing Offices shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the Marketing Offices activity from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (108)

Transfer or Assignment of Marketing Office

1. Subject to the legislation in force in the State, the Marketing Office may not be moved from one place to another without the approval of the EDE.
2. Without prejudice to the legislation in force in the State, the Ownership of the Marketing Office may be transferred to a third party with the approval of the EDE after providing evidence that a different Medical Products company has acquired the company

represented by the licensed Marketing Office and fulfilling the conditions and controls specified in the Executive Regulations of this Decree-Law.

Article (109)

Prohibitions

The Marketing Office may not:

1. Practice any activity not licensed.
2. Importing or storing Medical Products for sale or distribution.
3. Dealing with other unlicensed Pharmaceutical Establishments.
4. Any other prohibitions specified by the Executive Regulations of this Decree-Law.

The Owner of the Marketing Office and the person responsible shall be liable for violating the provisions of this Article.

Article (110)

Introductory Materials, Products and Free Samples

1. The Marketing Office may, through the licensed Medical Warehouse appointed by it, import the Medical Products necessary for it to perform its activity after obtaining approval from the EDE in accordance with the provisions of Article (32) of this Decree-Law.
2. As an exception to Clause (2) of Article (109) of this Decree-Law, the Marketing Office may retain free samples for identification and training on Medical Products, provided that they are stored in accordance with the conditions recommended by the manufacturer and that temperature control records related to storage are kept, and that each sample is stamped with a statement indicating that it is free and not authorized for sale in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.
3. The Executive Regulations of this Decree-Law shall specify the controls for bringing samples of Medical Products intended for the purposes of display, training and introduction to medical technologies.

Article (111)

License Suspension and Precautionary Closure

1. The EDE shall issue a decision to temporarily suspend the License of the Marketing Office, in any of the following cases:
   a. Transfer of Ownership of the Marketing Office to another person without the approval of the EDE.
   b. Move the Marketing Office from the licensed location before obtaining the EDE approval.
   c. The absence of a qualified person licensed to practice one of the health professions or the activity specified within the field of the pharmacy profession, and who is available to work in the Marketing Office.
   d. Proof that the Marketing Office has used forged documents and papers while practicing their licensed activities.
   e. Committing the prohibitions mentioned in Clauses (3) of Article (109) of this Decree-Law.
   f. Any other cases that require the temporary suspension of the Marketing Office license as determined by the Executive Regulations of this Decree-Law.
2. The EDE shall issue an immediate decision to close the Marketing Office as precaution if continuing its operation poses a threat to public health or as a result of committing violations requiring precautionary closure as determined by the Executive Regulations of this Decree-Law.
3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee within (7) seven working days from the date of the Temporary License Suspension or Precautionary Closure to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date refer the matter to it.

Article (112)

License Cancellation

The EDE shall issue a decision to cancel the License of the Marketing Office, in any of the following cases:

1. The Marketing Office is carrying out an unlicensed activity.
2. If it is proven that obtaining the license to open a Marketing Office or obtaining marketing approval for Medical Products was the result of submitting forged documents or incorrect data or information.
3. Marketing Office shall remain closed for a period exceeding (3) three consecutive months without an excuse acceptable to the EDE.
4. Failure to commence work in the Marketing Office within (3) three months from the date of the License to open it without an excuse acceptable to the EDE.
5. Repeating or not removing the violations mentioned in Article (111) of this Law within the period specified by the EDE.
6. Committing the prohibitions mentioned in Clauses (2) of Article (109) of this Decree-Law.
7. Committing a violation that requires to cancel the license Marketing Office as determined by the Executive Regulations of this Decree-Law.

Chapter Five

License Pharmaceutical Consulting Offices

Article (113)

License Conditions

1. No person may open a Pharmaceutical Consulting Office unless he has obtained a license from the EDE.
2. The following conditions shall be met to obtain a license to open a Pharmaceutical Consulting Office:
    a. To entrust its technical management to a responsible Pharmacist licensed to work in pharmaceutical consultations within the field of the pharmacy profession, and dedicated to working in it.
    b. Fulfilling other requirements specified by the Executive Regulations of this law;

3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Pharmaceutical Consulting Office or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a Pharmaceutical Consulting Office shall be issued in accordance with the commercial license issued by that authority.
4. Pharmaceutical Consulting Office operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other General Pharmacies specified by a resolution issued by the Cabinet.
5. The Owner of a Pharmaceutical Consulting Office shall appoint citizens in the professions required by the activity of this office in accordance with the percentages specified in the legislation in force in this regard.
6. The Pharmaceutical Consulting Office may provide its services electronically in accordance with a system issued by a decision of the Chairman or his delegate.
7. The EDE shall inform the Competent Health Authority of the licenses issued by it to Pharmaceutical Consulting Office and any other information related to Pharmaceutical Consulting Office, in accordance with the mechanism that is agreed upon in accordance with Article (174) of this Decree-Law.

Article (114)

License Term and Renewal

1. The License to open a Pharmaceutical Consulting Office shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License renewal application shall be submitted thirty (30) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.

3. The License Holder may not continue to practice the licensed Pharmaceutical Consulting Office from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (115)

Transfer or Assignment of Ownership of the Pharmaceutical Consulting Office

1. Subject to the legislation in force in the State, the Pharmaceutical Consulting Office may not be moved from one place to another without the approval of the EDE.
2. Without prejudice to the legislation in force in the State, the Ownership of the Pharmaceutical Consulting Office may be transferred to a third party with the approval of the EDE in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.

Article (116)

Prohibitions

Pharmaceutical Consulting Office may not:

1. Practicing any activity not licensed.
2. Import, export, store, distribute or sell any Medical Products.
3. Providing advice or consultations to areas and establishments outside the scope of its competencies specified in the Executive Regulations of this Decree-Law.
4. Dealing with other unlicensed Pharmaceutical Establishments or Biobanks.
5. Any other prohibitions specified by the Executive Regulations of this Decree-Law.

The Owner of the Pharmaceutical Consulting Office and the Pharmacist in charge shall be responsible for violating the provisions of this Article.

Article (117)

License Suspension and Precautionary Closure

1. The EDE shall issue a decision to temporarily suspend the License of the or Pharmaceutical Consulting Office, in any of the following cases:
   a. Transfer of Ownership of the Pharmaceutical Consulting Office to another person without the approval of the EDE.
   b. Moving the Pharmaceutical Consulting Office from the licensed location before obtaining the EDE approval.
   c. Lack of a responsible, licensed, and full-time Pharmacist to work in the Pharmaceutical Consulting Office.
   d. Proof that the Pharmaceutical Consulting Office has used forged documents and papers while practicing their licensed activities.
   e. Committing the prohibitions mentioned in Clauses (3-4) of Article (116) of this Decree-Law.
   f. Any other cases that require the temporary suspension of the License of the Pharmaceutical Consulting Office. The Executive Regulations of this Decree-Law.
2. The EDE shall issue an immediate decision to close the Pharmaceutical Consulting Office as precaution if continuing its operation poses a threat to public health or as a result of committing violations requiring precautionary closure as determined by the Executive Regulations of this Decree-Law.
3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee within (7) seven working days from the date of the Temporary License Suspension or Precautionary Closure to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date refer the matter to it.

Article (118)

License Cancellation

The EDE may issue a decision to cancel the license of the Pharmaceutical Consulting Office, in any of the following cases:

1. The Pharmaceutical Consulting Office is practicing an unlicensed activity.
2. If it is proven that obtaining the license to open a Pharmaceutical Consulting Office was the result of submitting forged documents or incorrect data or information.
3. The Pharmaceutical Consulting Office remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the EDE.
4. Failure to commence work in the Pharmaceutical Consulting Office within (6) six months from the date of the License to open it without an excuse acceptable to the EDE.
5. Repeating or not removing the violations mentioned in Article (117) of this Law within the period specified by the EDE.
6. Committing the prohibitions mentioned in Clauses (2) of Article (116) of this Decree-Law.
7. Any other cases that require the cancellation of the Pharmaceutical Consulting Office license as determined by the Executive Regulations of this Decree-Law.

Chapter Six

Pharmaceutical Products

Article (119)

License Conditions

1. No person may open a Pharmaceutical Laboratory unless he has obtained a license from the EDE.
2. The following conditions shall be met to obtain a license to open a Pharmaceutical Laboratory:
   a. Obtain a valid Good Laboratory Practice Certificate from the EDE.
   b. To entrust its technical management to a licensed person who is responsible and dedicated to working in it.
   c. The Pharmaceutical Laboratory shall comply with safety requirements and have preventive measures in place to ensure that no pollutants leak into the environment.

d. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.

3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Pharmaceutical Laboratory or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a Pharmaceutical Laboratory shall be issued in accordance with the commercial license issued by that authority.
4. Pharmaceutical Laboratory operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Pharmaceutical Laboratory specified by a resolution issued by the Cabinet.
5. The Owner of a Pharmaceutical Laboratory shall appoint citizens in the professions required by the activity of this laboratory in accordance with the percentages specified in the legislation in force in this regard.
6. The Executive Regulations of this Decree-Law shall specify the controls and conditions for accrediting pharmaceutical laboratories outside the State mentioned in Article (26) of this Decree-Law and the certificates issued by them.
7. The EDE shall inform the Competent Health Authority of the licenses issued by it to Pharmaceutical Laboratory and any other information related to Pharmaceutical Laboratory, in accordance with the mechanism that is agreed upon in accordance with Article (174) of this Decree-Law.

Article (120)

License Term and Renewal

1. The License to open a Pharmaceutical Laboratory shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.

2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed Pharmaceutical Laboratory activity from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (121)

Pharmaceutical Laboratory Obligations

1. The licensed Pharmaceutical Laboratory shall comply with the standards of good laboratory practice approved by the EDE.
2. The person responsible for the Pharmaceutical Laboratory shall approve the certificates of the results of laboratory tests conducted in his Establishment and issue them after they meet the quality standards approved by the EDE. He shall maintain records of data related to the tests in accordance with the systems and procedures specified by the EDE.
3. If the Pharmaceutical Laboratory wishes to import Medical Products, it shall obtain approval from the EDE in accordance with the provisions of Article (32) of this Decree-Law, provided that the purpose of the import is for the laboratory to perform its licensed activity and not for the purposes of trade and circulation.

Article (122)

Transfer or Assignment of Ownership of the Pharmaceutical Laboratory

1. Subject to the legislation in force in the State, it is not permitted to move the Pharmaceutical Laboratory from one place to another, or make any change in its plan in accordance with which its license was issued, without the approval of the EDE.
2. Without prejudice to the legislation in force in the State, the Ownership of the Pharmaceutical Laboratory may be transferred to a third party with the approval of the

EDE in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.

Article (123)

Prohibitions

The Pharmaceutical Laboratory may not:

1. Practicing any activity not licensed.
2. Importing or storing Medical Products for sale or advertisement or presenting
3. Conducting any research or testing on humans for any reason.
4. Dealing with other unlicensed Pharmaceutical Establishments or Biobanks.
5. Any other prohibitions specified by the Executive Regulations of this Decree-Law.

The Owner of the Pharmaceutical Laboratory and the person responsible shall be liable for violating the provisions of this Article.

Article (124)

License Suspension and Precautionary Closure

1. The EDE shall issue a decision to temporarily suspend the License of the Pharmaceutical Laboratory, in any of the following cases:
   a. Transfer of Ownership of the Pharmaceutical Laboratory to another person without the approval of the EDE.
   b. Move the Pharmaceutical Laboratory from the licensed location before obtaining the EDE approval.
   c. Lack of a qualified, licensed and dedicated person to work in the Pharmaceutical Laboratory.
   d. Proof that the Pharmaceutical Laboratory has used forged documents and papers while practicing their licensed activities.
   e. Committing the prohibitions mentioned in Clause (4) of Article (123) of this Decree-Law.
   f. Any other cases that require the temporary suspension of the Pharmaceutical Laboratory license as determined by the Executive Regulations of this Decree-Law.

2. The EDE shall issue an immediate decision to close the Pharmaceutical Laboratory as precaution if continuing its operation poses a threat to public health or as a result of committing violations requiring precautionary closure as determined by the Executive Regulations of this Decree-Law.
3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee within (7) seven working days from the date of the temporary license suspension or precautionary closure to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from The date the matter was referred to it.

Article (125)
License Cancellation

The EDE may issue a decision to cancel the License of the Pharmaceutical Laboratory, in any of the following cases:

1. The Pharmaceutical Laboratory is practicing an activity for which it is not licensed.
2. If it is proven that obtaining a license to open a Pharmaceutical Laboratory was the result of submitting forged documents or incorrect data or information.
3. The Pharmaceutical Laboratory remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the EDE.
4. Failure to commence work in the Pharmaceutical Laboratory within (6) six months from the date of the License to open it without an excuse acceptable to the EDE.
5. Repeating the activity in a manner that violates the standards and instructions of good laboratory practice.
6. Repeating or not removing the violations mentioned in Article (124) of this Law within the period specified by the EDE.
7. Committing the prohibitions mentioned in Clauses (3-2) of Article (123) of this Decree-Law.
8. Any other cases that require cancellation of the Pharmaceutical Laboratory license as determined by the Executive Regulations of this Decree-Law.

Chapter Seven

Licensing Medical Product Factories and Contracting Companies Manufacture Medical Products

Article (126)

License Conditions

1. No person may open a Medical Product Factories and Contracting Companies Manufacture Medical Products unless he has obtained a license from the EDE.
2. The following conditions shall be met to obtain a license to open a Medical Product Factories and Contracting Companies Manufacture Medical Products:
   a. Obtain a valid Good Manufacturing Practice Certificate from the EDE.
   b. The License Applicant or his legal representative shall be the Owner of the factory and be legally responsible for complying with the legislation and instructions issued by the EDE concerning the factory or contracting company for the manufacture of Medical Products.
   c. In the event of engaging in the activity of importing, exporting, marketing or distributing Medical Products in the State, a license shall be obtained from the EDE.
   d. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.
3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Medical Product Factories and Contracting Companies Manufacture Medical Products or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a Medical Product Factories and Contracting Companies Manufacture Medical Products shall be issued in accordance with the commercial license issued by that authority.
4. Medical Product Factories and Contracting Companies Manufacture Medical Products operating in free zones are exempted from the percentage referred to in Clause (3) of this

Article, as are any other Medical Product Factories and Contracting Companies Manufacture Medical Products specified by a resolution issued by the Cabinet.

5. The Owner of Medical Product Factories and Contracting Companies Manufacture Medical Products shall appoint citizens in the professions required by the activity of this factory or company in accordance with the percentages specified in the legislation in force in this regard.
6. The EDE shall inform the Competent Health Authority of the Licenses issued by it to Medical Product Factories and Contracting Companies Manufacture Medical Products and any other information related to Medical Product Factories and Contracting Companies Manufacture Medical Products, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.

Article (127)

Quality Management Standards and Good Manufacturing Practices

The Medical Products Manufacturer and the contracted Medical Products manufacturing company shall comply with the quality management standards and good manufacturing practices controls issued and approved by the EDE.

Article (128)

License Term and Renewal

1. The License to open a Medical Product Factories and Contracting Companies Manufacture Medical Products shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed Medical Product Factories and Contracting Companies Manufacture Medical Products activity from the date the License expires until its renewal.

4. As an exception to Clause (3) of this Article, the EDE may grant the Medical Product Factories and Contracting Companies Manufacture Medical Products an additional period of (30) thirty days after the expiration date of the license to practice its activity in accordance with the following conditions:
   a. Obtain a Valid Good Manufacturing Practice Certificate from the EDE.
   b. There is a previously submitted application for license renewal and it is under process with the EDE.
5. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (129)

Transfer of the Medical Product Factories and Contracting Companies Manufacture Medical Products or Waiving their Ownership, Taking into Account

1. Subject to the legislation in force in the State, no Medical Product Factories and Contracting Companies Manufacture Medical Products may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the EDE
2. Without prejudice to the legislation in force in the State, the Ownership of the Medical Product Factories and Contracting Companies Manufacture Medical Products may be transferred to a third party with the approval of the EDE in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law.

Article (130)

Prohibitions

Medical Product Factories and Contracting Companies Manufacture Medical Products may not:

1. Practicing any activity not licensed.
2. Remanufacturing a Medical Product that has a valid Marketing Approval with new technical specifications, except after the Marketing Right Holder obtains a new Marketing Approval to manufacture the product with these specifications from the EDE in accordance with the provisions of Article (15) of this Decree-Law.
3. Manufacture or Circulation in counterfeit or unusable products.
4. Dealing with other unlicensed Pharmaceutical Establishments.
5. The installation of Medical Products shall not commence until after obtaining the certificate referred to in Paragraph (a) of Clause (2) of Article (126) of this Decree-Law.
6. Any other prohibitions specified by the Executive Regulations of this Decree-Law.

The Owner of the Medical Product Factories and Contracting Companies Manufacture Medical Products shall be liable for violating the provisions of this Article.

Article (131)

License Suspension and Precautionary Closure

1. The EDE shall issue a decision to temporarily suspend the License of Medical Product Factories and Contracting Companies Manufacture Medical Products, in any of the following cases:
    a. Transfer of Ownership of the Factory or the Contracting Company to another person without the approval of the EDE.
    b. Move the Factory or the Contracting Company from the licensed location before obtaining the EDE approval.
    c. The absence of qualified persons for direct supervision and control in accordance with the rules in force in this field.
    d. Proof that the Factory or the Contracting Company used forged documents and papers while practicing their licensed activities.

e. Committing the prohibitions mentioned in Clauses (4) of Article (130) of this Decree-Law.
f. Any other cases that require suspension of the license of the Factory or Contracting Company as determined by the Executive Regulations of this Decree-Law.

2. The EDE shall issue an immediate decision to close the Medical Product Factories and Contracting Companies Manufacture Medical Products as precaution if continuing its operation poses a threat to public health or as a result of committing violations requiring precautionary closure as determined by the Executive Regulations of this Decree-Law.
3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee within (7) seven working days from the date of the Temporary License Suspension or Precautionary Closure to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date refer the matter to it.

Article (132)

License Cancellation

The EDE shall issue a decision to temporarily cancel the License of Medical Product Factories and Contracting Companies Manufacture Medical Products, in any of the following cases:

1. The factory or contracting company is carrying out an activity for which it is not licensed.
2. If it is proven that obtaining the license to open the Factory or Contracting Company or obtaining marketing approval for Medical Products was the result of submitting forged documents or incorrect data or information.
3. The Factory or Contracting Company remain closed for a period exceeding (3) three consecutive months without an excuse acceptable to the EDE.
4. Failure to commence work in the Factory or Contracting Company within (6) six months from the date of the License to open it without an excuse acceptable to the EDE.
5. Repeatedly performing the activity in a manner that contravenes the standards and instructions of good manufacture practice.

6. Repeating or not removing the violations mentioned in Article (131) of this Law within the period specified by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
7. Committing the prohibitions mentioned in Clauses (3-2) of Article (130) of this Decree-Law.
8. Any other cases that require cancellation of the license of the Factory or Contracting Company as determined by the Executive Regulations of this Decree-Law.

Article (133)

Setting the Price of the Medical Product

1. The Medical Product Factories and Contracting Companies Manufacture Medical Products shall place the selling price to the public on the outer packaging of the Medical Product subject to pricing and approved by the EDE in a clear and easy-to-read manner before selling and delivering it. It is also obligated to place a sign to identify the factory or the contracting company mentioned in the Marketing Approval issued by the EDE as an importer in the State. The factory or contracting company may entrust the licensed Medical Warehouse appointed by it to perform the tasks mentioned in this Clause in accordance with the controls mentioned in Article (105) of this Decree-Law.
2. Those responsible in Factory or the Contracting Company and their Owners shall be jointly liable for failure to place the public selling price approved by the EDE on the product outer packaging.

Chapter Eight

Licensing Contractual Companies for Research and Development

Article (134)

License Conditions

1. No person may open a Licensing Contractual Company for Research and Development unless he has obtained a license from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

2. The following conditions shall be met to obtain a license to open a Contractual Company for Research and Development:
    a. The License Applicant or his legal representative shall be the Owner of the Contractual Company for Research and Development and be legally responsible for complying with the legislation and instructions issued by the EDE concerning the Contractual Company for Research and Development.
    b. Obtain a valid Good Clinical Practice Certificate from the EDE.
    c. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.
3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Contractual Company for Research and Development or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open Contractual Company for Research and Development shall be issued in accordance with the commercial license issued by that authority.
4. Contractual Company for Research and Development operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Contractual Company for Research and Development specified by a resolution issued by the Cabinet.
5. The Owner of Contractual Company for Research and Development shall appoint citizens in the professions required by the activity of this pharmacy in accordance with the percentages specified in the legislation in force in this regard.
6. The Competent Health Authority may add any technical and health conditions and other controls for licensing Contractual Company for Research and Development within their jurisdiction.
7. The Competent Health Authority shall inform the EDE of the Licenses issued by it to Contractual Company for Research and Development and any other information related to Contractual Company for Research and Development, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.

8. In the event that the Contractual Company for Research and Development wishes to import pharmaceutical raw materials and Medical Products or export Medical Products in their final form to the Entity contracting with the Establishment, it shall obtain permit from the EDE in accordance with the provisions of Article (32) of this Decree-Law, provided that the purpose of the import is for the company to perform its licensed activity.
9. Contractual Company for Research and Development may provide their services electronically in accordance with a system issued by a decision of the Chairman or his delegate or the head of the Competent Health Authority, each within the limits of their jurisdiction.

Article (135)

License Term and Renewal

1. The License to open Contractual Company for Research and Development shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed Contractual Company for Research and Development activity from the date the License expires until its renewal.
4. As an exception to Clause (3) of this Article, the Competent Health Establishment or Authority, each within the limits of their jurisdiction, may grant the Contractual Company for Research and Development an additional period of (30) thirty days after the expiry date of the License to practice its activity, provided that there is a request to renew the License submitted in advance and is under process with the Competent Health Establishment or Authority, each within the limits of their jurisdiction.
5. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (136)

Transfer or Assignment of Ownership of the Contractual Company for Research and Development

1. Subject to the legislation in force in the State, no Contractual Company for Research and Development may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, with the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, the Ownership of the Contractual Company for Research and Development may be transferred to a third party in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law. The Competent Health Authority may add any other terms and conditions for transferring Ownership to a third party.

Article (137)

Prohibitions

The Contractual Company for Research and Development may not:

1. Practicing any activity not licensed.
2. Circulation in counterfeit or unusable products.
3. Manufacture of products for non-Research and Development purposes.
4. Dealing with other unlicensed Pharmaceutical Establishments or Biobanks.
5. Any other prohibitions contained in the Executive Regulations of this Decree-Law or in the local legislation in force in this regard. The Owner of the Contractual Company for Research and Development shall be liable for any violation of the provisions of this Article.

Article (138)

License Suspension and Precautionary Closure

1. The Ministry or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily suspend the License of Contractual Company for Research and Development for a period not exceeding one month, in any of the following cases:
   a. Withdrawal, cancellation or non-renewal of the Good Clinical Practice Certificate.
   b. Transferring Ownership of Contractual Company for Research and Development to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   c. Transferring Ownership of Contractual Company for Research and Development to another place without the approval of the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
   d. The absence of qualified persons for direct supervision and control in accordance with the rules in force in this field.
   e. Proof that the Contractual Company for Research and Development used forged documents and papers while practicing their licensed activities.
   f. Committing the prohibitions mentioned in Clauses (4) of Article (137) of this Decree-Law.
   g. Committing a violation that requires the Temporary Closure of the Contractual Company for Research and Development, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.
2. The EDE or the Competent Health Authority, each within their jurisdiction, shall issue an immediate decision to close the Contractual Company for Research and Development as precaution if its continued operation poses a risk to public health or results from its commission of violations that require precautionary closure, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.
3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee or the committee referred to in Clause (2) of Article (160) of this Decree-Law, as the case may be, within (7) seven working days from the date of temporarily suspending the license or Precautionary closure to consider and decide on disciplinary responsibility,

within a period not exceeding (10) ten working days from the date the matter is referred to it.

Article (139)

License Cancellation

The EDE or the Competent Health Authority, each within their jurisdiction, shall issue a decision to cancel the License of the Contractual Company for Research and Development, in any of the following cases:

1. The Contractual Company for Research and Development is carrying out an activity for which it is not licensed.
2. If it is proven that obtaining the license to open a Contractual Research and Development Company was the result of submitting forged documents or incorrect data or information.
3. The Contractual Research and Development Company remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
4. Failure to start work in the Contractual Research and Development Company within (6) six months from the date of licensing to open it without an acceptable excuse from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
5. Repeatedly engaging in an activity in a manner that contravenes relevant good practice standards and instructions.
6. Repeating or not removing the violations mentioned in Article (138) of this Law within the period specified by the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
7. Committing the prohibitions mentioned in Clauses (3-2) of Article (137) of this Decree-Law.

Any other cases that require the cancellation of the Contractual Company License for Research and Development as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

Chapter Nine

Biobank Licensing

Article (140)

License Conditions

1. No person may open a Biobank unless he has obtained a license from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. The following conditions shall be met to obtain a license to open Biobank:
   a. The existence of a quality management system that is compatible with the licensed activities.
   b. The existence of an appropriate system for tracking biological samples, and the existence of a system for reporting, investigating, recording, and transmitting information about the occurrence of any serious complications or adverse reactions that may affect the quality and safety of these samples.
   c. Fulfilling the technical and health requirements and other requirements specified by the Executive Regulations of this Decree-Law.
3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Biobank or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a Biobank shall be issued in accordance with the commercial license issued by that authority.
4. Biobank operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Biobank specified by a resolution issued by the Cabinet.
5. The Owner of Biobank shall appoint citizens in the professions required by the activity of this bank in accordance with the percentages specified in the legislation in force in this regard.
6. The Competent Health Authority may add any technical and health conditions and other controls for licensing Biobank within their jurisdiction.

7. If the Biobank wishes to import Medical Products, it shall obtain approval from the EDE in accordance with the provisions of Article (32) of this Decree-Law, provided that the purpose of the import is for the Biobank to perform its licensed activity and not for the purposes of trade and circulation.
8. The Competent Health Authority shall inform the EDE of the Licenses issued by it to Biobanks and any other information related to Biobanks, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.
9. Biobank may provide their services electronically in accordance with a system issued by a decision of the Chairman or his delegate or the head of the Competent Health Authority, each within the limits of their jurisdiction.
10. The Cabinet shall issue a decision based on a proposal from the President, in coordination with the Competent Health Authorities, to regulate the work of Biobanks in accordance with their activity.
11. The regulatory and operational standards for the blood transfusion system in the State shall be issued by a resolution of the Cabinet based on the proposal of the President.

Article (141)

Licensing of Blood Storage Units in Government and Private Health Establishments

1. Blood storage units may not be established in government or private Health Establishments without obtaining a license from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Blood storage units in government and private health facilities are licensed in accordance with the conditions and controls contained in the applicable legislation for licensing government and private health facilities by the ministry or the competent health authority, each within the limits of their jurisdiction.

Article (142)

License Term and Renewal

1. The License to open a Biobank shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed Biobank activity from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (143)

Transfer or Assignment of Biobank

1. Subject to the legislation in force in the State, no Biobank may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, with the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, the Ownership of the Biobank may be transferred to a third party in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law. The Competent Health Authority may add any other terms and conditions for transferring Ownership to a third party.

Article (144)

Prohibitions

Biobank may not:

1. Practicing any activity not licensed.
2. Importing or exporting biological samples without obtaining the approval of the Competent Health Establishment or Authority, each within the limits of their jurisdiction.
3. Dealing with other unlicensed Pharmaceutical Establishments or Biobanks.
4. Any other prohibitions contained in the Executive Regulations of this Decree-Law or in the local legislation in force in this regard. The Owner of the Biobank shall be liable for any violation of the provisions of this Article.

Article (145)

License Suspension and Precautionary Closure

1. The EDE or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily suspend the License of the Biobank, in any of the following cases:
   a. Transferring Ownership of a Biobank to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   b. Transferring Ownership of a Biobank to another place without the approval of the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
   c. The absence of qualified persons for direct supervision and control in accordance with the rules in force in this field.
   d. Proof that the Biobank has used forged documents and papers while practicing their licensed activities.
   e. Committing the prohibitions mentioned in Clauses (3) of Article (144) of this Decree-Law.
   f. Committing a violation that requires the Temporary Closure of the Biobank, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

2. The EDE or the Competent Health Authority, each within their jurisdiction, shall issue an immediate decision to close the Biobank as precaution if its continued operation poses a risk to public health or results from its commission of violations that require precautionary closure, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.
3. In all cases, the matter shall be referred to the committee referred to in Clause (2) of Article (160) of this Decree-Law, within (7) seven working days from the date of the Temporary Closure of the General Pharmacy, to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date of referring the matter to it.
4. In the event of a precautionary closure or temporary suspension of the Biobank, it shall take the necessary measures under the supervision of the Competent Health Establishment or Authority, each within their jurisdiction, to ensure that the biological samples stored therein will be transferred to another Establishment or Establishments licensed within the State to store biological samples.

Article (146)

License Cancellation

1. The Competent Health Establishment or Authority, each within the limits of their jurisdiction, may issue a decision to cancel the Biobank license, in any of the following cases:
   a. The Biobank is carrying out an unlicensed activity.
   b. If it is proven that obtaining the license to open the Biobank was the result of submitting forged documents or incorrect data or information.
   c. The Biobank remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
   d. Failure to start work in the Biobank within (6) six months from the date of licensing to open it without an acceptable excuse from the EDE or the Competent Health Authority, each within the limits of their jurisdiction.

e. Repeating or not removing the violations mentioned in Article (145) of this Law within the period specified by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
f. Committing the prohibitions mentioned in Clauses (2) of Article (144) of this Decree-Law.
g. Committing a violation that requires the License Cancellation of the Biobank, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

2. In the event of license cancellation of the Biobank, it shall take the necessary measures under the supervision of the Competent Health Establishment or Authority, each within their jurisdiction, to ensure that the biological samples stored therein will be transferred to another Establishment or Establishments licensed within the State to store biological samples.

Chapter Ten
Licensing Non-Clinical and Clinical Research Entities
Article (147)
License Conditions

1. No person may open Non-Clinical and Clinical Research Entity unless he has obtained a license from the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
2. The following conditions shall be met to obtain a license to open a Clinical Research Entity:
   a. Obtain a valid Good Clinical Practice Certificate from the EDE.
   b. The existence of a quality management system that is consistent with licensed activities and good clinical practice guidelines, and the existence of a documented system of written standard operating procedures that define the processes and responsibilities for conducting Clinical Research.
   c. The presence of a qualified and specialized cadre in the field of Clinical Research in accordance with the applicable legislation in this regard.

d. There is an appropriate system in place to protect and ensure the confidentiality of data, including personal data of research participants and Clinical Research outcomes.
e. Having an appropriate system in place to track and manage biological samples and to maintain and document records.
f. Having a system in place to report adverse events and reactions that could affect the health and safety of participants in Clinical Research.
g. Providing the necessary infrastructure and Establishments at the Clinical Research site to ensure the safety of participants.
h. Fulfilling the other conditions for the license, including the conditions for accrediting the clinical research site, which are specified in the Executive Regulations of this Decree-Law

3. The following conditions shall be met to obtain a license to open a Non-Clinical Research Entity:
   a. Compliance of the non-Clinical Research entity with relevant good practice principles and codes issued or approved by the EDE.
   b. The existence of a quality management system that is consistent with licensed activities and good clinical practice guidelines, and the existence of a documented system of written standard operating procedures that define the processes and responsibilities for conducting Clinical and non-clinical Research.
   c. The presence of a qualified and specialized cadre in the field of Clinical Research in accordance with the applicable legislation in this regard.
   d. Having an appropriate system to protect and ensure the confidentiality of data and research outputs.
   e. Having an appropriate system in place to track and manage biological samples and to maintain and document records.
   f. Fulfilling the other conditions for the license specified by the executive regulations of this Decree-Law.
4. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Clinical and non-clinical Research or to open the way for full foreign

Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open a Clinical and non-clinical Research shall be issued in accordance with the commercial license issued by that authority.

5. Clinical and Non-Clinical Research Entity operating in free zones are exempted from the percentage referred to in Clause (4) of this Article, as are any other Clinical and Non-Clinical Research Entity specified by a resolution issued by the Cabinet.
6. The Owner of Clinical and Non-Clinical Research Entity shall appoint citizens in the professions required by the activity of this pharmacy in accordance with the percentages specified in the legislation in force in this regard.
7. The Competent Health Authority may add any technical and health conditions and other controls for licensing Clinical and Non-Clinical Research Entity within their jurisdiction.
8. If the Clinical and Non-Clinical Research Entity wishes to import Medical Products, it shall obtain approval from the EDE in accordance with the provisions of Article (32) of this Decree-Law, provided that the purpose of the import is for the entity to perform its licensed activity and not for the purposes of trade and circulation.
9. The Competent Health Authority shall inform the EDE of the Licenses issued by it to Clinical and Non-Clinical Research Entity and any other information related to Clinical and Non-Clinical Research Entity, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.
10. Clinical and Non-Clinical Research Entity may provide their services electronically in accordance with a system issued by a decision of the Chairman or his delegate or the head of the Competent Health Authority, each within the limits of their jurisdiction.

Article (148)

License Term and Renewal

1. The License to open Clinical and Non-Clinical Research Entity shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.

2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed Clinical and Non-Clinical Research Entity activity from the date the License expires until its renewal.
4. Failure to submit a license renewal application within ninety (90) days from the date of expiry shall result in the automatic cancellation of the License and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (149)

Transfer or Assignment of Ownership of Non-Clinical and Clinical Research

1. Subject to the legislation in force in the State, Clinical and Non-Clinical Research Entity may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, with the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, the Ownership of the Clinical and Non-Clinical Research Entity may be transferred to a third party in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law. The Competent Health Authority may add any other terms and conditions for transferring Ownership to a third party.

Article (150)

Prohibitions

Non-Clinical and Clinical Research Entities may not:

1. Practicing any activity not licensed.
2. Conducting any clinical or non-Clinical Research without obtaining the necessary approvals in accordance with the relevant legislation.

3. Importing or exporting biological samples without obtaining the approval of the Competent Health Establishment or Authority, each within the limits of their jurisdiction.
4. Dealing with other unlicensed Pharmaceutical Establishments or Biobanks.
5. Any other prohibitions contained in the executive regulations of this Decree-Law or in the legislation regulating this regard or in the local legislation in force in this regard.

Article (151)

License Suspension and Precautionary Closure

1. The Ministry or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily suspend the License of the Non-Clinical and Clinical Research Entity for a period not exceeding one month, in any of the following cases:
   a. Withdrawal, cancellation or non-renewal of the Good Clinical Practice Certificate.
   b. Transferring Ownership of Non-Clinical and Clinical Research Entity to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   c. Transferring Ownership of Non-Clinical and Clinical Research Entity to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
   d. The absence of qualified persons for direct supervision and control in accordance with the rules in force in this field.
   e. Proof that the Non-Clinical and Clinical Research Entity used forged documents and papers while practicing their licensed activities.
   f. Committing the prohibitions mentioned in Clauses (4) of Article (150) of this Decree-Law.
   g. Committing a violation that requires the Temporary Closure of the Non-Clinical and Clinical Research Entity, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.
2. The EDE or the Competent Health Authority, each within their jurisdiction, shall issue an immediate decision to close the Non-Clinical and Clinical Research Entity as precaution if its continued operation poses a risk to public health or results from its commission of

violations that require precautionary closure, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

3. In all cases, the matter shall be referred to the committee referred to in Clause (2) of Article (160) of this Decree-Law, within (7) seven working days from the date of the Temporary Closure, to consider it and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date of referring the matter to it.

Article (152)

License Cancellation

The EDE or the Competent Health Authority, each within their jurisdiction, shall issue a decision to cancel the License of the Non-Clinical and Clinical Research Entity, in any of the following cases:

1. The Non-Clinical and Clinical Research Entity is engaged in an activity for which it is not licensed.
2. If it is proven that obtaining the license to open a Non-Clinical and Clinical Research Entity was the result of submitting forged documents or incorrect data or information.
3. The Non-Clinical and Clinical Research Entity remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
4. Failure to start work in the Non-Clinical and Clinical Research Entity within (6) six months from the date of licensing to open it without an acceptable excuse from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
5. Repeatedly engaging in an activity in a manner that contravenes relevant good practice standards and instructions.
6. Repeating or not removing the violations mentioned in Article (151) of this Law within the period specified by the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
7. Committing the prohibitions mentioned in Clauses (3-2) of Article (150) of this Decree-Law.

8. Committing a violation that requires cancellation of the Non-Clinical and Clinical Research Entity, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

Chapter Eleven

Licensing of Bioequivalence Centers

Article (153)

License Conditions

1. No person may open Bioequivalence Centre unless he has obtained a license from the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
2. The following conditions shall be met to obtain a license to open a Bioequivalence Centre:
   a. Obtain a valid Good Clinical Practice and/or Good Laboratory Practice certificate from the EDE.
   b. The existence of a quality management system that is consistent with licensed activities and good clinical practice guidelines, and the existence of a documented system of written standard operating procedures that define the processes and responsibilities for conducting Bioequivalence studies.
   c. The presence of a qualified and specialized cadre in the field of Bioequivalence studies and research in accordance with the applicable legislation in this regard.
   d. There is an appropriate system in place to protect and ensure the confidentiality of data, including personal data of research participants and Bioequivalence studies and research outcomes.
   e. Having an appropriate system in place to track and manage samples and to maintain and document records.
   f. Having a system in place to report adverse events and reactions that could affect the health and safety of participants in study and research.
   g. Providing the necessary infrastructure and Establishments at the study and research site to ensure the safety of participants.
   h. Fulfilling the other conditions for the license, including the conditions for accrediting the research or study site specified by the Executive Regulations of this Decree-Law.

3. Subject to the provisions of the Commercial Companies Law, the Local Authority responsible for corporate affairs in the relevant emirate shall have the EDE to determine a specific percentage of citizens' contribution to the capital of a company that carries out the activity of Bioequivalence Centre or to open the way for full foreign Ownership, while determining the percentage of citizens' participation in the BOD of companies established within their jurisdiction. The License to open Bioequivalence Centre shall be issued in accordance with the commercial license issued by that authority.
4. Bioequivalence Centre operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other General Pharmacies specified by a resolution issued by the Cabinet.
5. The Owner of Bioequivalence Centre shall appoint citizens in the professions required by the activity of this center in accordance with the percentages specified in the legislation in force in this regard.
6. The Competent Health Authority may add any technical and health conditions and other controls for licensing Bioequivalence Centre within their jurisdiction.
7. If the Bioequivalence Centre wishes to import Medical Products, it shall obtain approval from the EDE in accordance with the provisions of Article (32) of this Decree-Law, provided that the purpose of the import is for the laboratory to perform its licensed activity and not for the purposes of trade and circulation.
8. The Competent Health Authority shall inform the EDE of the Licenses issued by it to Bioequivalence Centre and any other information related to Biobanks, in accordance with the mechanism agreed upon in accordance with Article (174) of this Decree-Law.
9. Bioequivalence Centre may provide their services electronically in accordance with a system issued by a decision of the Chairman or his delegate or the head of the Competent Health Authority, each within the limits of their jurisdiction.

Article (154)

License Term and Renewal

1. The License to open Bioequivalence Centre shall be valid for a period of not less than one year, renewable. The License holder shall comply with practicing the licensed activity during the specified period of validity of the License.
2. The License Renewal Application shall be submitted sixty (60) days before its expiration date, and the renewal shall be made in accordance with the same terms and conditions specified for issuing the License for the first time.
3. The License Holder may not continue to practice the licensed Bioequivalence Centre activity from the date the License expires until its renewal.
4. Failure to submit a License Renewal Application within ninety (90) days from the date of expiry shall result in the automatic License Cancellation and the imposition of the fine specified in the Regulations of Violations and Administrative Penalties issued for the implementation of the Decree-Law.

Article (155)

Transfer or Transfer of Bioequivalence Centre

1. Subject to the legislation in force in the State, no Bioequivalence Centre may be transferred from one place to another, or any change made to its plan under which it was licensed, without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
2. Without prejudice to the legislation in force in the State, with the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, the Ownership of the Bioequivalence Centre may be transferred to a third party in accordance with the terms and conditions specified in the Executive Regulations of this Decree-Law. The Competent Health Authority may add any other terms and conditions for transferring Ownership to a third party.

Article (156)

Prohibitions

Bioequivalence Centre may not:

1. Practicing any activity not licensed.
2. Conducting any clinical or non-Clinical Research without obtaining the necessary approvals in accordance with the relevant legislation.
3. Importing or exporting biological samples without obtaining the approval of the Competent Health Establishment or Authority, each within the limits of their jurisdiction.
4. Dealing with other unlicensed Pharmaceutical Establishments or Biobanks.
5. Any other prohibitions contained in the Executive Regulations of this Decree-Law or in the local legislation in force in this regard. The Owner of the Bioequivalence Centre shall be liable for any violation of the provisions of this Article.

Article (157)

License Suspension and Precautionary Closure

1. The EDE or the Competent Health Authority, each within their jurisdiction, shall issue a decision to temporarily suspend the License of the Bioequivalence Centre, in any of the following cases:
    a. Withdraw or cancel or. Failure to renew the Good Clinical Practice and/or Good Laboratory Practice certificate.
    b. Transferring Ownership of a Bioequivalence Centre to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
    c. Transferring Ownership of Bioequivalence Centre to another person without the approval of the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
    d. The absence of qualified persons for direct supervision and control in accordance with the rules in force in this field.

e. Proof that the Bioequivalence Centre has used forged documents and papers while practicing their licensed activities. Committing the prohibitions mentioned in Clauses (4) of Article (156) of this Decree-Law.
f. Committing a violation that requires the license suspension of Bioequivalence Centre, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

2. The EDE or the Competent Health Authority, each within their jurisdiction, shall issue an immediate decision to close the Bioequivalence Centre as precaution if its continued operation poses a risk to public health or results from its commission of violations that require precautionary closure, as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.
3. In all cases, the matter must be referred to the EDE Pharmaceutical Practices Control Committee or the committee referred to in Clause (2) of Article (160) of this Decree-Law, as the case may be, within (7) seven working days from the date of temporarily suspending the license or Precautionary closure to consider and decide on disciplinary responsibility, within a period not exceeding (10) ten working days from the date the matter is referred to it.

Article (158)

License Cancellation

The EDE or the Competent Health Authority, each within their jurisdiction, shall issue a decision to cancel the license of the Bioequivalence Centre, in any of the following cases:

1. The Bioequivalence Centre is carrying out an unlicensed activity.
2. If it is proven that obtaining a license to open a Bioequivalence Centre was the result of submitting forged documents or incorrect data or information.
3. The Bioequivalence Centre remains closed for a period exceeding (3) three consecutive months without an excuse acceptable to the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.

4. Failure to start work in the Bioequivalence Centre within (9) six months from the date of licensing to open it without an acceptable excuse from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction.
5. Repeatedly engaging in an activity in a manner that contravenes relevant good practice standards and instructions.
6. Repeating or not removing the violations mentioned in Article (157) of this Law within the period specified by the EDE or the Competent Health Authority, each within the limits of their jurisdiction.
7. Committing the prohibitions mentioned in Clauses (3-2) of Article (156) of this Decree-Law.
8. Any other cases that require cancellation of the Bioequivalence Centre License as determined by the Executive Regulations of this Decree-Law or the local legislation in force in this regard.

Article (159)

Control and Inspection

1. The EDE, Ministry or Competent Health Authority, each within the limits of their jurisdiction, shall supervise the compliance of Pharmaceutical Establishments and Biobanks with the provisions of this Decree-Law, its Executive Regulations and the decisions issued in implementation thereof, including the licensing conditions, approvals and permits issued, and for this purpose it may carry out inspections, take samples and request the necessary information and documents.
2. The EDE shall supervise and inspect shipments of Medical Products and logistics centers in ports and outlets, in all regions of the State, including free zones. To this end, it may conduct announced and unannounced inspections, take samples, and request the necessary information and documents.
3. The EDE shall carry out inspections of Pharmaceutical Establishments and Biobanks licensed by the Ministry or the Competent Health Authority, in coordination with it, and for this purpose it may take samples and request the necessary information and documents.

4. The EDE may cooperate with the Ministry and the Competent Health Authority to conduct joint monitoring of the compliance of licensed Pharmaceutical Establishments and Biobanks and to ensure the availability of sufficient stock of Medical Products therein, and it may form work teams to conduct joint monitoring.

Part Eight

Administrative and Disciplinary Accountability and Criminal Sanctions

Chapter One

Administrative and Disciplinary Questioning

Article (160)

Disciplinary Sanctions

1. Without prejudice to the criminal penalties stipulated in this Decree-Law or any other laws, the EDE, Ministry or Competent Health Authority, each within the limits of their jurisdiction, may impose any of the following disciplinary penalties:
   a. Concerning violations committed by Pharmaceutical Establishments and Biobanks in violation of the provisions of this Decree-Law, its Executive Regulations, or the decisions issued in implementation thereof:
      1. Written warning.
      2. Written warning.
      3. A fine not less than on hundred thousand AED (1,000) and not exceeding one million AED (1,000,000) shall be imposed on any person who:
      4. Suspension of license for a period not exceeding (6) six months.
      5. License Cancellation.

         General Pharmacies affiliated with Government Health Establishments are exempted from the penalties of temporary suspension of the License and cancellation of the License.
   b. With regard to violations committed by practitioners of the pharmacy profession in violation of the provisions of this Decree-Law, its Executive Regulations, or the decisions issued in implementation thereof:
      1. Written warning.

2. Written warning.
3. A fine not less than one thousand AED (1,000) and not exceeding five hundred thousand AED (500,000) shall be imposed on any person who:
4. Temporary suspension of the professional license for a period not exceeding one year.
5. License Cancellation.

2. The disciplinary violations referred to in Clause (1) of this Article shall be considered by a committee established in each of the Ministry, the Competent Health Authority, or the Pharmaceutical Practices Control Committee established in the EDE, as the case may be.

Article (161)

Penalty Record

A record shall be established in each of the EDE, the Ministry and the Competent Health Authority, in which the penalties imposed on License Holders shall be recorded. These authorities shall exchange data on violations and penalties imposed on each of the Pharmaceutical Establishments, Biobanks and their employees.

Article (162)

Appeal Against Disciplinary Penalty

1. Anyone against whom a disciplinary penalty decision has been issued in accordance with Article (160) of this Decree-Law may appeal the decision before the Appeals Committee referred to in Article (170) of this Decree-Law, which is formed within the competent institution, Ministry or Health Authority, each within the limits of their jurisdiction, within (15) fifteen days from the date on which the appellant becomes aware of the decision.
2. The grievance shall be decided upon within (30) thirty days from the date of its submission, with a reasoned decision. Failure to respond to the grievance within that period shall be considered a rejection of it.
3. The resolution issued on the Appeal shall be final.

4. In all cases, the decision to suspend or cancel the License may not be implemented for any practitioner, Pharmaceutical Establishment, or Biobank, before the end of the deadline for filing a grievance or the deadline for deciding on it, as the case may be.

Article (163)

Non-Prejudice to Criminal and Civil Liability

Disciplinary accountability in accordance with the provisions of this Decree-Law shall not prejudice criminal or civil liability, where applicable.

Criminal Penalties

Article (164)

1. Any one who shall be punished by imprisonment for a period of not less than (6) six months and not exceeding (2) two years and a fine of not less than (50,000) fifty thousand AED and not more than (200,000) two hundred thousand AED, or either of these two penalties:
   a. Submits forged or incorrect documents, provides incorrect information, or resorts to illegal methods to obtain a license, in violation of the provisions of this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.
   b. Violated the provisions of Clause (3) of Article (71) of this Decree-Law.
   c. Opening a Pharmaceutical Establishment or Biobank without a license.
   d. Engaging in the activity of importing, exporting, distributing, marketing or promoting Medical Products or any raw materials or pharmaceutical raw materials used in their manufacture without obtaining a license to do so.
   e. Engaging in any other activity covered by this Decree-Law without obtaining a license to do so.
2. A penalty of imprisonment for a period of no less than one year and not exceeding five (5) years, and a fine not less than (100,000) one hundred thousand AED and not exceeding (500,000) five hundred thousand AED, or one of these two penalties shall be imposed on whoever:
   a. Violated the provisions of Clause (1) of Article (59) of this Decree-Law.

b. Violating the terms and conditions for circulation in semi-controlled medical materials and products stipulated in Article (61) of this Decree-Law.
c. Violates any provision of Articles: (4) Clause (2), (5) Clause (1), (19), (25) Clauses (1 and 2), (27), (31 Clause 1), (52) Clauses (31), (63), 144 Clause (2), (150) Clause (3), (156) Clause (3) of this Decree-Law.

3. Whoever violates the provisions of Article (64) of this Decree-Law shall be punished by imprisonment for a period of not less than one year and not more than (5) five years, or by a fine of not less than (100,000) one hundred thousand AED and not more than (500,000) five hundred thousand AED, or by either of these two penalties. If the violation of the provisions of this Article is with the intent to use chemical precursors in the manufacture or production of narcotic substances or psychotropic substances, the penalty shall be life imprisonment.

Article (165)

1. Any one who shall be punished by imprisonment for a period of not less than (6) six months and not exceeding one year and a fine of not less than (50,000) fifty thousand AED and not more than (200,000) two hundred thousand AED, or either of these two penalties:
   a. The Owner of the Pharmaceutical Establishment or Biobank and the person responsible therein if the Pharmaceutical Establishment or Biobank to which it belongs practices an unlicensed activity or deals with other unlicensed Pharmaceutical Establishments or Biobanks.
   b. He practiced the licensed activity after the expiry of the License validity period in violation of the provisions of this Decree-Law.
   c. Violates any provision of Articles (21) Clause (6), (23) Clause (3), (37), (38) Clause (1), (42) Clauses 1-3), (44), (48), (55), (68) Clause (3), (73) Clause (3), (75) Clause (7), (77), (82), (130) Clause (2) of this Decree-Law.
2. A criminal action shall not be initiated for violating the provisions of Articles (21) Clause (6), (23) Clause (3), (68) Clause 3, (73 Clause 3) except upon a written request from the President, the Minister, or the head of the Competent Health Authority, each within the limits of their jurisdiction.

Article (166)

A fine not exceeding two one hundred thousand AED (100,000) shall be imposed on any person who:

1. Violation of the approved pricing of Medical Products by the EDE, and the penalty will be doubled in the event of recurrence.
2. Practicing a pharmacy profession without a license.

Article (167)

Imprisonment and a fine not less than on two hundred thousand AED (200,000) and not exceeding two million AED (1,000,000) shall be imposed on any person who:

1. Fraud or counterfeiting a Medical Product, raw materials or chemicals, or selling them to others, or bringing them in illegally, or smuggling them into the State.
2. Manufacture of counterfeit or unfit Medical Products or violation of the provisions of Clause (1) of Article (39) of this Decree-Law.
3. Violated the provisions of Clause (5) or (6) of Article (75) of this Decree-Law.

Article (168)

Additional Penalties

1. In all cases, the court may, in addition to the prescribed penalties, rule to close the Pharmaceutical Establishment or Biobank for a period not exceeding (3) three months or to close it permanently with the withdrawal of the License.
2. In the event of conviction, the offending materials shall be confiscated.
3. The violator shall bear the cost of destroying the materials.

Article (169)

Non-Prejudice to a More Severe Penalty

The Application of the penalties stated in this Decree shall not prejudice any more severe penalty provided by any other law.

Part Nine

Final Provisions

Article (170)

Appeal Against Decisions Issued in Implementation of the Provisions of this Decree-Law

Subject to Article (162) of this Decree-Law, anyone against whom a decision has been issued in implementation of the provisions of this Decree-Law may file a grievance before the Grievance Committee formed for this purpose by a decision of the Chairman, the Minister, or the head of the Competent Authority, each within the limits of their jurisdiction, within (15) fifteen days from the date of his knowledge of the decision. The Committee shall decide on the grievance within (30) thirty days from the date of its submission to it by a reasoned decision. Failure to respond to the grievance within that period shall be considered a rejection of it, and the decision issued concerning the grievance shall be final.

Article (171)

Practicing the Profession of Pharmacy in Government Agencies

The Ministry, the Competent Health Authority, the federal Health Authority, and the federal and local non-health government authority may appoint Pharmacists to practice the profession, provided that they obtain a license to practice from the Ministry or the Competent Health Authority, each within the limits of their jurisdiction, and in accordance with the controls specified in this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.

Article (172)

Judicial Police Officers

By a decision of the Minister of Justice in agreement with the Chairman or the Minister, or by a decision of the head of the competent local judicial authority in agreement with the head of the competent health authority, as the case may be, to authorize some employees to have the status of judicial control officers to prove what falls within the scope of their jurisdiction in violation of the provisions of this Decree-Law, its executive regulations, and decisions. issued in implementation thereof.

Article (173)

Obtaining the Required Licenses

Obtaining the Licenses stipulated in this Decree-Law does not exempt from obtaining other licenses required by the laws, regulations or systems in force in the State.

Article (174)

Mutual Notice

The EDE, the Ministry and the Competent Health Authority shall establish a mechanism for mutual notification of licenses issued by them to Pharmaceutical Establishments and Biobanks and any information related thereto.

Article (175)

Regularization

Those who are under the provisions of this Law at the time of its issuance shall regularize their status in accordance with its provisions within a period not exceeding one year from the date of enforcement. This period may be extended by a resolution of the Cabinet for another similar period.

Article (176)

Executive Resolutions

1. The Executive Regulations of this Decree-Law shall specify, in particular, the terms and conditions of the following:
   a. Providing the necessary Pharmaceutical Products and medical supplies to meet the community needs on a permanent basis.
   b. Circulation donated Medical Products.
   c. Temporary licensing for visiting Pharmacists.
   d. Maintaining Medical Products during pharmacy maintenance.
2. The Executive Regulations of this Decree-Law shall be issued by a resolution of the Cabinet based on the proposal of the President and after coordination with the Ministry, the Competent Health Authorities and other concerned parties.
3. The Chairman, the Minister, or the head of the Competent Health Authority shall issue any other decisions necessary to implement the provisions of this Decree-Law, each within the limits of their jurisdiction, including the list of violations and administrative penalties, in compliance with the provisions of this Decree-Law.

Article (177)

Fees and Fines

The Cabinet shall issue, based on the proposal of the Minister of Finance, the necessary decisions to determine the fees for services provided by the EDE, the Ministry, and the Ministry of Interior, in implementation of the provisions of this Decree-Law, its Executive Regulations, and the decisions issued in implementation thereof.

Article (178)

Authorization

The Cabinet may issue a decision to delegate some of the powers of the Ministry or institution stipulated in this Decree-Law to any federal or local government EDE, based on the proposal of the minister or the president, each within the limits of their jurisdiction.

Article (179)

Committees

The Cabinet may establish one or more committees based on the President proposal to enable the EDE to exercise its powers stipulated in this Decree-Law.

Article (180)

Repeals

1. The aforementioned Federal Law No. (8) of 2019 is hereby repealed, as well as any provision that violates or contradicts the provisions of this Decree-Law.
2. The regulations and resolutions applying the aforementioned Federal Law No. (8) of 2019 shall remain in force without contradiction to the provisions of this Law, until regulations and resolutions have been issued to replace them.

Article (181)

Publication and Entry into Force of Decree-Law

This Decree-Law shall be published in the Official Gazette and shall enter into force as of January 02, 2025.

Mohammed Bin Zayed Al Nahyan

President of the United Arab Emirates

Issued by us at the Presidential Palace in Abu Dhabi:

On: 28 Rabi' Al-Awwal 1446 A.H.

Corresponding to: October 01, 2024 AD

List No. (1)

Number	Chemical Name in English	Chemical Name in Arabic	Synonyms IUPAC	CAS Number
1	N-Phenethyl-4-piperidone (NPP)	N-فينيتيل-4-بيبريدون	(1-(2-phenylethyl) -piperidin-4-one)	39742-60-4
2	1-Phenyl-2-propanone (P-2-P)	1-فينيل-2-بروبانون	(1-phenyl-2-propanone)	103-79-7
3	3,4-methylenedioxyphenyl -2-propanone (3,4- MDP-2-P)	3، 4- ميثيلين ديوكسو فينيل-2-بروبانون	(2-propanone,1-[3,4(methylenedioxy)phenyl]-)	4676-39-5
4	4-Anilino-N-phenethylpiperidine (ANPP)	4-أنيلينو - N- فينيتيل بيبيريدين	(N-phenyl-1-(2-phenylethyl) piperidin-4-amine)	21409-26-7
5	Acetic Anhydride	أنهيدريد الخل	(acetic oxide)	108-24-7
6	alpha-Phenylacetoacetonitrile (APAAN)	ألفا – فينيل أسيتو أسيتونيتريل	(3-oxo-2-phenylbutanenitrile)	4468-48-8
7	Ephedrine	الإيفيدرين	([R-(R*,S*)]-α-[1-(methylamino)ethyl]-benzenemethanol)	299-42-3
8	Ergometrine	الإيرغومترين	(ergoline-8-carboxamide,9,10-didehydro-N-(2-hydroxy-1-methylethyl)-6-methyl-,[8ß(S)])	60-79-7
9	Ergotamine	الإيرغوتامين	(ergotaman-3',6',18'-trione, 12'-hydroxy-2'-methyl-5'-(phenylmethyl)-,(5α))	113-15-5
10	Isosafrole	الإيسوسافرول	(1,3-benzodioxole,5-(1-propenyl) -)	120-58-1
11	Lysergic acid	حمض الليسرجيك	((8ß)-9,10-didehydro-6-methylergoline-8-carboxylic acid)	82-58-6
12	N-Acetylanthranilicacid	N- حمض أستيل الأنترانيل	(benzoic acid, 2-(acetylamino)-)	89-52-1
13	Norephedrine	النورإيفيدرين	(R*,S*)-α-(1-aminoethyl)benzenemethanol	14838-15-4

14	Phenylacetic acid	حمض فينيل الخل	(benzeneacetic acid)	103-82-2
15	Piperonal	البيبيرونال	(1,3-benzodioxole-5-carboxaldehyde)	120-57-0
16	Potassium Permanganate	برمنغنات البوتاسيوم	(permanganic acid (HMnO4), potassium salt)	7722-64-7
17	Pseudoephedrine	السودوإيفيدرين	([S-(R*,R*)]-α-[1-(methylamino)ethyl]-benzenemethanol)	90-82-4
18	Safrole	السافرول	(1,3-benzodioxole,5-(2-propenyl) -)	94-59-7
19	3,4-MDP-2-P methyl glycidate (PMK glycidate)	4,3 - ميثيلين ديوكسي فينيل -2- بروبانون ميثيل غليسيدات	(2-oxiranecarboxylic acid, 3-(1,3-benzodioxol-5-yl) -2-methyl-, methyl ester)	13605-48-6
20	Methyl alphaphenylacetoacetate (MAPA)	الميثيل ألفا - فينيل أسيتوأسيتات	(methyl 3-oxo-2-phenylbutanoate)	16648-44-5
21	alphaPhenylacetoacetamide (APAA)	ألفا – فينيل أسيتو أسيتاميد	(benzeneacetamide, α-acetyl-)	4433-77-6
22	3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid)	4،3 ميثيلين ديوكسي فينيل - 2- بروبانون حمض ميثيل غليسيديك	(2-oxiranecarboxylic acid, 3-(1,3-benzodioxol-5-yl) -2-methyl-)	2167189-50-4
23	4-AP (N-phenyl-4-piperidinamine)	N- فينيل -4- بيبيريدينامين (4- أنيلينو بيبيريدين)	(4-piperidinamine, N-phenyl-)	23056-29-3
24	1-boc-4-AP (tert-butyl- 4-(phenylamino) piperidine-1- carboxylate	ثلاثي - بوتيل 4 - (فينيل أمينو) بيبريدين - 1 - كربوكسيلات	(4-phenylamino) -1-piperidinecarboxylic acid,1,1 dimethylethyl ester)	125541-22-2
25	Norfentanyl	النورفنتانيل	(Propanamide, N-phenyl-N-4-piperidinyl-)	1609-66-1
26	Diethyl (phenylacetyl) propanedioate (DEPAPD)	داي إيثيل (فينيل أسيتيل) بروباندوات	Diethyl 2-(2- phenylacetyl) propanedioate, propanedioic acid, diethyl (phenylacetyl) malonate,1,3-diethyl ester	20320-59-6

List No. (2)

Number	Chemical Name in English	Chemical Name in Arabic	Synonyms IUPAC	CAS Number
1	Acetone	الأسيتون	(2-propanone)	67-64-1
2	Anthranilic acid	حمض الأنترانيل	(2-aminobenzoic acid)	118-92-3
3	Ethyl ether	إيتر الإيثيل	(1,1'-oxybis[ethane])	60-29-7
4	Hydrochloric acid	حمض الهيدروكلوريك	(hydrochloric acid)	7647-01-0
5	Methyl ethyl ketone	ميتيل إيثيل كيتون	(2-butanone)	78-93-3
6	Piperidine	البيبيريدين	(piperidine)	110-89-4
7	Sulphuric acid	حمض الكبريتيك	(sulfuric acid)	7664-93-9
8	Toluene	التولوين	(benzene, methyl-)	108-88-3