Federal Law No. (8) of 2019

on Medical Products, Pharmacy Profession and Pharmaceutical Establishments

We, Khalifa Bin Zayed Al Nahyan, President of the UAE,

Having reviewed the Constitution;

- Federal Law No. (1) of 1972 Concerning the Competences of Ministries and the Powers of Ministers, as amended;

- Federal Law No. (8) of 1980 on the Regulation of Labor Relations, as amended;

- Federal Law No. (18) of 1981 on the Regulation of Commercial Agencies, as amended;

- Federal Law No. (4) of 1983 on the Pharmacy Profession and Pharmaceutical Establishments;

- Federal Law No. (3) of 1987 Promulgating the Penal Code, as amended;

- Federal Law No. (35) of 1992 Promulgating the Criminal Procedure Law, as amended;

- Federal Law No. (37) of 1992 on Trademarks, as amended;

- Federal Law No. (18) of 1983 Promulgating the Commercial Transactions Law, as amended;

- Federal Law No. (14) of 1995 On the Combating of Narcotic Drugs and Psychotropic Substances, as amended;

-Federal Law No. (20) of 1995 on the Drugs and Products Derived from Natural Sources;

- Federal Law No. (17) of 2002 on the Regulation and Protection of Industrial Property of Patents, Industrial Drawings and Designs, as amended;

- Federal Law No. (1) of 2006 on Electronic Commerce and Transactions;

- Federal Law No. (24) of 2006 On Consumer Protection, as amended;

- Federal Law No. (51) of 2006 on Combating Human Trafficking Crimes, as amended;

- Federal Law No. (6) of 2007 on the Establishment of the Insurance Authority and Regulating its Work, as amended;

- Federal Law No. (14) of 2014 on Combating the Communicable Diseases;

- Federal Law No. (2) of 2015 on Commercial Companies, as amended;

- Federal Law No. (4) of 2015 on Private Health Facilities;

- Federal Law No. (8) of 2015 on the Federal Customs Authority;

- Federal Law No. (3) of 2016 Concerning Child Rights, (Wadeema's Law)

- Federal Law No. (4) of 2016 on Medical Liability;

- Federal Law No. (16) of 2016 Establishing the Emirates Health Services (EHS);

- Federal Law No. (19) of 2016 on Combating the Commercial Fraud;

- Federal Law No. (9) of 2017 on Veterinary Preparations;

- Federal Law No. (13) of 2018 on Voluntary Work;

- Federal Law No. (2) of 2019 on the use of Information and Communications Technology in Health Fields; and

- Based upon the proposal of the Minister of Health and Prevention, and the approval thereof by the Cabinet and Federal National Council, and the Ratification thereof of the Federal Supreme Council,

Hereby enact the following Law:

Part I

General Provisions

Article (1)

Definitions

For the purpose of applying the provisions hereof, the following words and expressions shall have the meanings assigned thereto respectively, unless the context otherwise requires:

State	:	The United Arab Emirates.
Ministry	:	The Ministry of Health and Prevention.
Minister	:	The Minister of Health and Prevention.
Competent Department	:	The Ministry's Administrative Unit concerned.
Body Concerned	:	The local government health body or the local authority, each within its area of competence.
Competent Body	:	The Ministry's Drugs Department or the equivalent units of the bodies concerned.
Supreme Committee on Drug Policies	:	The official body in charge of setting up the policies relating to the circulation, pricing and monitoring of medical products in the State.
Competent Committee	:	Any committee the composition of which is issued under a resolution by the Minister, and is charged with considering the matters entrusted thereto in connection with one or more of the duties set out in the Law.
Medical Product	:	Each drug product, medical means or product intended for health care.
Drug Product	:	Any product that has an active ingredient or a set of active ingredients that help achieve the hoped-for purpose of its use on or over the human or animal body through a biological effect, and is manufactured, sold or offered for sale in the following cases:

1. Diagnosis, treatment, cure, alleviation of pain or prevention from a disease.
2. Organ functions reactivation, modification or rectification.

Medical Means : A medical product that contains a substance, device, tool, implant, instrument, detector or system, including its accessories and operation software, and which achieves the hoped-for purpose of being used in or on the human or animal body with no pharmaceutical or immune impact or assimilation, and is manufactured, sold or displayed for use in the following cases:

1. Diagnosis, treatment, cure, alleviation of pain, control or prevention of disease, injury or disability.
2. Detecting, compensating or modifying an anatomical situation.

Healthcare Product : Any medical product used for general human healthcare and is not intended for the diagnosis, treatment, cure or prevention of any disease, and its sale does not necessitate a medical prescription or doctor's supervision upon use.

Veterinary Product : A medical product produced in a specific pharmaceutical form to be used only on or over the animal.

Pharmaceutical Product : A medical product produced in a specific pharmaceutical form and has specific uses in humans or animals.

New Medical Product : A medical product that has an altogether-new active ingredient, and no medical product that contains the same ingredient has ever obtained a Marketing Authorization within the State, and the marketing of products that contain its active ingredient has not been actually carried out for a period that exceeds two years.

Pharmaceutical Equivalent : The pharmaceutical product that is identical to another pharmaceutical product, and has the same type and quantity of active ingredients and the same pharmaceutical form, and is biologically equivalent thereto.

Defective Product : Any medical product that neither satisfies quality requirements nor fulfills the requirements specified in this Law or the Regulations or the resolutions

issued in implementation hereof.

Counterfeit Product : The medical product intentionally made for counterfeiting or fraudulent purposes, including:

1. Providing its cover or package, label or patient information leaflet with incorrect or false information about its identity or source, in a way quite contrary to true fact.
2. Imitating another medical product using the same technical shapes and colors of the original product's package, cover and label.
3. Adding or removing one or more active or inactive ingredients to or from its composition printed on its package, cover, label or patient information leaflet without the approval of the Competent Department.
4. Making a change in the quantity or size of one or more ingredients from its active or inactive ingredients without the approval of the Competent Department.

Raw Materials : The materials involved in the composition or manufacturing of the medical product.

Marketing Authorization : The approval granted by the Ministry to the holder of the medical product marketing right in the State.

Annex to Marketing Authorization : An attachment to the Marketing Authorization that contains all details relating to the product and its description, composition, active and inactive ingredients and their quantities, uses, dosages, methods of application, side effects and any further details specified by the Law and its Executive Regulations as well as the rules and instructions issued in implementation thereof.

Patient Information leaflet : an information leaflet that contains important and brief information of the Marketing Authorization Annex, which is directed to the medical product's users.

Active Ingredient	:	One or more substances that are responsible for the basic effects of the medical product, and can be obtained from the humans, animals, plants, microorganisms, chemicals or others.
Basic Effects of Medical Product	:	The effects that occur to the medical product's uses contained within its Marketing Authorization.
New Use	:	A use newly added to the former list of authorized uses of the medical product that has been approved to be marketed in the State, so that such a new use is the result of effects separate from the basic effects of its past uses.
Approved Pharmacopoeia	:	The reference drug pharmacopoeia approved in the State.
Pharmaceutical Form	:	The medical product's form that is prepared or manufactured, including the medical product's final form taken by the patient.
New Method of Use	:	A new method of administration of the medical product in respect of which no prior Marketing Authorization has been granted in the State, for the sake of getting the basic effects of the product.
Side Effect	:	Aggregate indicators and symptoms documented in the patient information leaflet and are expected to occur to certain patients, and which may be suffered by the patient in the course of using the medical product, according to the uses, dosage and methods of use written on the cover or card of the medical product, or in its patient information leaflet and are specified in the Marketing Authorization.
Adverse Reaction	:	Any unintended and unwanted effect or reaction that occurs to the user of the medical product within the dosages documented in the patient information leaflet and authorized uses within the Marketing Authorization, and which occur due to effects separate from the basic effects off the product.
Adverse Event	:	An unwanted medical occurrence to the medical product's user, and which does not necessarily have a causal relationship with the administration of

the medical product.

Unexpected Adverse Reaction : adverse reactions unexpected to occur in the course of using the medical product, and nature or severity of which exceeds that documented in the Marketing Authorization annex.

Serious Side Effect or Serious Adverse Event : Unwanted and unintended medical event of treatment, which causes any of the following results to the user of the medical product at any dosage or in any method:

1. Death
2. Causing a threatening case to his life, which requires his / her admission to hospital or causes prolonged stay in hospital.
3. Permanent disability or handicap.
4. Death, congenital or organ disfigurement of baby or any adverse effects to him / her.

Preclinical Studies : Toxic and pharmaceutical studies carried out on non-humans to ensure the viability of a medical product.

Clinical Studies : Studies or research intended to monitor a particular medical product, and are conducted on groups of humans to identify the ways of its absorption, metabolism, distribution and getting it out of the body, in order to pinpoint its basic effects, side effects and adverse reactions, with the aim of verifying the effectiveness, efficiency, quality and safe use of the medical product within the pre-approved uses according to the Marketing Authorization granted to the medical product or for new uses or any drugs undergoing research and development.

Non-Interventional Clinical Studies : Clinical studies in which medical products are used within dosages and methods of use and uses that are conforming to the Marketing Authorization thereof in the State, and which do not require persons undergoing such studies to have any change in the medical prescription or normal lifestyle.

Bioavailability : The speed and extent of absorption and availability of the active ingredient

of the medical product or any of its active receptors in the blood or the place of its effect on the body.

Bioequivalence : The absence of any clear statistical difference relating to the biological equivalence of the active ingredient in a pharmaceutical product with another product that has the same ingredient.

Research Information : Any information obtained as a result of research in chemistry, manufacturing, clinical and preclinical research for upholding the viability, effectiveness and quality of an altogether new medical product to get the Marketing Authorization.

Equivalent Substitute : A substitute drug product of another product, to which it is therapeutically equivalent and produces the same therapeutic effect, benefits and limits of drug safety for the patient, according to its approved uses.

Stability Studies : Tests performed under circumstances either similar to or more intense than the approved storage conditions, for increasing the rate of chemical or physical decomposition of the medical product, for the sake of monitoring the cracking reactions or detecting any signs of the product's non-viability, for the sake of determining the validity period of the product under approved storage conditions.

Batch : A particular quantity of the production unit of a particular medical product that is manufactured all at once and bears an identification number in addition to the manufacturing date after going through the necessary check and testing phases.

Product Recall : The process through which a product is taken back, either in whole or only a batch thereof, on the grounds of product defects or to verify the authenticity of a complaint claiming the occurrence of an adverse reaction or a serious side effect, or for any other reasons announced by the recalling entity. Product recall takes place either at the initiative of the manufacturer, distributor or importer, or under the order of the body concerned or the Ministry.

Reference State	:	The State whose approval of marketing the medical product therein is adopted as a ground for giving the approval for the same to be marketed in the target State.
Healthcare Practitioner	:	An educationally and technically qualified person who is licensed to practice a healthcare profession in the State named by the Executive Regulations hereof.
Pharmacy Profession	:	A healthcare profession aiming to improve the health level of medical products' users through correct or optimal use of the same, based upon scientific specialized knowledge. Pharmacy profession includes a number of activities for which the pharmacist is licensed to carry out, and is, by no means, limited to the manufacturing, composition, prescription, delivery (handling), sale or storage of any medical product, or providing pharmaceutical consultation, but also covers any other activities determined by a minister's resolution. It also involves the provision of a wide variety of healthcare services to the patient either directly or through the support of other licensed healthcare practitioners, through communication and providing the clinical consultation (technical and scientific).
Clinical Pharmacy	:	A branch of Pharmacy Profession that is based upon specialist technical knowledge to ensure that the patient takes advantage of the therapeutically treatment plan as much as possible for the sake of patient's recovery, health improvement, or protection from diseases or repercussions.
Qualified Person	:	An educationally and technically qualified person who is licensed to practice a particular activity within the scope of the pharmacy profession or medicine, in accordance with the provisions hereof and the Executive Regulations hereof.
Pharmacist	:	A person holding an education qualification of not less than bachelor's certificate in pharmacy or the equivalent thereof from a higher education institute, faculty or a university duly recognized in the State, and is licensed to engage in pharmacy profession within the State, in accordance with the

provisions hereof and the Executive Regulations hereof.

Pharmacist in-charge : A pharmacist whose licensed is attached to the licensed pharmacy, and is responsible for implementing the professions hereof and the executive regulations hereof within the scope of the duties assigned to him / her.

Precautionary Closure : A precautionary measure taken by the inspector against the pharmaceutical facility in case there is a gross violation that may lead to detriment to public health.

Clinical Pharmacist : A person holding certified educational certificates in clinical pharmacology, and has in-depth expertise in this field, and is in charge of developing therapeutical plans for patients, including the use of medical products based upon the scientific analysis of the patient's condition and the reports relating to the diagnosis of his / her case. He / She also is required to provide specialist medical consultation on the patient's drug therapy and the optimum use of medical products for healthcare practitioners who are members of the health team that is responsible for the patient, and for the patient himself / herself.

Pharmacy Technician : A person holding an education qualification of not less than diploma in pharmacy, and who spend an educational duration of not less than two years after obtaining the high school certificate or the equivalent thereof from a recognized institution, and is licensed to engage in pharmacy technician profession under the direct supervision of a pharmacist duly licensed under the provisions hereof.

Prescription : A written or electronic document issued by a healthcare practitioner who is legally licensed to make prescriptions, and delivered to a healthcare practitioner who is legally licensed to dispense of or handle the items prescribed, in accordance with the Executive Regulations of this Law and the resolutions, regulations and instructions issued in this respect. The prescription shall include the oral prescription uttered a healthcare

practitioner, provided that the same is subsequently documented in a written form as stipulated by a minister's resolution.

Patient Pharmaceutical Care Plan : A plan that includes the use of medical products designed depending on precise analysis of the patient's case and status to generate the best results possible for his / her treatment. The plan includes the timeline for administering the products with specified name, type, pharmaceutical form, gauge, method of use, quantity per dose, number of doses per day, treatment duration along with any other instructions, such as the consecutive use of products or gradual adjustment of doses and the like.

Medical Product Use Protocol : A system adopted by the health institution or the treating physician, specifying the medical cases where the medical product is permitted to be used, warnings against its use, conditions governing the sequential use of the product, dose, treatment duration and how to use it.

Medical Case Treatment Guide : The system which governs how to make progress in the treatment of a particular medical case based upon precise instructions that describe the diagnosis conditions of the medical case, the medical products and other therapeutic measures on a case-by-case basis, and their sequential use or employment.

Direct Supervision and Control : Full knowledge and comprehensive follow-up at all times on all activities carried out by those working at the pharmaceutical facility.

Distribution Channels : The pharmaceutical facilities through which the medical product passes as part of its distribution cycle, starting from the place of manufacturing its final form until it is disposed of to the end user in the State.

Pharmaceutical Facility : An entity duly licensed to engage in any of the pharmacy profession branches in the State, including the pharmacy, pharmacy chain, Medical Warehouse, marketing firms, marketing consultation firms, pharmaceutical lab, pharmaceutical research center, factory, along with any other entities specified by the Executive Regulations hereof.

Pharmacy : A facility duly licensed to store, process, compose, dispense of, display or sell

medical products to the public directly, through a fixed or mobile, permanent or temporary premises.

Pharmacy Chain : A group of pharmacies owned by a single natural or legal person and bearing the same title.

Medical Warehouse : The place duly licensed to store the medical product according to the provisions of this Law and the Executive Regulations hereof. The warehouse may be licensed either for import and distribution or for distribution only.

Storage : The process of keeping the medical product at any time within its cycle in manufacturing and distribution channels.

Distribution : Moving or bringing a medical product out of the facilities of the manufacturing facility or any other central point to the end user or to any other middle point between them, using well-equipped means of transport.

Importer : The person duly licensed to import any quantity of medical products from outside the State for the purpose of possession, storage, distribution or wholesale thereof.

Distributor : The person duly licensed to engage in any business activity relating to the circulation of a medical product, except for import and direct sale to the public.

Authorized Marketer : The legal person duly licensed in the State to market a particular medical product, and is responsible for all aspects of its marketing, promotion and follow up in the State.

Manufacturing : A set of activities involving the purchase of raw materials and products used in manufacturing, production operations, including the preparation, composition, derivation, packaging, re-packaging of any medical product and specific control over the same, or approving the product or others as set forth in the Executive Regulations hereof.

Factory : The facility intended for manufacturing medical products, in whole or in part.

Product Manufacturing Approval:	:	The Ministry-issued approval granted to the Manufacturer duly licensed in the State to manufacture a particular medical product, in whole or in part.
Authorized Manufacturer	:	The pharmaceutical facility duly licensed to manufacture the medical product, in whole or in part, in accordance with the conditions and procedures stipulated in the Executive Regulations hereof.
Marketing Firm	:	The pharmaceutical facility duly licensed to engage in the business activity of promoting medical products before healthcare practitioners and following up on the circulation of the same within the State.
Pharmaceutical Consulting Firm	:	The pharmaceutical facility duly licensed to engage in the business activity of providing specialist consultations in pharmacy profession application fields.
Pharmaceutical Laboratory	:	The pharmaceutical facility duly licensed to test and examine medical products and monitor their quality.
Laboratory Studies	:	Studies and research conducted on one or more medical products or any of its components within the scope of the laboratory and laboratory examinations, in order to identify its toxic, chemical, physical, microbiological or technical properties. Such studies may not be performed on humans, but may be performed on animals.
Research Center	:	The pharmaceutical facility duly licensed to conduct clinical research, bioavailability or bioequivalence research, and studies relating to the measurement of levels of active ingredients in liquids and biological tissues.
Toxic Substances and Plants	:	The substances and plants so described under the legislation governing such a type of substances and plants.
Narcotic Drugs and Psychotropic Substances	:	Medical, therapeutic and other products that contain any of the active ingredients specified in the Federal Law No. (14) of 1995 referred to hereinabove.
Semi-Controlled Substances	:	They are substances or drugs not classified as Narcotic drugs and Psychotropic Substances, yet their movement must be monitored within the

State, because their misuse may eventually be detrimental to the public health

Precursor Chemicals : A chemical substance involved in any phase of manufacturing or producing Narcotic drugs, psychotropic substances, hazardous substances or substances of psychological or toxic effect according to the lists attached to this Law and any subsequent amendments thereto.

Prohibited Veterinary Substances : The substances so defined according to the legislation regulating this category of substances.

Hazardous Medical Products : The products whose names and field of prohibited uses are specified under a resolution of the Minister.

Controlled Substances and Products : The products and substances whose medical and commercial circulation necessitates special supervisory measures; namely:

1. Toxic substances and plants;
2. Prohibited veterinary substances;
3. Narcotic drugs and psychotropic substances; and
4. Hazardous medical products

Article (2)

Scope of Application

The provisions hereof shall apply to medical products, pharmacy profession and pharmaceutical establishments in the State, including the free zones, in accordance with the controls stipulated in this Law and the Executive Regulations hereof.

Part II

Regulation and Circulation of Medical Products

Chapter I

Marketing Authorization and Authorized Marketer

Article (3)

Marketing Authorization

No medical product may be circulated in the State unless the marketing authorization or approval for exclusive marketing is obtained from the Ministry in accordance with the rules, conditions and procedures to be determined under the Minister's resolution, without prejudice to the applicable legislation on veterinary products.

Article (4)

Evaluation of Product's satisfaction of Research Information

Marketing authorization of the new medical product or for a new use or adopting a new method shall be issued by the Ministry depending on the evaluation of the product's satisfaction of research information that proves its effectiveness, safe use, conformity with the approved quality standards or marketing approvals of the product issued by the reference states, provided that the applicant has the right to market the product in accordance with the intellectual property and trademark rules.

Article (5)

Product Pricing

For the circulation of a medical product that has obtained the marketing authorization, it must have a price. Pricing shall not include the medical products determined under a resolution of the Minister.

Article (6)

Marketing Authorization of Pharmaceutical Equivalent

Without prejudice to both the provisions of international agreements to which the State is a party and the provisions of above-referenced Federal Law No. (17) of 2002, the Ministry may issue the marketing authorization of a pharmaceutical equivalent, depending on its biological and specific equivalence to a pharmaceutical product whose legal protection is removed, and a marketing authorization has been issued for it in accordance with the provisions hereof.

Article (7)

License Applicant's Obligations

The person applying for medical products marketing license shall abide by the following:

1. Appointing one or more qualified persons residing in the State, as determined by a minister's resolution.
2. Providing one or more Medical Warehouses to carry out all activities relating to the import, storage, distribution and wholesale of products licensed to be marketed.
3. Monitoring the movement of medical products throughout the distribution channels.
4. Proving the capabilities and systems required for satisfying the requirements of getting the marketing authorization of the medical product.

5. Monitoring the performance of the medical product licensed to be marketed, and receiving reports from health facilities in terms of effectiveness, safe use and quality of the medical product in question.
6. Reporitng to both the Ministry and the Body Concerned not later than (15) ffteen days from the date of being aware of unexpected side effects as well as unexpected adverse reactions, any Serious Side Effect or Serious Adverse Event being reported or detected in the course of circulation of the medical product or through the local and global clinical studies performed thereon.
7. Following on the medical product recall procedures.
8. Following up on the medical product's patent protection affairs as well as manufacturing rights.

Article (8)

Sale of Priced Medical Product

1. The priced medical product may not be sold at a price higher than that set by the Ministry.
2. Discounts from the prices set by the Ministry may not be granted, but special prices may be set in the course of applying the drugs dispensing system by the bodies named in the Executive Regulations of this Law.

Article (9)

Obligations of Person Appointed by Authorized Marketer

The qualified person appointed by the Authorized Marketer shall abide by the following:

1. Providing pharmaceutical or scientific information about the medical product intended to be marketed to health facilities, and ensuring that the same is accurate and conforming to the Ministry-approved information.
2. Reporting to the Ministry any change or updating in manufacturing or composition

methods, the source of active ingredients, labeling or packaging, methods of specific examination of the medical product, and of any new use of the medical product, or any change, updating, addition or removal of the uses specified in the marketing authorization, in order to get the Ministry's approval of the same. The Ministry shall communicate the information and data so reported to the bodies concerned after having them approved.

3. Monitoring the side effects of the medical product within the State, and reporting to the Ministry and bodies concerned of any side effect, unexpected adverse reaction or a serious adverse event caused by the medical product within or outside the State, not later than (15) fifteen days from the detection date.
4. Following up on post-marketing medical product reports, as well as the reports on its effectiveness, safe use and quality in the course of its circulation at health facilities in the State.
5. Reporting to both the Ministry and the Body Concerned any complaint or report for the sake of withdrawing the medical product's batch or the whole product within or outside the State not later than (15) fifteen days from the date of being aware of the complaint or the report.

Article (10)

Joint Liability

The Qualified Person and Authorized Marketer shall both be held jointly liable for any breach of the provisions hereof, particularly in relation to maintaining all entries and records pertaining to the medical product storage and distribution activity.

Article (11)

Medical Product Suspension and Recall

1. The Ministry may suspend the circulation of the medical product if there is a serious necessity to verify the information that demonstrates its poor quality, lack of safety or ineffectiveness. Consequently, the Competent Committee shall issue a resolution indicating that either the entire medical product or only batches thereof are to be recalled within (30) thirty days from the suspension date, in any of the following cases:
   A. If there is cogent evidence demonstrating that the medical product in question is counterfeit or fails to conform to quality, safe use or effectiveness standards adopted by the Ministry.
   B. If there is cogent evidence demonstrating that the medical product either is toxic or would be detrimental under the use circumstances recommended by the Manufacturer or Marketer.
   C. If there is cogent evidence demonstrating the occurrence of an unexpected or a serious side effect, an unexpected or a serious adverse reaction of the medical product after the same is used under the use circumstances recommended by the Manufacturer or Marketer.
   D. If the marketing authorization of the medical product is revoked, or if it production in the Reference State is suspended for quality-related issues.
   E. If there is cogent evidence demonstrating that the marketing authorization granted to the medical product had been based untrue documents or information or based upon the use of illegal methods.
   F. If any change occurs to the composition, shape, leaflet, manufacturing method or place of the medical product, with no approval obtained from the Competent Department.
   G. If any of the conditions set forth in this Law or its Executive Regulations or the Resolutions, Regulations or Instructions issued in implementation hereof is breached.
2. Under any circumstances, both the Ministry and Body Concerned shall make

coordination between themselves in respect of any actions to be taken under this Article. In addition, the bodies concerned may suspend the product's circulation at public and private health facilities falling within their respective areas of competence, and shall report the same to the Ministry in the manner defined in the Executive Regulations hereof.

Article (12)

Temporary License

If there is cogent evidence demonstrating the unavailability of a particular medical product and the absence of a substitute product in the State, the Minister may issue a resolution, based upon the recommendation of the Competent Committee which must have representatives of the bodies concerned as members thereof, to grant a temporary license to one or more Authorized Marketer, whereby the latter undertakes to make the medical product in question available in the State within the time limit, at the price and in the quantities specified by the Ministry, subject to the provisions of the Federal Law No. (17) of 2002 referred to hereinabove.

Chapter II

Clinical and Preclinical Studies

Article (13)

Prohibitions of Clinical and Preclinical Studies

Preclinical studies may not be conducted on humans. Likewise, no clinical studies may be performed before preclinical studies are performed, in order to initially ensure the level of safety and effectiveness of the medical intervention intended to come out of the clinical studies.

Article (14)

Clinical Study Requirements

Without prejudice to any other Law, no clinical study or any study involving the bioavailability or bioequivalence of a medical product may be conducted on humans, unless the approval of the Ministry or the Body Concerned, as the case may be, is obtained beforehand. In addition, any person undergoing the clinical studies shall be subject to prior medical examinations to ensure his / her safety, after his / her written consent is obtained, whereby he / she acknowledges being fully aware of all details of the clinical study and potential risks thereof. Non-interventional Clinical Studies shall not require such a consent, but both the Ministry and Body, as the case may be, shall be notified of the same.

Article (15)

Certified Bodies of Clinical Studies

1. The Ministry or Body Concerned may get the following bodies approved for conducting clinical studies:
   A. Public and private hospitals;
   B. Universities and specialist scientific research centers, but if it is not possible to get clinical studies conducted at such bodies, they may conduct the same at hospitals so licensed; and
   C. Laboratories;
2. No clinical studies and analyses may be conducted on study-related biological samples at any entity other than those certified under the provisions of this Article.

Article (16)

Obligations of The Body in Whose Favor Clinical Study is Performed

The body in whose favor clinical study is performed shall abide by the following:

1. Developing a plan for the study intended to be performed, containing its scientific grounds.
2. Providing licensed physicians to ensure the safety of persons on whom the study is to be conducted.
3. Entering into an insurance contract with an insurer operating in the State, which covers the potential risks of the intended study.
4. Complying with the Ministry's Manual of Best Practice in Clinical Studies.

Article (17)

Supreme Committee of Clinical Study Ethics

1. The Ministry shall create a supreme committee of Clinical Study Ethics, which shall comprise the various bodies concerned. The formation and functioning system of such a committee shall be subject to a resolution of the Minister. Members of such a committee shall have tremendous experience in health, Sharia and legal fields. The committee shall have the competence over ethics of clinical studies. Its duties shall include, among others, the following:
   A. Establishing the policies relating to ethics of clinical studies at the federal level;
   B. Supporting innovation and scientific research in the framework of respecting the ethics of clinical studies;
   C. Putting forward any proposals that would contribute to developing the federal legislative that stands in support of scientific research and innovations, subject to the ethics of clinical studies.
   D. Managing coordination among the Bodies Concerned in the field of ethics of clinical studies.

E. Approving the progress of clinical study phases depending on the number of volunteers undergoing the study.
F. Performing any other functions falling with the scope of its competence as entrusted thereto by the Minister.

2. The Body Concerned shall perform the following functions:
   A. Applying the national policies and legislation relating to ethics of clinical studies at the health facility's level.
   B. Making coordination with the Ministry's Supreme Committee of Clinical Study Ethics, and reporting thereto any negative or unknown findings on the medical product, which may emerge during or after the study is conducted.
   C. Approving the creation of subcommittees at the establishments that conduct clinical studies in accordance with the provisions of Article (18) hereof.
   D. Performing any other functions that fall within the scope of its competence as entrusted thereto by the Head of the Health Authority.
3. The Body Concerned may create one or more committees to perform its functions set out in Clause (2) of this Article.

Article (18)

Clinical Studies Subcommittee

The authorized clinical study body may form an ad-hoc subcommittee whose members shall have experience and specialization, including a jurist. Such a Committee shall perform the following functions:

1. Verifying the validity of scientific grounds underlying the conduct of the study.
2. Approving the study plan and giving consent that the study be conducted and following up on the same, and approving the progress of its phases.
3. Verifying the research team's professional efficiency, ability to conduct the study, and compliance with the Ministry-approved Good Laboratory Practice.
4. Verifying that the volunteer's acceptance to undergo the study has been made on his /

her own freewill without coercion, after the same is made well-acquainted with all aspects and potential risks of the study, and also verifying that the parent's consent is obtained when the study is to be conducted on his / her own child, taking into consideration the most favorable interest of the child and the laws applicable in the State.

5. Verifying that volunteering is not exploited by the volunteer as a source of income, except for the compensation payable to him/her for the volunteering expenses, such as the expenses of moving to and from the authorized clinical study body and compensation for absence from work.
6. Performing any other functions to be assigned thereto by the authorized authority.

Article (19)

Obligations of Principal Researcher and Body towards Clinical Studies

The principal researcher supervising the conduct of clinical studies as well as the body at which the research is to be conducted shall both comply with the study plan as well as the good practice manual of authorized clinical studies, and shall notify the body in whose favor the clinical study is to be conducted and the chairman of the subcommittee at the authorized body referred to in Article (18) hereof, and the Ministry or the Body Concerned, as the case may be, in any of the following cases:

1. The occurrence of a serious adverse event in the course of conducting the study, so that the notification shall be made not later than fifteen (15) days from being aware of such occurrence.
2. Before any change is made to the study plan for the sake of protecting the persons undergoing the study, or in case of urgency, when the change itself is carried out.
3. Reporting the reasons underlying the suspension of conducting the study and the withdrawal of any person undergoing the study.

Chapter III

Laboratory Studies

Article (20)

Accredited Laboratory

No laboratory study, product analysis certificate or a specific quality certificate of one or more batches of particular product may be relied upon as a document that demonstrates its quality or stability, unless the same has been conducted and certified by a laboratory accredited by the Ministry or the Body Concerned according to the Manual approved by the Minister's resolution.

Article (21)

Laboratory Accreditation Procedures, Controls and Conditions

Laboratory accreditation procedures, controls and conditions set out in Article (20) hereof as well as the certificates issued thereby shall be determined under a resolution of the Minster, subject to prior coordination with the bodies concerned.

Chapter IV

Medical Product Manufacturing

Article (22)

Medical Product Manufacturing Conditions

Any medical product may be manufactured in the State only after the Ministry's prior approval is obtained, provided that the manufacturing process takes place at a licensed or accredited factory in the State, in accordance with the controls and standards to be specified

by a resolution of the Minister.

Article (23)

Good Manufacturing Practice

The conditions and requirements of Good Manufacturing Practice, which must be satisfied by the manufacturing facilities of medical products, shall be issued under a resolution of the Minister, and the Competent Department shall be charged with monitoring compliance with the same.

Article (24)

Revocation of Approval by Competent Department

The Competent Department may revoke its approval of the manufacturing of a medical product, if the approval holder fails to apply for getting the marketing authorization without an acceptable justification within two years from the issue date of the product manufacturing approval.

Article (25)

Revocation of Approval by the Minister or His Authorized Designee

The Minister or the designee authorized thereby shall, based upon a recommendation of the Competent Department, issue a resolution revoking the manufacturing of the medical product in the State, in any of the following cases:

1. If there is cogent evidence demonstrating that the manufacturing license or the accreditation of the Manufacturer had been issued or made depending on untrue documents.

2. If there is a resolution issued which necessitates prohibited manufacturing of the product in the State, the Country of Origin or any of the reference bodies approved by the Ministry.
3. If there is cogent evidence demonstrating that the Manufacturer has repeatedly failed to abide by the Good Manufacturing Practice in a way which affects the medical product's quality.
4. If there is cogent evidence demonstrating that the product is lacking safety and security, or where the product fails repeatedly to conform to approved quality standards upon conducting the laboratory checks that are performed at the accredited laboratories in the State, and the Minister's resolution shall determine the repetition times which necessitate revocation of the manufacturing approval.
5. In case a resolution is issued requiring that the manufacturer's business be prohibited in the State, the Country of Origin or any of the reference bodies approved by the Ministry.

Chapter V

Import and Export of Medical Product and Raw Materials

Article (26)

Approval of The Ministry

No medical product or any raw materials that are involved in its manufacturing may be imported, exported or re-exported without the Ministry's approval, and the Minister may authorize the body concerned in this respect, within the limit of the medical products intended to be used by public health facilities affiliated thereto.

Article (27)

Appointment of Pharmaceutical Establishment

The Authorized Marketer shall appoint a pharmaceutical establishment duly licensed to engage in import business as an imported of the medical product whose right of marketing is acquired, and shall appoint one or more pharmaceutical establishments licensed for distribution as its distributor in the State. Under any circumstances, Authorized Marketer shall get such appointment approved by the Ministry, and shall follow up on the medical product's batches in the various distribution channels in the State.

Article (28)

Personal Use of Medical product

The Executive Regulations hereof shall set out the conditions and rules of the medical product to be brought, possessed or held by any person upon entering the State for personal use.

Chapter VI

Circulation of Medical Product

Article (29)

Supreme Committee on Drug Policies

The Supreme Committee on Drug Policies shall be composed under a resolution of the Minister. It shall have, among its members, representatives of the Ministries and Bodies Concerned, and shall have the competence to propose policies relating to the circulation, pricing and monitoring of medical products in the State. It shall also have the competence to set up the rules, conditions and procedures of obtaining the marketing authorization for

medical products, and its composition resolution shall establish the functioning procedures and system thereof.

Article (30)

Availability of Medical Product

The Authorized Marketer may not, either unlawfully or for monopoly grounds, withheld the medical product for which the marketing authorization is granted under the provisions hereof.

Article (31)

Medical Product Requiring Prescription

Non-pharmaceutical establishments may not sell, display, store or circulate any medical product whose dispensing necessitates a medical prescription.

Article (32)

Medical Product Not Requiring Prescription

Under a resolution of the Minister, types of non-pharmaceutical establishments that are permitted to sell, display, store and circulate medical products that are dispensed without a medical prescription as well as the names of such products shall be determined, in accordance with the controls set out in the Executive Regulations hereof.

Article (33)

Information and Data

No medical product may be circulated or marketed unless the information and data printed on its internal and external label and patient information leaflet thereof are identical to the information and data of the package contained in the annex to the marketing authorization thereof. The Competent Committee shall determine the data required to be recorded on the internal and external label and patient information leaflet of the medical product.

At least Arabic and English shall be used on the patient information leaflet in necessary cases determined under a resolution of the Minister

Article (34)

Outer package's Phrase

The Manufacturer, Authorized Marketer and Distributor shall print on the outer packages of healthcare products in a non-erasable ink the following phrase: ("This Product is not intended to diagnose, treat, cure or prevent any disease").

Article (35)

Reporting Negative or Harmful Results

Pharmaceutical Establishments, Health Facilities and healthcare practitioners hired by such entities shall report to both the Ministry and the Body Concerned any negative or harmful results of the medical product, in respect of non-conformity of its quality with the standards established by the Ministry, not later than fifteen (15) days from the date of knowledge.

Article (36)

Prescription of Medical Product

1. Physicians may neither prescribe the medical product for new uses not mentioned in the patient information leaflet, not prescribe a medical product for which no marketing authorization is applied for, except in inevitable necessity cases, provided that the Equivalent Substitute is unavailable, subject to the patient's approval.
2. Licensed Healthcare Practitioner may not provide advice, prescribe or dispense any medical product, unless the same is duly authorized to do the same in accordance with the provisions hereof.

Article (37)

Third Party Healthcare Practitioners

Licensed Healthcare Practitioners, who are not pharmacists or pharmacy technicians, shall be prohibited from selling any medical product directly or indirectly, without prior consent of the Ministry or the Body Concerned.

Article (38)

Prohibited Prescription of Product for Personal Gain

Healthcare Practitioners may not prescribe or recommend any medical product for the purpose of achieving a personal gain.

Chapter VII

Medical Product Promotion and Announcement

Article (39)

Prohibited Announcement and Permitted Cases

1. It shall be prohibited to announce, advertise or promote to the public any medical product by any means, in case such a product is dispensed only under a medical prescription.
2. Subject to the Ministry's prior approval, it shall be permitted to:
   A. Announce, advertise or promote the medical product on the journals and scientific sources intended to address Healthcare Practitioners.
   B. Announce, advertise or promote to the public any medical product that is dispensed without a medical prescription or any healthcare product that has obtained the marketing authorization.

Article (40)

Authorized Marketer

The Authorized Marketer shall ensure that the medical product's promotional advertisements comply with the conditions and rules set up by the Ministry.

Article (41)

Licensees

Those licensed to manufacture, market or distribute the medical product shall avoid any distortion, fraud, theft or plagiarism of the studies and research published, in such a way which would affect the well-established legal rights of the owners of such research.

Article (42)

Prohibitions on Circulation and Sale

1. Counterfeit, defective or expired medical products shall be prohibited from circulation.
2. Free promotional samples of medical products may not be sold, and inner and outer labels of such samples shall bear a clear phrase written in non-erasable ink that reads as follows: ("Free medical sample not intended for sale") in both Arabic and English.

Article (43)

Free Samples

Persons other than healthcare practitioners duly authorized to prescribe medical products may not be provided with free samples of medical products for prescription to patients, and a record shall be kept to show the movement of every item of the controlled product samples.

Part III

Regulating the Practice of Pharmacy Profession and Pharmaceutical Establishments

Chapter I

Licensing the Pharmacy Practitioners

Article (44)

Requirements for Business License and Registration Record

1. No person may engage in any activity in the field of pharmacy profession or work as a pharmacy technician, unless such a person is duly licensed by the Ministry or the Body

Concerned within the scope of its competence, in accordance with the controls set up by the Executive Regulations hereof.

2. The Ministry shall create a national record to document therein the data of pharmacy and pharmacy technician practitioners who are licensed to practice the profession in the State.
3. The Body Concerned shall create a record to document therein the data of pharmacy and pharmacy technician practitioners who are licensed by such Body to practice the profession.
4. Pharmacists shall be classified in the records set out in this Article into categories by educational qualification and experience.
5. The Executive Regulations hereof shall set out the conditions and procedures of updating the registration in the aforesaid records.

Article (45)

License and License Renewal Applications

1. The Ministry or the Body Concerned within its scope of competence shall consider and approve the applications submitted thereto for licensing or renewing the licenses of persons to practice pharmacy profession and pharmacy technician profession, in accordance with the controls set out by the Executive Regulations hereof.
2. The Ministry shall decide on the license application within thirty (30) days from the submission date thereof, and its resolution rejecting the license or license renewal application shall be substantiated. If the time limit expires with no response, the same shall be construed as rejection of the license application.

Chapter II

Duties and Prohibitions of Pharmacy Practitioners

Article 46

The pharmacist, duly licensed to practice any activity in the pharmacy profession, shall perform his / her duties in accordance with the highest principles and standards of professional practice, maintain the profession's honor and keep its secrets confidential, in accordance with the Code of Professional Conduct and Pharmacy Practice Ethics in the State. In particular, he/she shall:

1. Perform his/her duties at the pharmaceutical establishment in which he / she is licensed to work, within the scope of the activity licensed to be practiced in accordance with the conditions and rules set out in the Executive Regulations hereof.
2. Perform his/her duties accurately and honestly.
3. Report to the Ministry or the Body Concerned, as the case may be, any case that suffers from an unexpected or a serious side effect, an unexpected adverse reaction or a serious adverse reaction of a medical product within fifteen (15) days from the date on which either the case occurs or the pharmacist becomes aware of its occurrence. The Body Concerned shall report to the Ministry any of the cases mentioned in this respect.
4. Report the communicable diseases in accordance with the laws and resolutions applicable in this respect.

Article (47)

Clinical Pharmacy

Subject to the provisions of Article (46) hereof, the clinical pharmacist may provide his / her specialist services and practice clinical pharmacy, provided that the same takes place at a health facility duly licensed to provide therapeutic services to patients, in association with the licensed treating physician supervising the patient. In particular, he/she may:

1. Create and prescribe or amend the patient's drug treatment plan, including the substitution of a medical product for another product, unless the treating physician has issued any written or electronic instructions prohibiting any such amendment. The clinical pharmacist shall be prohibited from performing any action with regard to the patient until the latter is diagnosed by the licensed treating physician.
2. The drug treatment plan created or amended shall be compatible with both the medical product use system (protocol) and medical cases treatment guides.
3. The clinical pharmacist shall share with the treating physician the record and data of the patients attended.
4. Notify the treating physician of the implementation or amendment of the plan in writing through recording the data relating to the implementation or amendment of the plan in the patient's medical record kept for review by both the treating physician and clinical pharmacist, within the (24) immediately following the commencement of plan implementation.
5. Direct the patients and provide them with the specialist information including the information relating to the medical case, use of medical products and drug treatment plan. Consultations on such information shall also be provided to healthcare professionals who are members of the patient's treating team.
6. Perform any of the following duties, provided that they are compatible with the general instructions of the employer health facility and medical products use system (protocols):
    A. Requesting that routine examinations be performed for evaluating the condition of the patient in relation to selecting and identifying the drug treatment plan, including the measurement of pulse rate, temperature, blood pressure and respiration rate.
    B. Requesting that laboratory examinations be performed in relation to selecting and identifying the drug treatment plan.
    C. Administering the treatment dose to the patient in conformity with the physician's instructions, such as injections and various vaccines.

Article (48)

Licensee's Prohibitions

Pharmacy licensee may not carry out any act involving a breach of the professional duties, honor or honesty, and, in particular, the following acts shall be prohibited:

1. Carrying out any action that would degrade the profession's dignity, such as illegal competition, improper appearance or smoking at the workplace.
2. To notify anybody of the diseases indicated by the prescription submitted to him / her, or of the drugs contained in such a prescription that may have come to his/her knowledge in any other manner, by virtue of practicing his / her profession, except as required by the laws applicable in the State.
3. Adopting unlawful means aiming to urge the patients to purchase medical products from the establishment at which he/she works.
4. Withholding or hiding medical products or selling them at a price other than the one set by the Ministry.
5. Altering the medical products in his/her possession in terms of quantity, type and form, in violation of the provisions hereof.
6. Selling medical products that are unfit for consumption, defective, expired or those products failing to get marketing authorization from the Ministry, or counterfeit or smuggled products that have been brought into the State by unlawful means.
7. Engaging in medical or healthcare activities which are not licensed to be practiced by him/her, such as nursing, diagnosis of diseases, except for those related to first aid activities defined by the Executive Regulations hereof.
8. Dispensing medical products that need a medical prescription in the absence of the same.
9. Dispensing medical prescriptions bearing any symbol or sign not agreed upon scientifically.
10. Entering into agreement with a physician or a healthcare practitioner who is duly authorized to prescribe medical products, on writing medical prescriptions in a special

way or by any other signs agreed upon between themselves.

11. Humiliating or criticizing any healthcare practitioners before other persons.

Article (49)

Prescription

The licensed pharmacist may not dispense medical product without a prescription, if the same inevitably requires a prescription. Under any circumstances, the prescription shall:

1. Be written in a clear handwriting or electronically printed in an understandable language.
2. Be issued by a healthcare practitioner duly licensed to issue prescriptions.
3. Bear the name, seal, signature of the healthcare practitioner who issued the prescription, along the prescription date.
4. Bear the scientific name and/or trade name, pharmaceutical form, gauge, administration method and duration of use.
5. Bear the full name of patient and his/her age, weight, address, ID number and phone number.
6. Bear the information about potential allergic reactions to be suffered by the patient, if any.
7. Be compatible with any other requirements defined by the Executive Regulations hereof.

Article (50)

Prescription of Narcotic Drugs and Psychotropic Substances

1. The Pharmacist may not dispense prescriptions that contain medical products comprising narcotic drugs and psychotropic substances pursuant to the Federal Law No. (14) of 1995, as amended, referred to hereinabove, unless the following requirements are satisfied:

   A. The prescription must be written on the form designed and numbered by the

Ministry or the Body Concerned, as applicable.

B. The prescription shall be written in a non-erasable, unchangeable material or electronically printed out.
C. The prescription must bear the commercial name of the drug product, the active ingredient, quantity of the drug product, the dose in both figures and words method and duration of use, full name of the patent and his/her age and address.
D. The dose prescribed may not exceed the scientific references kept by the Ministry.

2. The prescription of controlled medical products may not be dispensed if a higher duration than that specified in the Executive Regulations hereof has passed ever since the issuance of the prescription.
3. Drugs may be dispensed under e-prescriptions in accordance with the controls established by the Ministry.

Article (51)

Substitution or Replacement of Prescription Items

The pharmacist may not replace or substitute any item of the prescription unless the issuing person is consulted, with the exception of cases where the pharmacist replaces a pharmaceutical product for an equivalent pharmaceutical product in accordance with the controls set out in the Executive Regulations hereof.

Article (52)

Dispensing of Repeated Prescription

The pharmacist may not re-dispense the Prescription that contains controlled and semi-controlled substances which have the characteristic of accumulation in the body, or where their frequent use would lead to addiction, unless the Prescription bears a note by the issuing person indicating that it is to be re-dispensed, within the scope of product items

specified under a resolution of the Minister.

Article (53)

Error in Prescription

If the pharmacist notes any error in the Prescription submitted to him/her or has any concerns about its details, he shall be required to call the issuing person to seek clarification, or may send the same back to the issuing person if the latter's clarifications do not make sense and are unacceptable. In such a case, the issuing person shall include in the Prescription any necessary clarifications and sign again next to such clarifications.

Article (54)

Documentation of Prescriptions

The pharmacist shall document in the records to be designated under a resolution by the Minister the prescriptions relating to controlled and semi-controlled products and substances being dispensed.

Article (55)

Prescription Prohibited for Oneself or Relatives

The practitioner of a healthcare profession, who is duly licensed to prescribe medical items, may not prescribe for himself/herself, his/her spouse or relatives up to the second degree medical items involving controlled substances and products.

Article (56)

Licensing Requirements

1. No person shall start up a pharmaceutical establishment unless he/she obtains a license from the Ministry or the Body Concerned within the scope of its competence.
2. In the event of engaging in the business of import, export or marketing of medical products in the State, a relevant license shall be obtained from the Ministry.
3. The local authority concerned with corporate affairs in the relevant emirate shall have the power to determine a certain rate of the nationals' contribution to the capital or the boards of directors of the companies established within its scope of competence. The license to open the pharmaceutical establishment shall be issued in accordance with the license issued by such authority.
4. Pharmaceutical establishments operating in free zones shall be excluded from the rate referred to in Clause (3) of this Article. Further, any other pharmaceutical establishments determined by a Cabinet resolution shall be excluded.
5. The Minister shall issue a resolution determining the rates with which the owner of the pharmaceutical establishment shall comply with regard to the appointment of nationals in the profession of pharmacy.

Article (57)

License Term

The license for starting up a pharmaceutical establishment shall be valid for the term specified by the Executive Regulations hereof, and the license holder shall engage in the business activities within the license validity duration.

Article (58)

Unlicensed Activity Prohibited

Pharmaceutical establishments shall be prohibited from engaging in any unlicensed activity. In addition, they may not deal with establishments that are not licensed for the circulation of medical products in the State, and the Establishment's Manager shall be held responsible for any violation of the provisions of this Article.

Article (59)

Relocation of Pharmaceutical Establishment

Subject to the applicable legislation in the State, no pharmaceutical establishment may be relocated from a place to any other place, nor may its plan issued under a resolution of the Minister be changed without the approval of the Ministry or the Body Concerned within the scope of its of them.

Article (60)

Assignment of Ownership

Without prejudice to the applicable legislation in the State, and subject to prior approval of the Ministry or the Body Concerned within the scope of competence of each, ownership of the pharmaceutical establishment may be assigned to Third Parties, in accordance with the conditions specified by the Executive Regulations hereof.

Chapter IV

Licensing of Pharmacies

Article (61)

Licensing Requirements

Without prejudice to the conditions of Chapter III of this Part, the license to start up a pharmacy shall be conditional upon assigning its technical management to a full-time licensed pharmacist, and the pharmacy must satisfy the technical and health conditions specified under a resolution of the Minister.

Article (62)

Compounding Pharmacy

Without prejudice to the conditions of Chapter III of this Part, the license to engage in compounding pharmacy business shall be conditional upon assigning the pharmacy's technical management to a full-time licensed pharmacist, and the pharmacy must satisfy the technical and health conditions specified under a resolution of the Minister.

Article (63)

Temporary Closure of Pharmacy

1. The Ministry or the Body Concerned, as the case may be, shall issue a resolution for temporary closure of the pharmacy for not more than one month, in any of the following cases:
   A. If the pharmacy's ownership is transferred to any other person without the approval of the Ministry or the Body Concerned - within the scope of its competence – is obtained.
   B. If there no licensed pharmacist working at the pharmacy, or failure to appoint licensed pharmacists to manage the same in the required number as determined by

the resolutions, regulations and instructions issued by the Ministry.

C. If serious violations are committed in accordance with the Executive Regulations of this Law, so that the continued operation of the pharmacy before their removal would give rise to damage to the public health.

2. In all cases, the matter shall be referred to the Disciplinary Committee referred to in Article (102) hereof, within seven business days from the closure date, in order to consider the matter and decide on the disciplinary liability, not later than ten business days form the date on which the matter is referred to the Committee.

Article (64)

Revocation of Pharmacy License

The Ministry or the Body Concerned, as the case may be, shall issue a resolution revoking the pharmacy license after an investigation is conducted in accordance with the provisions hereof, in any of the following cases:

1. If the pharmacy engages in an unlawful activity.
2. If there is cogent evidence demonstrating that the license to start up a pharmacy was issued on the basis of counterfeit documents submitted or untrue data or information provided.
3. In case the pharmacy is kept closed for more than three consecutive months without an acceptable excuse.
4. If the pharmacy's operation is not commenced within six months from the issue date of its operation license without an acceptable excuse.
5. If serious violations are committed as specified by the Executive Regulations hereof.
6. If counterfeit or invalid medical products are circulated.

Article (65)

Absenteeism of Responsible Pharmacist

In case of absenteeism of the pharmacist who is in charge of the pharmacy, the pharmacy owner shall assign its management to a licensed pharmacist, subject to prior approval of the Ministry or the body concerned within the scope of its competence. In such a case, the license may be granted for a specified period in accordance with the conditions stipulated in the Executive Regulations hereof.

Article (66)

Pharmacy Chain and Online Pharmacy

1. A license may be issued for starting up more than one Pharmacy in accordance with the pharmacy chain system specified by the Executive Regulations hereof.
2. The Pharmaceutical Establishment may provide its services online according to a regulations to be issued by the Minister.

Article (67)

Medical Checkups in Pharmacy Prohibited

The pharmacy may not constitute a premises for medical checkups, and its operation shall be limited to the licensed activities as specified by the Executive Regulations hereof.

Article (68)

Subsidiary Pharmacies

The Ministry or the Body Concerned, within the scope of its competence, may issue a license for starting up private pharmacies affiliated to a governmental non-healthcare body, a public establishment or associations or organizations of public welfare, or the private hospitals and medical centers, provided that such pharmacies are managed by a licensed pharmacist, and the Executive Regulations hereof shall establish the conditions of starting up such pharmacies and their respective operation systems.

Chapter V

Medical Warehouse License

Article (69)

Conditions of Licensing the Establishment of Medical Warehouse

1. Without prejudice to the conditions set out in Chapter III of this Part, the license to start up a Medical Warehouse shall require a license from the Ministry, and the Medical Warehouse must be managed by a licensed pharmacist who works on a full-time basis for supervising the warehouse, and the warehouse shall satisfy the technical and health requirements set out in the Executive Regulations hereof.
2. Notwithstanding the requirement of providing a full-time pharmacist for managing the warehouse as provided for in the foregoing clause, if the Medical Warehouse's activity is limited to medical equipment, the same may be managed by a medical equipment engineer, subject to compliance with the remaining requirements of the foregoing clause.

Article (70)

Precautionary Closure or License Suspension

1. The Licensing Authority shall, within the scope of its competence, issue a resolution either to close the Medical Warehouse on precautionary grounds or to suspend its license temporarily until the violation is removed, in any of the following cases:
   A. If the Medical Warehouse's ownership is transferred to any other person without the approval of the Ministry or the Body Concerned - as the case may be - is obtained.
   B. If the Medical Warehouse's premises is moved away from the licensed place without the prior approval of the Ministry or the Body Concerned, as the case may be, is obtained.
   C. If serious violations are committed, so that the continued operation of the Medical Warehouse before their removal would give rise to damage to the public health, as stipulated in the Executive Regulations of this Law.
   D. The unavailability of a licensed full-time pharmacist to manage the warehouse.
2. The resolution on precautionary closure or temporary license suspension shall be issued based upon an inspection report by the Competent Department of the Ministry or the Body Concerned within the scope of its competence. Regarding the warehouse that engages in import or export business, the Body Concerned shall issue the resolution on precautionary closure or temporary license suspension, as soon as a relevant request is submitted thereto by the Ministry.
3. In all cases, the matter shall be referred to the Disciplinary Committee referred to in Article (102) hereof within seven business days from the license suspension or closure date, in order to consider the same and decide on the disciplinary liability not later than ten business days from the date on which the referral is delivered to the Disciplinary Committee. In addition, the Body Concerned shall notify the Ministry of the resolution issued in this respect with regard to the warehouse that engages in import or export business.

Article (71)

Medical Warehouse License Revocation

1. The license-issuing body shall, within the scope of its competence, issue a resolution revoking the Medical Warehouse's license in any of the following cases:
   A. In case counterfeit or invalid products are circulated;
   B. If any activity, which is different from the licensed activity, is practiced.
   C. If there is cogent evidence demonstrating that the license to start up the Medical Warehouse had been issued on the basis of counterfeit documents submitted or untrue data or information provided.
   D. In case the Medical Warehouse continues to be inoperative for three consecutive months without an acceptable excuse.
   E. In case the Medical Warehouse's operation does not commence within six months from the date of obtaining the warehouse license, without an acceptable excuse furnished.
   F. In case the violation is not removed within the time limit set by the Ministry or thee Body Concerned pursuant to Article (70) hereof.
   G. If a serious violation is committed as set forth in the Executive Regulations hereof.
2. The Body Concerned shall notify the Ministry of the Resolution on revoking the license of the Medical Warehouses that engages in import or export business as soon as it is issued.

Article (72)

Maintaining General Record or Information System

The Pharmacist assuming responsibility for the Medical Warehouse shall keep a general record or an information system, in order to regularly enter therein the type and quantity of medical products and chemicals received by the warehouse, their receipt date, the quantities released from the Medical Warehouse, the entity to which they are dispensed. He/she shall also keep a separate record for controlled substances and products.

The owner as well as the pharmacist in charge of the management of the Medical Warehouse shall both be jointly liable for such records and the authenticity of the information therein contained.

Article (73)

Affixing Price Label

The Medical Warehouse shall affix the Ministry-approved price label on the outer cover of the medical product in a clear way before the same is sold and delivered. The Authorized Marketer, pharmacists in charge at pharmaceutical establishments and their owners shall all be held jointly liable for affixing the Ministry-approved price label on the outer cover of the medical product.

Article (74)

Delivery or Sale Requirement

The Medical Warehouse shall be prohibited from delivering or selling the drug products, medical devices or raw materials to any persons other than the licensed pharmacist in charge at the pharmaceutical establishment and the body licensed to handle the same.

Article (75)

Import and Export License and Consent of Authorized Marketer

The Medical Warehouse shall be prohibited from importing or exporting any medical product, unless the same is duly licensed by the Ministry to engage in import and export business. In addition, the Medical Warehouse shall also be prohibited from importing, storing, distributing or selling any medical product without obtaining the prior consent of the Authorized Marketer approved by the Ministry.

Chapter VI

Licensing of Marketing Firms

Article (76)

Licensing Conditions

Without prejudice to the conditions set out in Chapter III of this Part, it shall be a prerequisite for starting up a marketing firm that an official license be obtained from the Ministry, and that the person in charge of its management shall be duly qualified in a health profession and available on a full-time basis to supervise the firm, and that the firm shall satisfy the requirements specified under a resolution by the Minister, without prejudice to any other licenses provided for in the applicable legislation of the State.

Article (77)

Prohibitions of Marketing Firm

The Marketing Firm shall be prohibited from importing or storing medical products for sale or distribution purposes, but it may keep free samples for the purpose of promoting the medical products, provided that each sample shall be bear a stamp indicating that they are free and not intended for sale.

Chapter VII

Licensing of Pharmaceutical Consulting Firms

Article (78)

Firm Establishment Conditions

Without prejudice to the conditions set out in Chapter III hereof, it shall be a prerequisite for starting up a pharmaceutical consulting firm that a relevant license be obtained from the Ministry, and the person in charge of the firm shall be a pharmacist who is available on a full-time basis for direct supervision and control, and shall also be licensed to provide pharmaceutical consultations. In addition, the firm and its team shall both satisfy the conditions specified under a resolution of the Minister.

Article (79)

Prohibitions of Consulting Firm

Pharmaceutical consulting firms shall be prohibited from importing, exporting, distributing or storing the medical products, and the Executive Regulations hereof shall specify the functions to be performed by the firm.

Chapter VIII

Licensing of Pharmaceutical Laboratories and Research Centers

Article (80)

Requirements for Starting up Pharmaceutical Laboratories or Research Center

Without prejudice to the conditions set out in Chapter III of this Part, it shall be a perquisite for granting a license to start up a pharmaceutical laboratory or a research center that the following conditions are met:

1. The license shall be issued by the Ministry;
2. The person in charge of the pharmaceutical laboratory or research center shall be duly qualified, available on a full-time basis and licensed in accordance with the conditions set out in the Executive Regulations hereof.
3. The pharmaceutical laboratory or research center shall be conforming to safety requirements, and shall satisfy preventive measures to ensure absence of any environmental pollutants.
4. The pharmaceutical laboratory or research center shall satisfy any other requirements specified under a resolution of the Minister.

Article (81)

Prohibitions of pharmaceutical laboratory or research center

Except for chemical substances used for analyses and medical products intended for study and research, the pharmaceutical laboratory or research center may not import, export or store medical products for sale or distribution purpose or for promotional or advertising purposes.

Article (82)

Good Laboratory Practice

The licensed pharmaceutical laboratory and licensed research center shall comply with the Ministry-established Good Laboratory Practice.

Article (83)

Research and Tests on Humans

The pharmaceutical laboratory shall be prohibited from performing any research or tests on humans for any reason whatsoever.

Article (84)

Results of Lab Analyses

The person in charge of the pharmaceutical laboratory shall issue approval certificates of laboratory analysis results in accordance with the quality standards set by the Ministry, and shall keep the data records of analyses in accordance with the rules and procedures established by the Ministry.

Chapter IX

The License to Start up Medical Product Factories

Article (85)

Conditions for Licensing Medical Product Factories

Without prejudice to the conditions set out in Chapter III of this Part, starting up medical product factories shall require a license to be issued by the Ministry in accordance with the conditions and procedures specified under a resolution of the Minister.

Article (86)

License Suspension or Precautionary Closure of Factory

1. The Ministry shall, sua sponte and in coordination with the Bodies Concerned or based upon a recommendation by the Bodies Concerned, issue a resolution for precautionary closure of the factory or temporary suspension of its license in any of the following cases:
   A. If the Factory's ownership is transferred to any other person without the approval of the Ministry is obtained.
   B. If the Factory's premises is moved away from the licensed place before the Ministry's approval is obtained.
   C. If serious violations are committed as specified by the Executive Regulations of this Law, so that the continued operation of the Factory before their removal would give rise to damage to the public health.
   D. If there are no qualified persons to perform direct supervision and control in accordance with the applicable rules in this respect.
2. In all cases, the matter shall be referred to the Disciplinary Committee referred to in Article (102) hereof, within seven business days from the license suspension or closure date, in order to consider the matter and decide on the disciplinary liability, not later than ten business days form the date on which the matter is referred to the Committee.

Article (87)

Revocation of Factory License

The Ministry shall, sua sponte and in coordination with the Bodies Concerned or based upon a recommendation by the Bodies Concerned, issue a resolution for revoking the factory's license in any of the following cases:

1. In case counterfeit or invalid products are circulated;
2. If any activity, which is different from the licensed activity, is practiced.
3. If there is cogent evidence demonstrating that the license to start up the Factory had been issued on the basis of counterfeit documents submitted or untrue data or information provided.
4. In case the Factory continues to be inoperative for three consecutive months without an acceptable excuse.
5. In case the Factory's operation does not commence within six months from the date of obtaining the operation license thereof, without an acceptable excuse furnished.

Article (88)

Quality Management Standards and Good Manufacturing Practice

The medical products factory shall comply with the quality management standards and Good Manufacturing Practice established by the Ministry.

Article (89)

Remanufacturing under New Technical Specifications

A licensed medical product may be remanufactured under new technical specifications only after the Manufacturer obtains the approval from the Ministry to have the product manufactured based on such new specifications.

Chapter X

Controlled and Semi-controlled Substances and Products

Article (90)

Prohibitions of Controlled Substances and Products and Relevant Instructions

Subject to the provisions of any other legislation:

1. No medical product that is not listed on an approved prescription may be composed, and no item of the controlled substances and products may be imported, re-exported or composed in a way contrary to the medical prescription, without a permission is obtained from the Ministry beforehand.
2. Active ingredients that are involved in manufacturing any of the products referred to in clause (1) of this Article may only be used for manufacturing the medical products licensed to be manufactured.
3. The Minister shall issue the necessary instructions that would ensure protection from the hazards of controlled substances and products and prevent misusing or falling vulnerable to their impacts.

Article (91)

Warehousing and Circulation of Controlled Substances and Products

The controls relating to the warehousing and circulation of controlled substances and products shall be determined under a resolution of the Minister.

Article (92)

Possession of Controlled Substances and Products

Subject to the provisions of Article (93) hereof, controlled substances and products may only be possessed under a license to be issued by the Ministry or the Body Concerned within the scope of its competence. Such possession shall exclusively be limited to the following categories:

1. The pharmacist in charge of managing the medical warehouse, by means of import or purchase from any other medical warehouse that falls under the supervision of the Ministry.
2. The pharmacist who is responsible for managing a pharmacy, by means of purchase from a licensed medical warehouse that is subject to the supervision of the Ministry and/or the Body Concerned within the scope of its competence.
3. The licensed physician, to be used for the purposes of his/her professional duties, and the Executive Regulations hereof shall specify the quantities of controlled products which the physician is permitted to possess.
4. Drug factories, provided that their possession of controlled substances and products or raw materials of their active ingredients takes place by means of import or purchase subject to the Ministry's supervision, I accordance with the provisions of this Law and the Executive Regulations hereof.
5. Scientific Institutes and Research Centers, provided that they are subject to the supervision of the Ministry or the Body Concerned within the scope of its competence.

In all cases, the possession by such categories of controlled substances and products shall be limited to the places where they perform their job duties.

Article (93)

Dispensing of Controlled Substances and Products

The licensed pharmacist who is in charge of managing a pharmacy may dispense controlled substances and products for medical use only in the following cases:

1. To patients; under a medical prescription issued by a licensed physician.
2. To owners of sick animals; under a medical prescription issued by a licensed veterinarian.
3. To physicians; under requests signed by them and containing an undertaking that the quantities of such controlled or hazardous substances they demand are intended solely for use in their clinics, in accordance with the conditions specified under a resolution of the Minister.

Article (94)

Circulation of Controlled Substances and Products

The circulation of controlled substances and products among licensed pharmaceutical establishments or health facilities shall be subject to prior approval of the Ministry or the Body Concerned within the scope of its competence in accordance herewith.

Article (95)

Import Procedures of Controlled Substances and Products

Neither the medical warehouse nor the medical products factory may import controlled substances and products or raw materials for their active ingredients, unless and until the Ministry's prior approval is obtained based upon an application to be submitted thereto and signed by the licensed pharmacist who is in charge of managing the medical warehouse or the factory manager, including all details relating to the controlled substances and products required to be imported and their quantities and types, shipping method and the certified clearance center in the State.

Article (96)

Periodic Inventory Check of Controlled Substances and Products

The person in charge of the custody of controlled substances and products within any of the categories set out in Article (92) hereof shall perform a periodic inventory check on such custody, and notify the Ministry or the Body Concerned, as the case may be, of the inventory check's findings. In case any deficit is found, the Ministry or the Body Concerned, as the case may be, shall be notified not later than two business days.

Article (97)

Hazardous or Toxic Medical Substances and Products

Without prejudice to the provisions of international agreements to which the State is a party, hazardous or toxic medical substances and products may only be circulated in conformity with the rules established under a resolution of the Minister. Lists of hazardous or toxic medical substances and products shall be specified under a resolution of the Minister in coordination with the Competent Bodies in the State.

Article (98)

The Entity's Cessation of Business

If the entity, which is granted a permit for possessing controlled substances and products, ceases to operate, or if the person in charge of the custody of such controlled substances and products is no longer working for the entity for whatever reason, the entity shall make an inventory check of the controlled substances and products and take the actions for their delivery, in accordance with the rules and controls specified by the Executive Regulations hereof.

Article (99)

Semi-Controlled Medical Substances and Products

The Minister shall issue a resolution containing a list of semi-controlled medical substances and products and their conditions as well as controls of their circulation, in coordination with the Bodies Concerned.

Chapter XI

Circulation of Precursor Chemicals

Article (100)

Lists of Precursor Chemicals

1. Without prejudice to both the International Agreements to which the State is a Party and any other Law, two lists of Precursor Chemicals that are involved in the manufacturing of medical and pharmaceutical products shall be attached to this Law.
2. The two lists of Precursor Chemicals hereto may be amended by way of addition or removal, and any other lists of Precursor Chemicals may be added and amended by way of addition or removal, under a resolution of the Cabinet based upon the recommendation of a Committee to be composed under a resolution of the Minister, and includes, among its members, representatives of the Ministry, Ministry of Interior,

the Body Concerned and any other Competent Body.

Article (101)

Prohibitions of Precursor Chemicals

Precursor Chemicals may not be brought, imported, exported, manufactured, extracted, separated, produced, possessed, distributed, used or traded in unless and until a prior permission is obtained from the Ministry, in accordance with the conditions and procedures to be set under a resolution of the Minister. Such a resolution shall specify the method of keeping the records and documents relating to such Precursor Chemicals. Customs clearance procedures of Precursor Chemicals may only be processed if the import license is attached to the clearance transaction, and the Customs Department concerned shall get back the import license of Precursor Chemicals as soon as the clearance process is completed, and then deliver it back to the Ministry after it is annotated in confirmation of being received and delivered to the lawful owner thereof.

Part IV

Administrative, Disciplinary Accountability and Penalties

Chapter I

Administrative and Disciplinary Accountability

Article (102)

Disciplinary Penalties

1. Without prejudice to the penalties prescribed under this Law or under any other laws, the Competent Authority in charge of licensing the Pharmaceutical Establishments and their personnel may impose the following disciplinary penalties:

A. With regard to the violations committed by Pharmaceutical Establishments in breach of the provisions of this Law or the Executive Regulations or the Resolutions issued in implementation hereof:
   a. Writing Notice;
   b. Written warning;
   c. Fine of not less than (AED 1,000) one thousand dirhams and not exceeding (AED 1,000,000) one million dirhams;
   d. Temporary suspension of the License for not more than six months; and
   e. Revocation of the License.

B. With regard to the violations committed by Pharmacy Practitioners in breach of the provisions of this Law or the Executive Regulations or the Resolutions issued in implementation hereof:
   a. Writing Notice;
   b. Written warning;
   c. Fine of not less than (AED 1,000) one thousand dirhams and not exceeding (AED 500,000) five hundred thousand dirhams;
   d. Temporary suspension of the Professional License for not more than one year; and
   e. Revocation of the License.

2. Disciplinary penalties set out in clause (1) of this Article shall be considered by the Disciplinary Committee to be composed at the Ministry or the Body Concerned.

Article (103)

Penalties Record

Each licensing authority shall keep a record to enter therein the penalties imposed on the licensees. Competent Disciplinary Committees in the State shall share the details of violations imposed on Pharmaceutical Establishments and Practitioners depending on the competences of such committees.

Article (104)

Grievance against the Disciplinary Penalty

1. Any person against whom a disciplinary penalty resolution is issued pursuant to Article (102) hereof, may file a grievance with the Grievance Committee composed at the Health Facility, within fifteen (15) days from the date on which the Grievant becomes aware of the resolution in question.
2. The Grievance shall be decided on within thirty (30) days from the submission date thereof under a substantiated resolution. If no response to the grievance is made within such a time limit, the grievance shall be deemed rejected.
3. The resolution on the Grievance shall be final.
4. Under any circumstances, the penalty involving suspension of operation, license revocation or closure of the Pharmaceutical Establishment in cases other than precautionary-closure cases defined herein, may not be enforced prior to the expiration of the time limit set filing grievances or for deciding on the grievances filed, as the case may be.

Article (105)

No Prejudice to Criminal or Civil Liability

The disciplinary accountability established hereunder shall be without prejudice to the criminal or civil liability if necessary.

Article (106)

Mutual Notification of Disciplinary Penalty

Both the Ministry and the Body Concerned shall notify each other of the disciplinary penalty imposed, excluding the disciplinary penalty involving warning, notice and administrative fine.

Chapter II

Criminal Penalty

Article 107

1. Imprisonment sentence for a term of not less than six months and not exceeding two years and/or a fine of not less than (AED 50,000 - Fifty Thousand Dirhams) and not exceeding (AED 200,000 – Two Hundred Thousand Dirhams) shall be imposed against whoever:
   A. Submits counterfeit or untrue documents, furnishes untrue information or takes advantage of unlawful means to obtain a license, in violation of the provisions of this Law and the Executive Regulations and Resolutions issued in implementation hereof.
   B. Violates any of the provisions of Articles (44), (56 - Clauses 1 and 2) and (57) of this Law.
   C. Engages in any other business activity covered by this Law without obtaining the relevant official license.
2. Imprisonment sentence for a term of not less than one year and not exceeding five years and/or a fine of not less than (AED 110,000 – One Hundred Thousand Dirhams) and

not exceeding (AED 500,000 – Five Hundred Thousand Dirhams) shall be imposed against whoever:

A. Circulates any of the hazardous and toxic medical products or substances in violation of the provisions hereof.
B. Breaches the circulation conditions and controls of semi-controlled medical substances and products outlined in Article (99) hereof.
C. Breaches any of the provisions of Articles (3), (13), (14), (22), (26), (41), (90) and (101) hereof.

Article 108

1. Imprisonment sentence for a term of not less than six months and not exceeding one year and/or a fine of not less than (AED 50,000 - Fifty Thousand Dirhams) and not exceeding (AED 200,000 – Two Hundred Thousand Dirhams) shall be imposed against whoever breaches any of the provisions of Articles (7.6), (9.3 and 9.5), (19), (30), (33), (35), (36), (39), (46.3), (48.7), (50), (55), (58), (89) and (93) hereof.
2. The criminal lawsuit shall be instituted on the grounds of any breach of the provisions of Article (7.6), (9.3 and 9.5), (19), (35), (46.3) only based on a written request of the Minister. In addition, the Minister may disregard the request to institute a criminal lawsuit on justified grounds.

Article 109

A fine not exceeding (AED 100,000 – One Hundred Thousand Dirhams) shall be imposed on whoever:

1. Acts in violation of the Ministry-set price of medical products; and the penalty shall be doubled in case of recidivism.
2. Engages an unlicensed pharmacist or a pharmacy technician, or if the violator is well aware that the license had been obtained on fraudulent or misinformation grounds.

Article 110

Temporary detention together with a fine of not less than (AED 200,000 – Two Hundred Thousand Dirhams) and not exceeding (AED 1,000,000 One Million Thousand Dirhams) shall be imposed against whoever:

1. Counterfeits, imitates, sells to third parties, or unlawfully brings into the State a medical product, raw materials, chemicals, health foods or cosmetics of a medical nature.
2. Breaches the provisions of Article (42.1) hereof.
3. Breaches any of the provisions of Articles (48.5) and (48.6) hereof.

Article 111 Supplementary Penalties

1. In all cases, the Court may, in addition to the penalties prescribed, order that either the Establishment be closed for not more than three months or be permanently closed and its license be withdrawn.
2. In the event of conviction, the Court may order that the substances involved in the violation be confiscated.
3. The Violator shall bear the cost of destroying the hazardous substances.

Article (112)
No Prejudice to More Severe Penalty

The penalties provided for herein shall be without prejudice to any more severe penalty

provided for in any other Law.

Article (113)

Grievance against the Implementing Resolutions of this Law

Subject to Article (104) hereof, any person against whom any of the resolutions issued in implementation of the provisions hereof, may file a grievance with the Grievance Committee to be composed for such purpose under the resolution of the Minister or the Head of the Body Concerned, within fifteen (15) days from the date of being aware of the resolution in question. The Committee shall decide on the Grievance within thirty (30) days from the date of its submission by virtue of a substantiated resolution. If no response is made to the Grievance within such a time limit, the same shall be deemed rejected, and the resolution on the grievance shall be final.

Article (114)

Government Bodies' Practice of Pharmacy Profession

Federal and local government bodies may practice the pharmacy profession in accordance with the controls set out in this Law and the Executive Regulations hereof, while other the bodies may apply for the license to practice the pharmacy profession accordance with the controls set out in this Law and the Executive Regulations hereof.

Article (115)

Judicial Officers

Employees of the Ministry and the Body Concerned, who are designated by a resolution of

the Justice Minister in coordination with the Minister or the Head of the Body Concerned, shall have the capacity of judicial officers, for the sake of detecting and processing the violations committed in breach of the provisions of this Law and the Regulations issued in implementation hereof, within the scope of their respective competences.

Article (116)

Obtaining Necessary Licenses

Obtaining the licenses provided for herein shall nor relieve the licensee from obtaining the other licenses required by the applicable laws, regulations or rules in the State.

Article (117)

Exceptions

Repealed pursuant to Federal Law No. (4) of 2022.

Article (118)

Adjustment of Affairs

Effective as of the entry into force date of this Law, all persons covered by the provisions hereof shall be required to adjust their affairs in accordance with the provisions hereof, not later than one year from the entry into force date hereof. However, the Minister may extend such a time limit for an aggregate duration of not more than five years.

Article (119)

Executive Regulations of this Law

1. The Executive Regulations hereof shall, in particular, set out the conditions and controls of the following matters:

A. Providing drug products and medical means required for the society's need permanently.
B. The circulation of medical products donates.
C. Temporary licensing of visiting pharmacists.
D. Maintaining the medical products in the course of carry out maintenance of the pharmacy.

2. The Executive Regulations hereof shall be issued under a resolution of the Cabinet based upon the recommendation of the Minister, within six months from the date of its publication in the Official Gazette.
3. The Minister shall issue any other resolutions as required for implementing the provisions hereof.

Article (120)

Authorization

The Cabinet may issue a resolution delegating any of the Ministry's competencies provided for herein to any Body Concerned.

Article (121)

Repeals

Federal Law No. (4) of 1983 and Federal Law No. (20) of 1995 - referred to hereinabove - shall both be repealed, but the Regulations and Resolutions issued in implementation

thereof shall remain in full force and effect insofar as they do not go against the provisions hereof, until the implementing Regulations and Resolutions hereof are issued.

Article (122)

Repeal of Repugnant or Conflicting Provision

Any provisions that contradicts or is repugnant to the provisions hereof shall be repealed.

Article (123)

Publication and Entry into Force

This Law shall be published in the Official Gazette and shall enter into force thirty (30) days following its publication date.

Signed

Khalifa Bin Zayed Al Nahyan

UAE President

Issued by us at the Presidential Palace in Abu Dhabi

On: 22 Rabi' Al-Thani, 1441 AH

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