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

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

- After perusal of the Constitution;
- Federal Law No. 1 of 1972 on Competencies of the Ministries and Powers of the Ministers, and its amendments;
- Federal Law No. 8 of 1980 on the Regulation of Labor Relations, and its amendments;
- Federal Law No. 18 of 1981 on the Organization of Trade Agencies, and its amendments;
- Federal Law No. 4 of 1983 on the Profession of Pharmacy and Pharmaceutical Institutions;
- Federal Law No. 3 of 1987 Promulgating the Penal Code, and its amendments,
- Federal Law No. 35 of 1992 Promulgating the Penal Procedures Law, and its amendments;
- Federal Law No. 37 of 1992 on Trademarks;
- Federal Law No. 18 of 1993 on Promulgating the Commercial Transactions Law;
- Federal Law No. 14 of 1995 on Combating Narcotic and Psychotropic Substances Law; and its amendments;
- Federal Law No. 20 of 1995 on the Medicines and Products Derived from Natural Sources;
- Federal Law No. 17 of 2002 on the Regulation and Protection of Industrial Property for Patents, Industrial Drawings and Designs, and its amendments;
- Federal Law No. 1 of 2006 on Electronic Commerce and Transactions;
- Federal Law No 24 of 2006 on Consumer Protection,
- Federal Law No. 51 of 2006 on Combating Human Trafficking Crimes, and its amendments
- Federal Law No. 6 of 2007 on the Establishment of the Insurance Authority and Regulation of its Operations, and its amendments;
- Federal Law No. 14 of 2014 on the Control of Communicable Diseases;
- Federal Law No. 2 of 2015 on Commercial Companies, and its amendments;
- Federal Law No. 4 of 2015 on Private Health Facilities;
- Federal Law No. 8 of 2015 on the Establishment of Federal Customs Authority;
- Federal Law No. 3 of 2016 on Child Rights (also known as Wadeema's Law);
- Federal Decree-Law No. 4 of 2016 on Medical Liability;
- Federal Decree-Law No. 16 of 2016 on the Establishment of Emirates Healthcare Services Establishment;
- Federal Law No. 19 of 2016 on Combating Commercial Fraud;
- Federal Law No. 9 of 2017 on Regulation of Veterinary Products;

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- Federal Law No. 13 of 2018 on Voluntary Works;
- Federal Law No. 2 of 2019 on the Use of the Information Technology and Communication in Healthcare Sector;
- Pursuant to the proposal of the Minister of Health and Prevention, the approval of the Cabinet and the Federal National Council and the ratification of the Federal Supreme Council;

Have issued the following Law:

Title I

General Provisions

Article (1)

Definitions

The following words and expressions, whenever used in this Law, shall have the meaning ascribed thereto hereunder unless the context otherwise requires:

The Country	:	United Arab Emirates
The Ministry (MOHAP)	:	Ministry of Health and Prevention (MOHAP)
The Minister	:	Minister of Health and Prevention
Competent Department:	:	Competent department at MOHAP.
Concerned Authority	:	Local government medical authority or local authority according to their respective powers.
Competent Authority	:	Drug Department in MOHAP or an equivalent concerned authority.
Higher Committee of Drug Policies	:	A committee in charge of development of policies of medical product circulation, pricing and control within the country.
Competent Committee	:	Any committee formed by virtue of a resolution issued by the Minister to consider the issues that were assigned to and related to one or more tasks set out under this Law.
Medical Product	:	All drugs, medical devices or healthcare products.
Drug	:	Any product that contains an active ingredient or a group of active ingredients that accomplish the intended purpose when applied on/in human or animal through a biological effect. This product is manufactured, sold or made available to be applied in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of illness. 2. Restoration, renovation, modification or

correction of organ's functions.

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Medical Device	:	A medical product that contains any element instrument, tool, machine, appliance, implant, in vitro reagent, calibrator or a system, including its accessories and operating software, which achieves the intended purpose to be applied in or on humans or animals, without pharmacological, immunological or metabolic effect. Medical devices are manufactured, sold or offered to be applied in the following cases: 1. Diagnosis; treatment, cure, relief, monitoring, prevention of illness, injury or disability; 2. Diagnosis, treatment, relief or compensation for an anatomical position; 3. Pregnancy control.
Healthcare Product	:	Any medical product used for general health of a human and not specific for the diagnosis, treatment or cure, which does not require a prescription on dispensing or direct medical supervision when applied.
Veterinary Product	:	A pharmaceutical product designed to be applied in or on animals only.
Pharmaceutical Product	:	A medical pharmaceutical product that is produced in a specific approach and has specific applications for human and animal.
New Pharmaceutical Product	:	A medical product that contains a new active ingredient, where no other medical product containing the same ingredient has obtained marketing authorization within the country, while the period during such product containing the same active ingredient has been marketed globally did not exceed 2 years.
Generic Pharmaceutical Product	:	A product that is similar to another pharmaceutical product with the same quality and quantity of active ingredients, pharmaceutical formula and bio-equivalency.
Defective Product	:	A product that does neither meet quality specifications nor the requirements set out under this Law, executive decree or resolutions implementing it.
Counterfeit Product	:	A product that deliberately and fraudulently produced with intent of deception and fraud, including: 1. Providing its cover, packing, identification label or patient information leaflet with false or incorrect information in regards with its identity

or origin and in means not identical to the reality.
2. Counterfeiting another drug using the same technical design, cover colors, packing and identification label of the original product.

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3. Addition or removal of an active or non-active ingredient(s) of the drug's formulation prescribed on its cover, packing, identification label, patient information leaflet without the permission of the competent department.
4. Change of volume or quantity of its active or non-active ingredient(s) without the permission of the competent department.

Raw Materials	:	Materials contained within medical product's composition or manufacture.
Marketing Authorization	:	Approval issued by MOHAP to franchisee of the marketing of a product within the country.
Marketing Authorization Appendix	:	An appendix that contains product-related information, description, formulation and volume of active and non-active ingredients, applications, doses, route of administration, side effects and any other details defined by the Law, its executive decree, implementing orders and institutions.
Patient Information Leaflet	:	A leaflet that contains an important brief information of Marketing Authorization Appendix intended for medical product users.
Active Ingredient	:	Any substance(s) of major effects in the product. Such substances may be derived from human, animal, plant, microorganisms, chemicals or others.
Major Effects of Medical Product	:	Effects on medical product user, under which the product is applied according to its indications in its marketing authorization.
New Indication	:	A newly introduced indication to the existing indication list of a medical product, which marketing is previously authorized within the country, provided that such new indication has resulted from other effects than those major effects of the previous indications.
Approved Pharmacopoeia	:	Pharmacopoeia approved within the country as references.
Pharmaceutical Form	:	The form of produced or manufactured medical product, including its final form to be administered by the patient.
New Route of	:	A new route of administration which has not

New Route of Administration	:	A new route of administration, which has not previously obtained marketing authorization within the country to obtain the product's major effects.
Side Effect	:	A number of indications and effects documented in the patient information leaflet, which is expected to occur on some patients and may occur during drug application according to the applications, doses, and methods of application shown on the cover, label and patient information leaflet as set out in the marketing authorization.
Adverse Reaction	:	Any unintentional or undesirable effect that occur on medical product user as a result of the prescribed doses and authorized applications in the marketing authorization, which may occur as a result of effects other than those major effects of the medical product.
Adverse Event	:	An undesirable medical event occurs on a medical product user, which is not necessarily resulted from product's application.
Unexpected Adverse Reaction	:	Adverse reaction unexpected to occur during application of medical product and which nature or occurrence exceeds the limit prescribed in the Marketing authorization Appendix.
Critical Side Effect or critical adverse reaction	:	Undesirable or unintentional non-treating occurrence that leads the medical product user, by any dose or method, to undergoing the following result(s): 1. Death; 2. Causing an event that threatens the patient's life, which require admission or extends stay at hospital; 3. Causing a permanent disability or deformity; 4. Death, congenital or physical malformation of fetus or any negative effects thereon.
Non-Clinical Trials	:	Toxic or pharmaceutical trials aimed at assessment of medical product and that are not conducted on humans.
Clinical Trials	:	Trials or researches observing a specific product and conducted on groups of humans to identify absorption, metabolism, circulation and excretion, to identify its major effects, side effects and adverse reactions to verify the medical product's effectiveness, efficiency, quality and safety according to the previously agreed applications subject to the marketing authorization granted to the medical product, new indications or drugs under research and development

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drugs under research and development.

Non-Intervening Clinical Trials	:	Clinical trials in which medical products are applied according to doses, methods of administration, applications in line with the marketing authorization within the country, which may not require those undergoing it any change in their medical prescription or normal lifestyle.
Bioavailability	:	Speed and extent of active ingredient absorption and availability of a medical product and any of its active metabolites in blood or place of drug action in body.

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Bioequivalence	:	The absence of a significant difference in the rate and extent to which the active ingredient in pharmaceutical equivalents with the same active ingredient.
Research Information	:	Any piece of Information obtained as a result of chemical, manufacturing, controls, pre-clinical and clinical studies to support the safety, efficiency or quality of new pharmaceutical product to obtain marketing authorization.
Equivalent Alternative	:	Equivalent alternative drug of another drug, which is therapeutically equivalent, gives the same therapeutic effect and benefits and the extent of pharmaceutical safety for the patient according to its approved applications.
Stability Studies	:	Examinations performed in similar approved storage conditions or in severe conditions to increase the rate of chemical or physical decomposition of a medical product to monitor decomposing interactions or any evidence on invalidity of the product so as to assess the product's validity period under the approved storage conditions.
Batch	:	A quantity of a specific medical product produced at one time. A batch contains a unique identification number and date of manufacture after undergoing the necessary inspections and tests.
Product Withdrawal	:	Withdrawal procedure of the entire product or a batch due to a defect, or to verify the validity of a report on critical adverse or side effect, or any other reasons stated by the authority requiring product withdrawal. Withdrawal may be by the manufacturer, distributor, importer, by an order of the concerned authority or by MOHAP.
Reference Country	:	The country which approved a medical product

Reference Country	:	The country which approval of medical product marketing is adopted to approve product marketing within the country.
Healthcare Practitioner	:	Scientifically and technically qualified person, licensed to practice a healthcare profession within the country according to executive decree of this Law.
Profession of Pharmacy	:	A healthcare profession that aims at improving the health standard of medical product users through proper and appropriate usage of such products, based on specialized scientific knowledge. The profession of pharmacy includes a number of licensed activities to be practiced by the pharmacist and shall not be limited to manufacturing, composition, dispensing, administration, sale and storage of medicinal product,

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		or providing pharmaceutical advises, however it includes any other activities determined by a ministerial resolution. It also includes a variety of healthcare services to the patient, directly or through an assistance for other licensed healthcare practitioners, by communicating and providing clinical (technical and scientific) advices.
Clinical Pharmacy	:	A branch of pharmacy based on scientific knowledge to ensure utmost patient benefit from medication treatment plan, cure, health enhancement, and disease or complication prevention.
Qualified Person	:	Scientifically and technically qualified person, licensed to practice a pharmacy or medicine profession according to this Law and its executive decree.
Pharmacist	:	A person who holds a scientific qualification no less than bachelor of pharmacy or an equivalent degree from a higher institution, college or university recognized in the country. A pharmacist must be licensed to practice pharmacy within the country according to this Law and its executive decree.
Pharmacist In-Charge	:	A licensed pharmacist for a licensed pharmacy. The pharmacist shall be responsible of implementing the provisions of the Law and its executive decree within the limits of assigned tasks.
Precautionary Closure	:	A precautionary action taken by the pharmacy's inspector in case a serious violation that may lead to damages of public health is observed.
Clinical Pharmacist	:	A person who holds approved clinical pharmacy

		certificates and has extensive experience in this field. A Clinical pharmacist develops treatment plans for patients, including usage of medical products based on scientific analysis of the patient's condition as well as a report on patient's diagnosis. Further, clinical pharmacists provides professional advices on therapeutic treatment plan and the optimal application of pharmaceutical products for healthcare practitioners, who are members of medical staff responsible of the patient, and the patient himself.
Pharmacy Technician	:	A person who holds a scientific qualification no less than diploma of pharmacy, with a study duration must not be less than two years after secondary school or an equivalent, from a recognized authority in the country. Pharmacy technician must be licensed to practice pharmacy technician profession under the direct supervision of a licensed pharmacist according to the provisions of this Law.
Medical Prescription	:	A written or electronic document issued by healthcare professional a duly licensed to dispense according to the executive decree of this Law, resolutions, orders and instructions issued in this regard. Further, oral order issued by a healthcare professional is deemed a prescription, provided it must be documented later according to a ministerial resolution.
Therapeutic Treatment Plan for the patient	:	The plan that includes medicinal products designed based on careful analysis of the pathological status and patient condition to obtain the best possible results for treatment. The plan also includes schedule for administration of drugs, which stipulates the name, type, pharmaceutical form, titer, route of administration, dose volume, number of daily doses, duration of treatment and any other instructions such as sequence of use of products or gradual modification of doses… etc.
Medical Product Application System (Protocol)	:	The system approved by the health establishment or therapist, which sets out the cases permitted to apply the medical product, contraindications, terms of product application sequence, duration of treatment and route of administration.
Guidelines of Treatment of Cases	:	A system that governs the method to advance cases according to accurate instructions. Such guidelines set

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		out the terms of diagnosis, determine the medical product and the other therapeutic actions for each case and the sequence of their usage and functioning.
Direct Supervision and Control	:	Full knowledge and complete follow-up at all times of all activities carried out by pharmaceutical facility staff.
Distribution Channels	:	The pharmaceutical facilities that the medical product passes through during its distribution process, from the location at which it is finally manufactured to dispensing to end-user in the country.
Pharmaceutical Facility	:	A facility licensed to operate in any discipline of the profession of pharmacy within the country, including pharmacy, pharmacy chain, medical warehouse, marketing offices, marketing consultation offices, pharmaceutical laboratory, pharmaceutical research offices, factory and other facilities stipulated by the executive decree of this Law.
Pharmacy	:	The facility licensed to store, prepare, compound, dispense, display or directly sell the medical products

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		to the public through a fixed or mobile, permanent or temporary facility.
Pharmacy Chain	:	A number of pharmacies owned by a natural or legal person under the same name.
Medical Warehouse	:	A place licensed to store medicinal product according to the provisions of this Law and its executive decree. The warehouse may be licensed for imports and distribution or for distribution purpose only.
Storage	:	Keeping the medical product in any time during its cycle in manufacturing and distribution channels.
Distribution	:	Transportation or movement of medical product from the producing factory to any other central point to the end user or to an intermediary point, using equipped transportations.
Importer	:	A person licensed to import any quantity of medical products from outside the country for the purpose of possession, storage, distribution or wholesale.
Distributor	:	A person licensed to practice any activity related to medical product circulation, except for importation and direct sale to the public.
Marketing Authorization Holder	:	The legal person authorized to market a specific medical product within the country and is responsible of all marketing, promotion and follow-up aspects of

		the product within the country.
Manufacturing	:	A number of activities including purchase of raw materials and equipment used in manufacturing, production processes including preparation, compounding, extraction, packaging or re-packaging of any medical product, product quality control, product approval and other processes according to the executive decree of this Law.
Manufacturer	:	The facility intended to totally or partially produce medical products.
Product Manufacturing Approval	:	The approval issued by MOHAP to the manufacturer licensed in the country to totally or partially produce a specific medical product.
Manufacturing Authorization Holder	:	The pharmaceutical facility licensed to totally or partially manufacture medicinal product according to terms and actions stipulated under the executive decree of this Law.
Marketing Office	:	The pharmaceutical facility licensed to practice medical product introduction to healthcare professional and following up circulation of such products in the country.

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Marketing Consultation Office	:	The pharmaceutical facility licensed to provide specialized consultations in pharmacy applications field.
Pharmaceutical Laboratory	:	The pharmaceutical facility licensed to inspect, test and conduct quality control on medicinal products.
Laboratory Studies	:	Studies and researches performed on a medical product(s) or its active ingredient(s) within the scope of the laboratory and laboratory tests to identify its toxic, chemical, physical microbiological or technical characteristics. Laboratory studies are not conducted on human; however, they may be conducted on animal.
Research office	:	The pharmaceutical facility licensed to conduct clinical, bioavailability or bioequivalence researches and studies related to measurement of the levels of active ingredients in bio liquids and tissues.
Compounding Pharmacy	:	The pharmaceutical facility licensed to compound a pharmaceutical product based on prescription or to meet the health facilities needs of necessary compounded products.

Toxic Substances and Plants	:	Substances and plants identified according to the legislations governing this type of substances or plants.
Narcotic and Psychotropic Substances	:	Medical and therapeutic products and others containing any of the active ingredients according to Federal Law No. 14 of 1995, and its amendments.
Semi-Controlled Substances	:	Substances or drugs not listed as narcotic or psychotropic substances, however they must be controlled inside the country, as its misuse may lead to harm of public health.
Chemical Precursor	:	A chemical substance that become incorporated into a narcotic drug, psychotropic substance, hazardous substance, psychoactive or toxic substance during the manufacturing process according to both lists attached hereto, as subsequently amended.
Prohibited Veterinary Substances	:	Substances listed according to the legislations governing this type of substances.
Hazardous Medical Products	:	Products for which determination and scope of prohibited applications a ministerial resolution must be issued.
Controlled Substances and Products	:	Products and substances which medical and commercial circulation require controlling actions. such products include: 1. Toxic substances and plants. 2. Prohibited veterinary substances.

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3. Narcotic and psychotropic substances, whether in form of raw materials or incorporated in a medical product.
4. Hazardous medical products.

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Article (2)

Law's Scope of Application

The provisions of this Law shall apply to the medical products, the profession of pharmacy and pharmaceutical facilities in the country, including free zones according to the regulations stipulated herein and the executive decree.

Title II

Regulation and Circulation of Medical Products

Chapter 1

Marketing Authorization and Marketing Authorization Holder

Article (3)

Marketing Authorization

No medical product may be circulated within the country unless after obtaining marketing authorization or exclusive marketing authorization from MOHAP according to the terms and procedures set out by a ministerial resolution, without prejudice to the applicable veterinary product legislations.

Article (4)

Assessment of Product Compliance with Research Information

New medical product, application or route of application's marketing authorization shall be issued by MOHAP based on assessment of compliance with research information, which proves efficacy and safety of its application and compliance with the approved quality specifications or marketing authorizations issued for the product by the Reference countries, provided that the approval applicant should have the right to market the product according to intellectual property and trademark regulations.

Article (5)

Product Pricing

To circulate the medical product that obtained the marketing authorization, it must be priced. Medical products priced under a resolution from the Minister are excluded from such pricing.

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Article (6)

Marketing Authorization of Generic Pharmaceutical Product

Without prejudice to the provisions of international conventions in which the country is a member, and to the provisions of Federal Law No. 17 of 2002 mentioned, MOHAP may issue marketing authorization to a generic pharmaceutical product, based on its bioequivalence and qualitative equivalence to another product on which the legal protection is ended and has previously obtained marketing authorization according to the provisions of this Law.

Article (7)

Authorization Applicant's Obligations

Medical product marketing authorization applicant is obliged as follows:

1. To appoint one or more qualified persons residing in the country according to a resolution from the Minister.
2. To provide a medical warehouse(s) to carry out the activities of importation, storage, distribution and wholesale of marketing approved products.
3. To follow-up medical product through distribution channels.
4. To provide the necessary capabilities and systems to follow up the requirements of medical product marketing authorization.
5. To monitor the performance of the licensed medical product and receive reports by the pharmaceutical facilities in regards with its effectiveness, safety, usage and quality.
6. To inform MOHAP and the concerned authority within a maximum period of fifteen (15) days as of the date of observance of unexpected side effects, unexpected adverse effects, critical side effects or critical adverse effects reported or monitored during circulation or local or global clinical researches conducted thereon.
7. To follow up procedures of medical product withdrawal.
8. To follow up product patent and manufacture right protection.

Article (8)

Sale of Priced Medical Product

1. The priced medical product must be sold at the price fixed by MOHAP.
2. No discounts shall apply to the price fixed by MOHAP. However, special prices may be set according to a dispensing system by the authorities mentioned in the executive decree of this Law.

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Article (9)

The Obligations of the Person Appointed by Marketing Authorization Holder

The qualified person appointed by the marketing authorization holder shall:

1. Provide pharmaceutical or scientific information on the marketed medical product to the health facilities and shall be careful of its accuracy and compliance with the information approved by MOHAP.

with the information approved by MOHAP.

2. Inform MOHAP of any change or modification of manufacturing or compounding methods, the origin of active ingredients, the form, packing or quality inspection of the medical product, as well as any new indication, change, modification, addition or removal of the indications set out within the marketing authorization to obtain approval on any of the above. MOHAP shall inform the concerned authorities of the reported data and information after its approval.
3. Monitor the side effects of the medical product within the country and inform MOHAP and the concerned authorities of any side effects, unexpected adverse effects or dangerous adverse effects caused by the medical product inside or outside the country within fifteen (15) days as of the date of its observance.
4. Follow up post-marketing medical product reports, along with reports of effectiveness, safety and quality of product application within the health facilities in the country.
5. Inform MOHAP and the concerned authority of any complaint or report to withdraw a medical product batch or the entire product inside or outside the country within fifteen (15) days as of the date the complaint or report is received.

Article (10)

Joint Liability

The qualified person shall be jointly liable with the marketing authorization holder for any violation of the provisions of Law, especially in regards with keeping all records and registries of medical product storage and distribution.

Article (11)

Medical Product Suspension and Withdrawal

1. MOHAP may suspend medical product if it is found necessary to verify information regarding lack of quality, safety or effectiveness. The concerned Authority shall issue a decision of withdrawal of the entire product or a number of batches thereof within thirty (30) days as of the date of suspension in any of the following cases:

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a) If the medical product is proved to be counterfeit or non-conforming to the quality, safety or effectiveness specifications approved by MOHAP;
b) If the medical product is proved to be toxic or harmful under the conditions of application recommended by the manufacturer or marketer;

c) If an unexpected side effect or unexpected adverse effect occur under the conditions of application recommended by the manufacturer or marketer;
d) If the marketing authorization of the medical product is cancelled or the product's production is ceased in the Reference country due to reasons related to product's quality;
e) If it is proved that the marketing authorization is obtained based on false documents, incorrect information or illegal means;
f) If any change has occurred on the product's formulation, form, patient information leaflet, method of manufacture or place of manufacture without the consent of the Competent Department; or
g) In case of violating any of the conditions stipulated under this Law, its executive decree, implementing decisions, terms and instructions.

2. In all cases, MOHAP and the concerned authority shall mutually coordinate in regards with any actions to be taken according to this Article. The concerned authorities, according to their respective powers, shall have the right to suspend the product in government and private health facilities with obligation that MOHAP shall be notified according to the executive decree of this Law.

Article (12)

Temporary License

In the event a specific product is proved to be unavailable and an equivalent product is absent in the country, a resolution of the Minister, by virtue of the recommendation of a competent committee, composited of the concerned authorities' representatives, may be issued to permit issuance if a temporary license to another marketing authorization holder(s), under which the licensee shall provide the unavailable product in the country in time, according to the price approved by MOHAP, agreed quantities, subject to the provisions of the said Federal Law No. 17 of 2002.

Chapter 2

Clinical and Non-Clinical Trials

Article (13)

Prohibition of Clinical and Non-Clinical Trials

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Non-clinical trials must not be conducted on humans. Further, clinical trials cannot be

conducted prior to performing non-clinical trials to ensure the extent of safety and effectiveness of medical intervention subject of clinical trials.

Article (13)

Clinical Trials Provision

Without prejudice to any other laws, no clinical or bioequivalence or bioavailability studies of a medical product may be conducted on humans, unless after obtaining approval from MOHAP or the concerned Authority, as the case may be, in addition to conducting the necessary medical investigations for the person subject of clinical study to ensure his safety after obtaining a written approval containing an acknowledgment on his part of the clinical study and its potential risks. An exception from this approval may apply to non-intervening clinical trials. MOHAP or the concerned Authority, as the case may be, shall be notified.

Article (15)

Approved Clinical Trial Conduction Entities

1. MOHAP or the concerned Authority may approve the following entities to conduct the clinical trials:
   a) Public and private hospitals;
   b) Universities and specialized scientific research centers. In the event of inability to conduct clinical trials therein, trials may be conducted in authorized hospitals; or
   c) Laboratories.
2. Clinical trials and tests may not be conducted on bio samples of the trials in any entities other than those approved according to this provision.

Article (16)

Obligations of the Entity that Clinical Trial is Conducted in Favor

The entity that clinical trial is conducted in favor is committed:

1. To develop the trial plan to be performed, including scientific justifications.
2. To provide licensed physicians to supervise the safety of persons subject of the trial.
3. To conclude an insurance contract at an insurer operating within the country to cover the damages that may be resulted from the trial.

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4. To comply with the code of good clinical trials practices adopted by MOHAP.

Article (17)

Higher Committee of Clinical Trials Ethics

1. A Higher Committee of Clinical Trials Ethics shall be established within MOHAP and shall include all the concerned authorities. A resolution from the Minister shall be issued for the formation and functioning of the committee, with members experienced in healthcare, sharia and legal fields. The committee's scope shall be the clinical trials ethics, which duties shall include:
   a) To develop policies related to clinical trials ethics on federal level.
   b) To support innovation, scientific research in line with respecting clinical trials ethics.
   c) To present any suggestions that may contribute to the development of federal legislations supporting scientific research and innovations, in line with clinical trials ethics.
   d) To coordinate between the concerned authorities in the field of clinical trials ethics.
   e) To approve transition between clinical trials phases according to the number of volunteers subject of trials.
   f) Any other activities related to its work as assigned by the Minister.
2. The concerned authority shall:
   a) Apply the policies and local legislations related to clinical trials ethics on health authority level.
   b) Coordinate with MOHAP's Higher Committee of Clinical Trials Ethics and notify it of any negative or unknown results of the medical product that may occur during or post trial.
   c) Approve establishment of sub-committees at the facilities conducting clinical trials according to Article No. 18 of this law.
   d) Any other activities related to its functions as assigned by the head of health authority.
3. The concerned authority may form a committee(s) to carry out the duties mentioned in Item No. 2 of this article.

Article (18)

Sub-Committee of Clinical Trials

Approved Clinical Trial Conduction Entity shall form a specialized sub-committee, which members shall be qualified and competent persons, including one legal employee. The sub-committee's activities shall be as follows:

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

Article (19)

Obligations of the Main Researcher and Entity towards Clinical Trial

The main researcher supervising conduction of clinical trial and the entity at which trial is conducted shall adhere to the trial plan and code of good clinical trials practices and inform the entity in which favor the trial is conducted, the head of sub-committee of the approved entity referred to in Article No. 18 herein, MOHAP or the concerned authority, as the case may be, in any of the following cases:

1. Occurrence of dangerous adverse event during the trial. This must be informed within fifteen (15) days as of the date of occurrence.
2. Prior to any changes to the trial plan so as to protect those persons subject of the trial, or in case of urgency to make the change.
3. Reporting the request that caused pausing the trial and in case of withdrawal of any of the persons subject of the trial.

Chapter 3

Laboratory Studies

Article (20)

Accredited Laboratory

No laboratory study, product-testing certificate or quality certificate for a batch(s) of medical product may be approved as a document proving its quality or stability, unless

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it is conducted and approved by an accredited laboratory approved by MOHAP or the concerned Authority according to guidelines adopted by a resolution from the Minister.

Article (21)

Laboratory Accreditation Procedures, Term and Conditions

Laboratory accreditation procedures, terms and conditions stipulated in Article No. 20 herein and the certificates issued thereto shall be specified by a resolution of the Minister after coordination with the concerned Authorities.

Chapter 4

Manufacturing Medical Product

Article (22)

Provisions of Manufacturing Medical Product

A medical product may not be manufactured within the country unless after obtaining MOHAP's approval, provided that it is manufactured by a licensed or approved factory in the country according to the standards and criteria issued by virtue of a resolution of the Minister.

Article (23)

Good Manufacturing

Good manufacturing conditions and requirements to be met by all medical product-manufacturing factories shall be issued by virtue of a resolution of the Minister. The concerned Authority shall be in charge of monitoring compliance with such conditions and requirements.

Article (24)

Cancellation of Authorization by the Competent Department

The Competent Department may cancel medical product manufacturing authorization, in case of authorization holder's failure to apply for product marketing authorization without reasonable justification within two years as of the date of product manufacturing authorization.

Article (25)

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Cancellation of Authorization by the Minister or His Deputy

The Minister or his deputy shall, based on a recommendation of the competent committee, issue a resolution to cancel the medical product manufacturing authorization in the country in any of the following cases:

1. If it is proved that the manufacturing authorization or factory's accreditation is based on false documents;
2. If a resolution issued for prohibition of product manufacturing in the country or the country of origin or any of the reference entities approved by MOHAP;
3. If it is proved that the factory does not apply the principles of good manufacturing practice, which affects the quality of the medical product;
4. If the product is found unsafe or has repeatedly failed to comply with the approved quality standards at the time of laboratory tests performed in the accredited laboratories in the country. A resolution of the Minister shall specify the number of failures that require cancellation of manufacture authorization; or
5. If a resolution is issued to ban the factory's activities in the country, country of origin or any of the reference entities approved by MOHAP.

Chapter 5

Import and Export of Medical Products and Raw Materials

Article (26)

MOHAP Approval

Medial products and the raw materials contained therein may not be imported, exported or re-exported unless by MOHAP's approval. The Minister may delegate the concerned Authority in this regard, within the scope of medical products intended to be used by government health facilities.

Article (27)

Appointment of a Pharmaceutical Facility

The marketing authorization holder shall appoint a pharmaceutical facility licensed to import, as an importer of the medical product that the marketing authorization holder has the authority to market. In addition, the marketing authorization holder shall appoint a pharmaceutical facility or facilities licensed to distribute, as distributors within the country.

In all cases, marketing authorization holder shall obtain MOHAP's approval on appointment and shall follow up the product's batches through various distribution channels within the country.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Article (28)

Personal Application of Medical Product

The executive decree of this Law specifies the conditions and requirements of importation, possession or obtainment of medical product for personal application when entering into the country.

Chapter 6

Circulation of Medical Product

Article (29)

High Committee for Drug Policies

The Minister shall issue a resolution to form High Committee for Drug Policies, which members shall include representatives of MOHAP and the concerned Authorities and shall suggest policies related to circulation, pricing and monitoring the medical products in the country. In addition, the Committee shall approve the rules, conditions and procedures to obtain marketing authorization approval on medical products. Resolution of Committee's formation shall set out the Committee's functioning procedures.

Article (30)

Product Provision

Marketing authorization holder may not illegally or for purpose of domination refrain from providing the medical product that obtained marketing authorization according to the provisions of this Law.

Article (31)

Prescribed Products

Non-pharmaceutical facilities may not sell, display, store or circulate any medical products that require a medical prescription

products that require a medical prescription.

Article (32)

Non-Prescribed Products

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

A Minister's resolution shall be issued to specify the non- pharmaceutical facilities, which are allowed to sell, display, store or circulate medical products that may be dispensed without a prescription, along with the names of such products, according to the conditions set out in the executive decree of this Law.

Article (33)

Information and Data

A medical product may not be circulated or marketed unless the information and data shown on the internal and external labels and patient information leaflet are identical to those shown on the packing according to the marketing authorization appendix. The competent committee shall specify the data to be noted on the internal and external labels and the patient information leaflet.

The patient information leaflet should be written in at least Arabic and English languages, except for the cases of necessity, where a resolution of the Minister shall be issued.

Article (34)

External Packing Remark

Every manufacturer, marketing authorization holder and distributor must place the following remark ineffaceable material on the healthcare product: "This is a non-diagnosing, treating, curing or preventive product".

Article (35)

Reporting Negative or Harmful Results

All pharmaceutical facilities, healthcare facilities and healthcare professionals working at both of them shall report to MOHAP and the concerned Authority any negative or harmful results of the medical product due to quality's non-conformity to the standards

harmful results of the medical product due to quality's non-conformity to the standards adopted by MOHAP within fifteen (15) days as of the date of knowledge thereof.

Article (36)

Prescription of Medical Products

1. Physicians may not prescribe a medical product to be applied for new indications other than those specified within patient information leaflet or a medical product

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

that did not apply to obtain marketing authorization, except it is necessary to do so, provided the absence of bioequivalent and subject to the patient's consent.
2. Licensed healthcare professionals may not advice, prescribe or dispense any medical product, unless he is authorized so according to the provisions of this Law and Executive decree thereof.

Article (37)

Other Healthcare Professionals

Licensed healthcare professionals other than pharmacists and technical pharmacists shall not directly or indirectly sell any medical product unless after obtaining an approval from MOHAP or the concerned Authority.

Article (38)

Prohibition on Prescription for Personal Gain

Healthcare professionals are prohibited to prescribe or advise any product to obtain a personal gain.

Chapter 7

Promotion and Advertisement of Medical Product

Article (39)

Disallowing and Allowing Advertisement

1. A medical product dispended by a medical prescription may not be publicized or advertised to the public by whatsoever means.

2. It is permissible with MOHAP's approval:
   a) To publicize or advertise a medical product in the scientific fields and sources intended to the healthcare professionals.
   b) To publicize or advertise to the public a medical product, which is not necessarily dispensed under a medical prescription or a medical product that obtain a marketing authorization.

Article (40)

Marketing Authorization Holder

Marketing Authorization Holder is committed that medical product advertisements and promotions shall be in line with the terms and conditions set out by MOHAP.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Article (41)

Licensee

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

Article (42)

Prohibition on Circulation and Sale

1. Counterfeit, defective or expired medical products cannot be circulated.
2. Free medical product promotion samples cannot be sold and the externals and internal labels of such samples shall be clearly sealed in ineffaceable material with the following remark "Free medical sample, not for sale" in both Arabic and English.

Article (43)

Free Samples

Non-healthcare professionals licensed to prescribe medicines may not receive free medical samples for purpose of prescription. A record shall be kept showing all controlled drug samples entries.

Title III

Regulating the Profession of Pharmacy and Pharmaceutical Facilities

Chapter 1

Licensing Pharmacists

Article (44)

Requirement of Licensing for Commencement of Business and Registration

1. No one is authorized to be a pharmacist or technical pharmacist, unless he is licensed by MOHAP or the concerned Authority according to the terms specified under the executive decree of this Law.
2. A national register shall be established at MOHAP, in which the data of licensed pharmacists and technical pharmacists in the country shall be entered.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

3. The concerned Authority shall obtain a record containing data of pharmacists and technical pharmacists licensed by the concerned Authority.
4. Pharmacists noted in records according to this Article shall be classified according to their qualifications and expertise.
5. The Executive decree of this Law shall set out the terms and procedures of registration in the said records.

Article (45)

License Applications and License Renewal

1. MOHAP or the concerned Authority shall, according to its powers, review and approve applications for pharmacist or technical pharmacist license or license renewal, according to the terms set out by the Executive decree of this Law.
2. MOHAP shall issue its decision on license application within thirty (30) days as of the date of application. In the event license or license renewal application is rejected, it must be substantiated. If the said period expired without reply, license application shall be deemed as rejected.

Chapter 2

Pharmacist Duties and Prohibitions

Article (46)

Licensed Pharmacist Duties

The licensed pharmacist shall carry out the work thereof in accordance with the rules and traditions of the profession preserve the honor and keep the secrets thereof according to the principles of pharmacy code of ethics. He shall in particular:

1. To work in the pharmaceutical facility in licensed to work at, within the limits of activities licensed to practice according to the terms and conditions stipulated in the Executive decree in this Law.
2. To be accurate and honest in carrying out his work.
3. To inform MOHAP or the concerned Authority, as the case may be, of any unexpected side effects, unexpected adverse effects or dangerous adverse effects caused by the medical product within fifteen (15) days as of the date of its observance. The concerned Authority shall inform MOHAP of any of the events stipulated in this provision.
4. To report any communicable diseases, according to the applicable laws and decisions in this regard.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Article (47)

Clinical Pharmacy

Subject to the provisions of Article 46 of this Law, clinical pharmacist shall provide his specialized services and practice clinical pharmacy, provided the practices is in a licensed health facility providing therapeutic services to patients, in collaboration with the licensed attending physician supervising the patient. In particular, he shall:

1. Prescribe or modify treatment plan, including replacement of drug with another, unless written or electronic instructions were issued by the attending physician prohibiting any modifications. Clinical pharmacist may not take any action towards the patient, unless the patient is diagnosed by the licensed attending physician.
2. The prescribed or modified treatment plan must be in accordance with medical product application protocol and guidelines of patient treatment.
3. Clinical pharmacist shall participate with the attending physician of record and data of patients he is in charge of.
4. To notify the attending physician in writing of implementation or modification of the plan by noting information of the plan and modifications thereto in patient record intended to be reviewed by the attending physician and the clinical pharmacist, within twenty four (24) hours following implementation of the plan

pharmacist, within twenty four (24) hours following implementation of the plan.

5. Advise patients and provide them with diagnostic information including patient-related information, application of medical products and treatment plan information. Further, the clinical physician shall provide such information to healthcare professionals, who are members of patient's treating team.
6. Any of the following activities, provided that they are in line with the general instructions of the healthcare facility he is working at and the medical product application protocols:
   a) To conduct routine tests on the patient's condition in relation with selection and determination of treatment plan, including measurement of pulse, temperature, blood pressure, and spirometry.
   b) To conduct laboratory tests related to the selection and determination of treatment plan.
   c) Dispensing dosages to the patient in line with the physician's instructions such as injections and vaccinations.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Article (48)

Prohibitions on Licensee

A licensee authorized to practice the profession of pharmacy may not breach the duties of his profession or violate the requirements of honesty and honor. In particular, he shall not:

1. Conduct any behavior that degrades the profession, such as illegal competition, improper appearance or smoking in the workplace.
2. Divulge to anyone the diseases known thereby through the medical prescription submitted thereto or related to the work thereof in any other way due to the practice of the profession thereof, unless the applicable laws in the country require so.
3. Follow illicit methods to encourage patients to purchase medical products from the facility he is working at.
4. Withhold, hide or sell the medical products at higher prices than those specified by MOHAP.
5. Change the quantity, type or form of medical products in his possession in contrary to the prescribed provisions of this Law.

6. Sell invalid, defective or expired medical products, products failed to obtain marketing approval from MOHAP, counterfeit or smuggled products illicitly entered into the country.
7. Practice medical or healthcare activities other than those licensed to practice, such as nursing and disease diagnosis, except for first aid stipulated under the executive decree of this Law.
8. Dispense medical products that require prescription, without receiving such prescription.
9. Dispense prescriptions under symbols or references other than those scientifically agreed.
10. Conclude an agreement with the physician or healthcare professional authorized to prescribe medical products, to prescribe specific prescriptions in a special way or other signs agreed between them.
11. Verbally abuse or criticize any healthcare professionals before others.

Article (49)

Medical Prescription

A licensed pharmacist may not dispense any medical product without a medical prescription, if its' dispense requires that. In all cases, a prescription should be:

1. Written in clear handwriting or electronically written in a clear language.
2. Issued by a healthcare professional licensed to issue prescriptions.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

3. Stating the name of the physician who has issued the prescription, his stamp, signature and issue date.
4. Containing the scientific and commercial name or both, pharmaceutical form, and dose, route of administration and duration of application.
5. Stating the patient's full name, age, weight, address, identification number and phone number.
6. Containing information of potential allergic reactions on patient, if any.
7. In compliance with any other terms stipulated under the executive decree of this Law.

Article (50)

Prescription of Narcotic and Psychotropic Substances

1. The Licensed Pharmacist may not dispense drugs containing narcotic or psychotropic substances according to Federal Law No. 14 of 1995 and its

psychotropic substances according to Federal Law No. 14 of 1995 and its amendments as mentioned, unless they satisfy the following terms:

a) The medical prescription shall be issued on the numbered form prepared by MOHAP or concerned authority, according to the respective competencies.
b) It shall be written with an ineffaceable material or electronically written.
c) The prescription shall include commercial drug name, active ingredient(s) name, the volume of medicine, the dose in figures and letters, route and duration of administration and the patient's full name, age and address.
d) The prescribed dose shall not be more than the amount stated in the Pharmacopoeia adopted by MOHAP.

2. Controlled drugs prescriptions may not be dispensed, if the prescription's issue date is beyond the period specified in the executive decree of this Law.
3. Drugs may be dispensed through electronic prescriptions according to the regulations issued by the Minister.

Article (51)

Alteration or Change of Prescription's Items

A Licensed Pharmacist may not substitute or change any content of the medical prescription except after consulting the physician who issued the prescription. However, the pharmacist may replace a pharmaceutical product with an equivalent generic product according to the regulations prescribed by executive decree of this Law.

Article (52)

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Dispensing Refills of Medicines

Pharmacist may not dispense refills of medical prescriptions that includes controlled and semi controlled substances that can accumulate in the body or whose habitual consumption leads to addiction, unless a refill is indicated by the physician who issued the prescription according to the types of products set forth in a resolution by the Minister.

Article (53)

Mistakes in Medical Prescription

If the Pharmacist discovers a mistake in the medical prescription or becomes doubtful

about some of its particulars, he must contact the physician who issued the prescription for clarification. He should return the prescription to the physician if he does not accept the clarifications; in that case, the physician shall underline the point of disagreement in the prescription and sign it.

Article (54)

Registration of Prescriptions

The Pharmacist shall enter the medical prescriptions of controlled and semi-controlled drugs, which he has dispensed, in a register designated for this purpose as decided by virtue of resolution of the Minister, according to the regulations and conditions set forth in the executive decree of this Law.

Article (55)

Prohibition on Issuance of Prescription for Self or Relatives

A licensed healthcare professional may not issue controlled drug prescriptions for himself, spouse or relatives to the second degree.

Chapter 3

Licensing Pharmaceutical Facility

Article (56)

Requirements of Licensing

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

1. No person may open a pharmaceutical facility unless he is a citizen of the UAE National and holder of MOHAP's or the concerned Authority's license, according to their scope of competency.
2. In case of medical product exports, imports and marketing in the country, a proper license from NMOHAP must be obtained.

Article (57)

Duration of License

The pharmacy's license shall be valid until the period specified by the executive decree of this Law. License holder shall practice the profession during the validity period of the license.

Article (58)

Prohibition of Unauthorized Activity

A pharmacy may not carry out any unlicensed activities and may not deal with unlicensed facilities in regards with circulation of medical products within the country. The facility manager shall be held liable in the event of violation of this provision.

Article (59)

Moving the Pharmacy

The pharmacy may not be moved to another location, or the blueprint thereof be altered without the consent of MOHAP or the concerned Authority, according to their respective competencies.

Article (60)

Transfer of Ownership

Without prejudice to the applicable legislations within the country, a pharmacy may be transferred to third party subject to the consent of MOHAP or the concerned Authority, according to the terms specified by the executive decree of this Law.

Chapter 4

Licensing Pharmacy

Article (61)

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Requirements of Licensing

Without prejudice to the conditions specified in Chapter 3 herein, to obtain the license to open a pharmacy, such pharmacy is to be managed by a licensed full-time pharmacist, and that the pharmacy fulfills the technical and health conditions set forth by virtue of resolution of the Minister.

Article (62)

Compounding Pharmacy

Without prejudice to the conditions specified in Chapter 3 herein, to obtain the license to be a compounding pharmacy, it is provided that such pharmacy is to be managed by a licensed full-time pharmacist, and that the pharmacy fulfills the technical and health conditions set forth by virtue of resolution of the Minister.

Article (63)

Temporary Closure of Pharmacy

1. MOHAP or the concerned Authority, as the case may be, may issue a decision to temporarily close a pharmacy for no longer than one month in any of the following cases:
   a) Transfer of pharmacy's ownership to a third party without the consent of MOHAP or the concerned Authority;
   b) The absence of licensed pharmacist or non-appointment of licensed pharmacist to manage the pharmacy according to the required number of pharmacists, as stipulated by MOHAP's decisions, regulations and instructions; or
   c) Committing serious violations according to the executive decree of this Law, which result in causing public health damages if the pharmacy continued to be opened.
2. In all cases, the matter must be referred to the Disciplinary Committee prescribed in Article No. 102 herein, within seven days as of the date of closure to review and consider the disciplinary liability within ten days as of the date of referral.

Article (64)

Cancellation of Pharmacy's License

MOHAP or the concerned Authority, as the case may be, may issue a decision to cancel a pharmacy's license after conducting investigations according to the provisions of tis Law in any of the following cases:

1. Conducting an activity other than those licensed;

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

2. If it is proved that the license to open the pharmacy is obtained based on false documents or incorrect information;
3. The pharmacy is closed for six consecutive months without reasonable justification;

4. Non-commencement of work in the pharmacy within six months from the date of the license issuance without reasonable justification;
5. Committing serious violations according to the executive decree of this Law; or
6. Circulation of counterfeit or invalid medical products.

Article (65)

Absence of Pharmacist In-Charge

Should the licensed pharmacist be absent from the pharmacy managed thereby, he shall entrust the responsibility and the supervision thereof to another licensed pharmacist, subject to the approval of MOHAP or the concerned Authority, as the case may be. In this case, a license may be granted for a limited period according to the terms set forth in the executive decree of this Law.

Article (66)

Pharmacy Chain and Electronic Pharmacies

1. License may be granted to open more than one pharmacy according to pharmacy chain regulations set forth by the executive decree of this Law.
2. A pharmaceutical facility may provide its services electronically according to a resolution of the Minister.

Article (67)

Prohibition on Medical Examinations within Pharmacy

A pharmacy may not be used to conduct Medical Examinations and shall be limited to the licensed activities according to the executive decree of this Law.

Article (68)

Affiliated Pharmacy

MOHAP or the concerned Authority, as the case may be, may issue a license to open a pharmacy affiliated to non-health government authorities, public institutions, public welfare organizations or associations and private hospitals and medical centers, provided that such pharmacies are managed by a licensed pharmacist. The executive

decree of this Law shall set forth the terms of opening such pharmacies and the

respective functioning provisions.

Chapter 5

Licensing Medical Warehouse

Article (69)

Requirements of Medical Warehouse Licensing

1. Without prejudice to the conditions specified in Chapter 3 herein, to obtain the license to open a medical warehouse, it is provided that such medical warehouse is to be managed by a licensed full-time pharmacist, and that the medical warehouse fulfills the technical and health conditions set forth by virtue of a executive decree of this law.
2. An exclusion of the above full-time pharmacist provision may apply in the event that the activity of the medical warehouse was limited to medical equipment, hence an equipment engineer should manage the warehouse and shall comply with the conditions stipulated under the previous article.

Article (70)

Precautionary Closure or Suspension of License

1. The issuer of license, according to its scope, may decide precautionary closure of the medical warehouse or temporarily suspend its license until the violation is remedied , in any of the following cases:
   a) Transfer of medical warehouse's ownership to a third party without the consent of MOHAP or the concerned Authority;
   b) Movement of the medical warehouse from the location to which a license was issued prior to obtaining MOHAP or the concerned Authority's approval;
   c) Committing serious violations, which result in causing public health damages if the medical warehouse continued to be opened, according to the executive decree of this Law; or
   d) Absence of full-time pharmacist to manage the warehouse.
2. A precautionary closure or temporary suspension of license's decision may be issued based on an inspection report from the Competent Authority in MOHAP or the concerned Authority, as the case may be. As to the warehouse carrying on imports and exports, the concerned Authority shall issue precautionary closure or temporary suspension of license's decision once a request from MOHAP is submitted.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

3. In all cases, the matter must be referred to the Disciplinary Committee prescribed in Article No. 102 herein, within seven days as of the date of license suspension or closure to review and consider the disciplinary liability within ten days as of the date of referral. The Concerned Authority shall inform MOHAP of the decision issued for the matter of warehouse carrying on exports and imports once it is issued.

Article (71)

Cancellation of Medical Warehouse's License

1. The issuer of license, according to its competency, may issue a decision to cancel a medical warehouse's license in any of the following cases:
   a) Circulation of counterfeit or expired medical products;
   b) Conducting an activity other than those licensed;
   c) If it is proved that the license to open the medical warehouse is obtained based on false documents or incorrect information;
   d) The medical warehouse is closed for three consecutive months without reasonable justification;
   e) Non-commencement of work in the medical warehouse within six months from the date of the license issuance without reasonable justification;
   f) Failure to remedy the violation within the grace period specified by MOHAP or the concerned Authority according to Article (70) herein; or
   g) Committing serious violations according to the executive decree of this Law.
2. The Concerned Authority shall inform MOHAP of the decision issued for the matter of cancelling the license of the warehouse carrying on imports or exports once it is issued.

Article (72)

Maintaining General Record or Information System

The pharmacist in charge of the medical warehouse shall maintain a general record or information system, in which the type and quantity of medical products and chemicals stored in the warehouse, date of importation, dispensed volume and the party that received such dispense shall be regularly noted in such record. Further, the pharmacist must maintain a controlled drugs record.

The owner and the pharmacist in charge of the management of the medical warehouse shall be jointly liable of such records and the accuracy of information contained therein.

Article (73)

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Placing Pricing Label

The medical warehouse must place a clear label of the price approved by MOHAP on the external cover of the medical product prior to sale and delivery of the product.

The marketing authorization holder, pharmacists in charge and owners of pharmaceutical facilities shall be jointly liable of the pricing label approved by MOHAP on the external product packing.

Article (74)

Delivery or Sale Provision

Medical warehouse may not may not deliver or sell the pharmaceutical products, medical devices or raw materials to any person other than the licensed pharmacist in charge of pharmaceutical facility or the facility licensed to circulate such products.

Article (75)

License of Imports, Exports, and approval of Marketing Authorization Holder

The medical warehouse may not export or import any medical product unless it is licensed to carry on exports and imports by MOHAP. Further, the medical warehouse may not undergo import, storage, distribution or sale of any medical product without the approval of marketing authorization holder approved by MOHAP.

Chapter 6

Licensing Marketing Office

Article (76)

Requirements of Licensing

Without prejudice to the conditions specified in Chapter 3 herein, to obtain the license to open a marketing office, MOHAP's approval must be obtained. In addition, the marketing office's manager must be a qualified healthcare professional to supervise it. The office must fulfill the conditions set forth by virtue of resolution of the Minister, without prejudice to any other licenses stipulated by the applicable legislations.

Article (77)

Prohibitions on Marketing Office

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

A marketing office may not import or store medical products for the purpose of sale and distribution; however, it may keep free samples for product identification purpose, provided that each sample shall be sealed as Free Sample and Not for Sale.

Chapter 7

Licensing Pharmaceutical Consultation Offices

Article (78)

Requirements of Licensing

Without prejudice to the conditions specified in Chapter 3 herein, to open a pharmaceutical consultation office, MOHAP's approval must be obtained, in addition the office's manager must be a full-time pharmacist to directly supervise and manage the office and licensed to work in pharmaceutical consultation. The office and its staff must fulfill the conditions set forth by virtue of a resolution of the Minister.

Article (79)

Prohibitions on Consultation Office

A consultation office may not import, export, distribute or store medical products. The executive decree of this Law shall prescribe the competencies of consultation office.

Chapter 8

Licensing Pharmaceutical Laboratory and Research Office

Article (80)

Requirements of Licensing

Without prejudice to the conditions specified in Chapter 3 herein, to obtain a license to open a pharmaceutical laboratory or research office, it is provided:

1. License must be issued from MOHAP.
2. The person in charge of the pharmaceutical laboratory or research office must be qualified person, who is free to supervise the pharmaceutical laboratory or research office and licensed according to the executive decree of this Law.
3. Pharmaceutical laboratory or research office must be in compliance with the safety conditions and should provide the precautionary procedures to ensure containment of environmental pollutants.
4. Pharmaceutical laboratory or research office must fulfill any other conditions determined by virtue of resolution of the Minister.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Article (81)

Prohibitions on Laboratory or Research Office

Except for chemicals used in medical tests and products prepared for studies and researches, a laboratory or research office may not import, export or store medical products for the purpose of sale, distribution or identification.

Article (82)

Good Laboratory Practice

Licensed pharmaceutical laboratory or research office shall comply with the standards adopted by MOHAP for good laboratory practice.

Article (83)

Researches and Tests on Human

Pharmaceutical laboratory shall not conduct any researches or tests on humans for whatsoever reasons.

Article (84)

Results of Laboratory Tests

Pharmaceutical laboratory person in charge shall issue accreditation certificates for the laboratory tests according to quality standards approved by MOHAP. Further, the person in charge shall maintain test information records according to the regulations and procedures specified by MOHAP.

Chapter 9

Licensing Pharmaceutical Product Factories

Article (85)

Requirements of Licensing

Without prejudice to the conditions specified in Chapter 3 herein, to open a medical product factory, MOHAP's license must be obtained according to the terms and

procedures set forth by virtue of resolution of the Minister, provided the owner is a holder of the country's nationality.

Article (86)

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Factory's Precautionary Closure or Suspension of License

1. MOHAP shall automatically, in coordination with the concerned authorities, or based on a recommendation from the concerned authorities, issue a decision of precautionary closure or suspension of license of a factory in any of the following cases:
   a) Transfer of factory's ownership to a third party without the consent of MOHAP;
   b) Movement of the factory from the location to which a license was issued prior to obtaining MOHAP approval;
   c) Committing serious violations, which result in causing public health damages if the factory continued to be opened, according to the executive decree of this Law; or
   d) Absence of qualified persons for direct supervision and management according to the common rules in this regard.
2. In all cases, the matter must be referred to the Disciplinary Committee prescribed in Article No. 102 herein, within seven days as of the date of license suspension or closure to review and consider the disciplinary liability within ten days as of the date of referral.

Article (87)

Cancellation of Factory's License

MOHAP shall automatically, in coordination with the concerned authorities, or based on a recommendation from the concerned authorities, issue a decision of cancellation of factory's license in any of the following cases:

1. Circulation of counterfeit or invalid medical products;
2. Conducting an activity other than those licensed;
3. If it is proved that the license to open the factory is obtained based on false documents or incorrect information;
4. If the factory is closed for three consecutive months without reasonable justification; or
5. Non-commencement of work in the factory within six months from the date of the license issuance without reasonable justification;

Article (88)

Quality Management Standards and Good Manufacturing Controls

Medical product manufacturer must comply with the set quality management standards and good manufacturing controls approved by MOHAP.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

Article (89)

Re-Manufacture Using New Technical Specifications

A licensed medical product may not be remanufactured using new technical specifications, unless after the factory obtains an approval from MOHAP on manufacturing the product under these specifications.

Chapter 10

Controlled and Semi-Controlled Substances and Drugs

Article (90)

Prohibitions and Instructions of Controlled Drugs

Without prejudice to the provisions of any other law:

1. Compounding of any medical product not contained within the medical prescription, importation or re-exportation of any controlled drug or compounding of controlled drug in contrary to the prescription may not be conducted without the consent of MOHAP.
2. Active ingredients used to manufacture drugs mentioned in Item (1) of this Article may not be used in drugs other than those authorized.
3. The Minister shall issue the necessary instructions that ensure protection from controlled drug risks and prevent misuse or exposure to the effects thereof.

Article (91)

Store and Circulation of Controlled Drugs

A resolution of the Minister shall specify the controls of storing and circulation of controlled drugs.

Article (92)

Possession of Controlled Drugs

Subject to Article 93 of this Law, controlled drugs may not be possessed unless under a permission issued by MOHAP or the concerned Authority, according to its power, and shall be exclusively granted to the following:

1. The pharmacist in charge of medical warehouse, importing or purchasing the controlled drugs from another medical warehouse regulated by MOHAP.

*In Case of any misinterpretation, the Arabic version of this legislation prevails**

2. The pharmacist in charge of management of the pharmacy, purchasing controlled drugs from a licensed medical warehouse regulated by MOHAP and/or the concerned Authority.
3. Licensed physician, using the controlled drugs for purposes of his profession. The Executive decree of this Law shall prescribe the quantities of controlled drugs permitted to be possessed by the physician.
4. Pharmaceutical factories provided that possession of controlled drugs and raw materials of their active ingredients by importation or purchase is regulated by MOHAP according to this Law and its Executive decree.
5. Scientific institution and research offices, provided that they are regulated by MOHAP or the concerned Authority, according to its competencies.

In all cases, possession of controlled drugs shall be limited to the places where they are practicing their profession.

Article (93)

Dispensing Cases of Controlled Drugs

Licensed pharmacist in charge of pharmacy management may not dispense the controlled drugs, except in the following cases:

1. For patients according to a medical prescription issued by a licensed physician.
2. For Owners of sick animals according to medical prescription issued by licensed veterinarian.
3. For Physicians pursuant to signed applications, including an acknowledgment that the requested quantities of controlled or hazardous drugs are for use in their clinics according to the terms set forth by virtue of a resolution of the Minister.

Article (94)

Circulation of Controlled Drugs

To circulate the controlled drugs between licensed pharmaceutical facilities and healthcare facilities, the consent of MOHAP or the concerned Authority must be obtained, based on the competencies of each according to this law

Article (95)

Procedures of Controlled Drug Importation

Neither the medical warehouse nor the medical factory shall be entitled to import controlled or, primary products due its raw ingredients unless after obtaining MOHAP's consent, by virtue of an application signed by the licensed pharmacist in charge of the

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management of the medical warehouse, or the manager of the factory, including all details related to the controlled products and substances to be imported, as well as the quantities, types, method of shipment and approved clearance location in the country.

The executive decree of this law shall determine the customs clearance controls for these substances.

Article (96)

Periodic Inventory of Controlled Drugs

The licensed pharmacist in charge of the controlled drugs of any type specified in Article No. 92 herein must carry out a periodic inventory for the controlled products and substances and notify MOHAP of its results. Should he notice a difference therein, he must notify MOHAP or the concerned Authority, as the case may be, within two (2) working days.

Article (97)

Hazardous and Toxic Substances and Products

Without prejudice to the provisions of the international conventions in which the country is member, hazardous and toxic substances may not be circulated except in accordance with the terms issued by virtue of the Minister's resolution.

Lists of hazardous and toxic substances shall be determined by virtue of a resolution of the Minister in coordination with the concerned authorities in the country.

Article (98)

Entity Work Cessation

In the event the entity holding controlled substances and products possession authorization stopped its work or the person in charge of its custody disclaimed such custody for whatsoever reason, such entity shall conduct inventory and initiate handing over such substances and products according to the terms and procedures stipulated under the Executive decree of this Law.

Article (99)

Semi-Controlled Drugs

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List of semi-controlled drugs and terms and conditions for circulation thereof shall be determined by virtue of a resolution of the Minister in coordination with the concerned authorities in the country.

Chapter 11

Circulation of Chemical Precursors

Article (100)

Lists of Chemical Precursors

1. Without prejudice to the provisions of the international conventions in which the country is member and to any other laws, two lists of chemical precursors used in manufacturing medical and therapeutic products shall be annexed hereto.
2. The two chemical precursors lists attached hereto may be modified by addition or deletion and other lists may be added thereto and modified by addition or deletion by virtue of a cabinet's resolution, based on a recommendation of a committee to be formed by the Minister and shall include among its members: representatives of MOHAP, Ministry of Interior, the concerned Authority and any other competent authority.

Article (101)

Prohibitions on Chemical Precursors

Chemical precursors may not be supplied, imported, exported, manufactured, derived,

separated, produced, possessed, distributed, used or traded without MOHAP's consent, according to terms and procedures determined by virtue of a resolution of the Minister, containing the method to maintain records and documents related to such substances and chemical precursors.

Customs clearance may not be made with respect to imported substances and chemical precursors, unless the import permit is enclosed with the clearance formality. The competent customs department must retrieve the import permit subsequent to the end of the clearance operation, and return it to MOHAP after having added a mention thereto stating that the imported chemical precursors have arrived and were handed to the rightful owner thereof.

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Title IV

Administrative and Disciplinary Liabilities and Sanctions

Chapter 1

Administrative and Disciplinary Liabilities

Article (102)

Disciplinary Liabilities

1. Without prejudice to sanctions prescribed herein or by any other laws, the Pharmaceutical Facility Licensing authority and its staff may inflict the following disciplinary liabilities:
   a) Pharmaceutical facilities' violation constituting a breach of the provisions hereof, or of the regulations and decisions issued in implementation thereof:
      1) Written notification.
      2) Written warning.
      3) A fine ranging between AED 1000 (One Thousand UAE Dirhams) and AED 1,000,000 (One Million UAE Dirhams).
      4) Temporary suspension of license for six months.
      5) Cancellation of license.
   b) Pharmacy professional's violation constituting a breach of the provisions hereof, or of the regulations and decisions issued in implementation thereof:

hereof, or of the regulations and decisions issued in implementation thereof:

1) Written notification.
2) Written warning.
3) A fine ranging between AED 1000 (One Thousand UAE Dirhams) and AED 500,000 (Five Thousand UAE Dirhams).
4) Temporary suspension of license for six months.
5) Cancellation of license.

2. Violations mentioned in Item No. 1 herein shall be considered by Disciplinary Committee to be formed at MOHAP or the concerned Authority.

Article (103)

Disciplinary Record

Every licensing authority shall maintain a record in which the sanctions imposed on licensee shall be noted. The Disciplinary Committees in the country shall exchange the information of violations made by the pharmaceutical facilities and pharmacy professionals according to the powers of such committees.

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Article (104)

Grieving Against Sanctions

1. Every person against whom a disciplinary decision is issued, pursuant to Article 102 herein, may grieve against such decision to the Grievance Committee at health authority within fifteen (15) days from the date of notification thereof.
2. The decision regarding the grievance shall be issued within thirty (30) days from the date of submission thereof, according to a substantiated decision. Non-reply to the grievance during this time shall be deemed a rejection of grievance.
3. The settlement decision regarding the grievance shall be deemed final.
4. In all cases, the sanction of suspension from work, cancellation of the license, or closure of the pharmaceutical facility, in other than precautionary closure events prescribed herein, may not be implemented prior to the expiry of the date set for the grievance or the date set for the settlement thereof, as the case may be.

Article (105)

Non-Prejudice to Criminal or Civil Liabilities

The disciplinary liability shall not prejudice the criminal and civil liabilities, as the case may be, in accordance with the provisions herein.

Article (106)

Exchange of Disciplinary Sanction's Notifications

MOHAP and the concerned Authority shall notify each other with the issued disciplinary sanction, except for notification, warning and administrative fines.

Chapter 2

Criminal Sanctions

Article (107)

1. An infringer shall be sentenced to imprisonment for a period of at least six months and at most one year, and to a fine of at least AED 50,000 (Fifty Thousand UAE Dirhams) to at most AED 200,000 (Two Hundred Thousand UAE Dirhams), or to either penalty for:
   a) Whoever submits documents, makes untrue statements, or has recourse to illegal methods that require the granting of a license in contradiction to the

provisions hereof, Executive decree and decisions issued in implementation thereof;
   b) Whoever breached the provision or Articles No. 44, 56 or 57 hereof; or
   c) Whoever practices the profession of pharmacy without obtaining a license.
2. An infringer shall be sentenced to imprisonment for a period of at least one year and at most five years, and to a fine of at least AED 100,000 (One Hundred Thousand UAE Dirhams) to at most AED 500,000 (Five Hundred Thousand UAE Dirhams), or to either penalty for:
   a) Whoever circulated a hazardous or toxic medical products in contrary to the provisions hereof;
   b) Whoever violated the terms and conditions of semi-controlled medical product circulation prescribed under Article No. 99 hereof; or
   c) Breached any of the following provisions: 3, 13, 14, 22, 26, 41, 90 or 101 hereof.

Article (108)

1. An infringer shall be sentenced to imprisonment for a period of at least six months and at most one year, and to a fine of at least AED 50,000 (Fifty Thousand UAE Dirhams) to at most AED 200,000 (Two Hundred Thousand UAE Dirhams), or to either penalty for whoever breached the following provisions: 7(6), 9(3),(5), 19, 30, 33, 35, 36, 39, 46(3), 48(7), 50, 55, 58, 89 or 93 hereof.
2. A criminal lawsuit for breaching the provisions 7(6), 9(3),(5), 19, 35 or 46(3) may be filed according to a written request from the Minister.
   The Minister may not file the criminal lawsuit if reasonable justifications were presented thereto.

Article (109)

An infringer shall be sentenced to a fine of at most AED 100,000 (One Hundred Thousand UAE Dirhams) for:

1. Whoever breaches the pricing enforced by MOHAP for the pharmaceutical products. Should the breach be repeated, the penalty shall be multiplied.
2. Whoever works as pharmacist or technical pharmacist without a license, or knowingly obtained license based on fraud or misrepresentation.

Article (110)

An infringer shall be sentenced to a fine of at least AED 200,000 (Two Hundred Thousand UAE Dirhams) to at most AED 1,000,000 (One Million UAE Dirhams), for:

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1. Whoever falsifies or imitates a medication, raw materials, chemicals, health foods or therapeutic cosmetics, or knowingly sells to third parties, illicitly imports or smuggles the same into the country;
2. Breached the provision 42(1) hereof; or
3. Breached the provision 48(5), (6) hereof.

Article (111)

Complementary Sanctions

1. In all cases, the court may, in addition to the prescribed sanctions, order closure of facility for a maximum period of three months or permanent closure and withdrawal of license.

2. In the event a breach is confirmed, to confiscate the substances subject of breach.
3. Infringer shall bear the costs of harmful substance disposal.

Article (112)

Non-Prejudice to Severer Sanctions

The sanctions prescribed hereof shall not prejudice to any severer sanctions set forth by any other law.

Title V

Final Provisions

Article (113)

Grieving Against Decisions Issued In Implementation of the Provisions of this Law

Subject to the provision 104 hereof, every person against whom a decision is issued, in implementation of the provisions hereof, may grieve against such decision to the Grievance Committee, formed by virtue of a resolution of the Minister or Head of concerned authority, within fifteen (15) days from the date of notification thereof. The decision regarding the grievance shall be issued within thirty (30) days from the date of submission thereof, according to a substantiated decision. Non-reply to the grievance during this time shall be deemed a rejection of grievance. The settlement decision regarding the grievance shall be deemed final.

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Article (114)

Practicing the Profession of Pharmacy among Government Bodies

Federal and local government bodies may practice the profession of pharmacy according to the regulations set forth in this Law and the Executive decree hereto. Other entities shall apply for obtainment of license to practice the profession of pharmacy according to the regulations set forth in this Law and the Executive decree hereto.

Article (115)

Judicial Officers

A decision shall be issued by the Minister of Justice, in agreement with the Minister of Head of the concerned Authority, regarding the determination of the persons who shall have the capacity of judicial officers to monitor compliance to the provisions of this Law and the regulations issued in implementation thereof, according to their respective powers.

Article (116)

Obtaining the Necessary Permits

Obtaining the licenses set forth by this Law does not exempt obtaining the other necessary permits required by the applicable laws, regulations or orders.

Article (117)

Exceptions

1. Those covered by the provisions hereof in free zones are exempted from holding the citizenship of the country.
2. A pharmaceutical facility owned by non-citizens of the country may be exempted from the requirement of holding the country citizenship by virtue of a cabinet's resolution.

Article (118)

Settlement of Conditions

Those whom this Law apply to at the time of its issuance must settle their conditions to be in line with the provisions hereof within a period not exceeding one year as of the date of the enforcement thereof. This period may be extended by virtue of a resolution of the Minister for an accumulate period of five years.

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Article (119)

Executive Decree of this Law

1. The Executive Decree of this Law shall prescribe in particular the terms and conditions of the following:
   a) Provision of pharmaceutical products and medical devices necessary for the

a) Provision of pharmaceutical products and medical devices necessary for the community's need permanently.
b) Circulation of donated pharmaceutical products.
c) Temporary licensing of visiting pharmacists.
d) Keeping pharmaceutical products during maintenance of the pharmacy.

2. The Executive decree of this Law shall be issued by virtue of a resolution of the Minister and based on the Minister's proposal within six months as of the date of publication in the Official Gazette.
3. The Minister shall issue the necessary decisions to implement the provisions of this Law.

Article (120)

Authorization

Cabinet may issue a decision authorizing part of MOHAP's powers set forth herein to a concerned authority.

Article (121)

Abrogation

Federal Law no. (4) Of 1983 and Federal Law no. (20) Of 1995 shall be abrogated. Regulations and decisions issued in implementation of the above two Laws shall remain in force, without prejudice to the provisions hereto, until the issuance of implementation regulations and decisions hereof.

Article (122)

Abrogation of Contrary or Conflicting Provision

Any provision in contradiction or conflict with the provisions of this Law shall be abrogated.

Article (123)

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Publication and Application of Law

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

Khalifa bin Zayed Al Nahyan

President of the United Arab Emirates

Promulgated by Us at the Presidential Palace in Abu Dhabi;

On 25 Rabi‘ II 1441 A.H.

Corresponding to 19 December 2019 A.D

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List No. 1

Number	Chemical Name	CAS Number
1	*N*-Phenethyl-4-piperidone (NPP)	39742-60-4
2	1-Phenyl-2-propanine	103-79-7
3	3,4-methylenedioxyphenyl- 2-propanone	4676-39-5
4	4-Anilino-*N*-phenethypiperidine (ANPP)	21409-26-7
5	Acetic Anhydride	108-24-4
6	*Alpha*-Phenylacetoacetontrite (APAAN)	4468-48-8
7	Ephedrine	299-42-3
8	Erometrine	60-97-7
9	Ergotamine	113-15-5
10	Isosafrole	120-58-1
11	Lysergic acid	82-58-6
12	N-acetylanthranilic acid	89-51-1
13	Norephedrine	14838-15-4
14	Phenylacetic acid	103-82-2
15	Piperonal	120-57-0
16	Potassium permanganate	7722-64-7
17	Pseudoephedrine	90-82-4
18	Safrole	94-59-7

List No. 2

Number	Chemical Name	CAS Number
1	Acelone	67-64-1
2	Anthanilic acid	118-92-3
3	Ethul ether	60-29-7
4	Hydrochlori acid	7647-01-0
5	Methyl ethyl ketone	79-93-3
6	Piperdine	110-89-4
7	Sulphuric acid	7664-93-9
8	Toluene	108-88-3

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