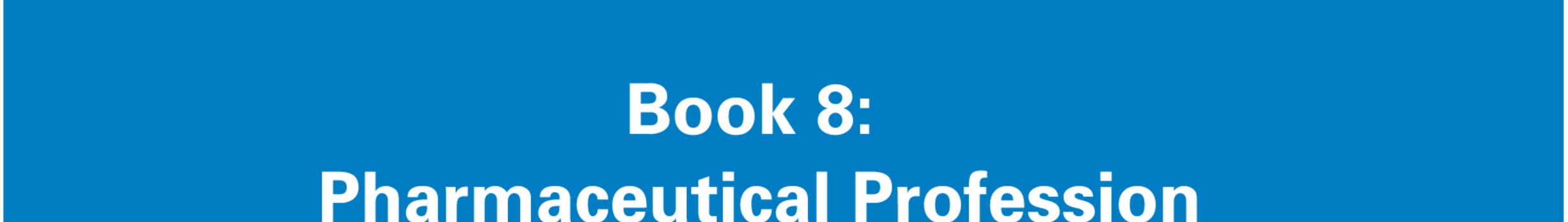
هيئة الصحة - أبوظبي
HEALTH AUTHORITY - ABU DHABI

Book 8:
Pharmaceutical Profession and Medicines



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Book 8: Pharmaceutical Profession and Medicines

Federal Law No. (4) of 1983 Concerning Pharmaceutical Profession and Establishments

Federal Law No (20) of 1995 Concerning Medicines and Preparations derived from Natural Sources

Federal Law No. (4) of 1983
Concerning Pharmaceutical Profession and Establishments

Federal Law No. (4) of 1983 Concerning Pharmaceutical Profession and Establishments

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

Upon consideration of the Provisional Constitution,

And Federal Law No. (1) of 1972, concerning the Jurisdictions of Ministries and the Powers of Ministers, as amended,

And Federal Law No. (5) of 1974, concerning the Practice of the Pharmaceutical Profession and the Trading in Medicines,

And based upon the proposal of the Minister of Health, the approval of the Cabinet and the Federal National Council, and the ratification of the Supreme Council of the Federation,

Have promulgated the following Law:

Article 1

In applying the provisions of this Law, the following words and expressions shall have the meanings set forth opposite each one, unless the context determines otherwise:

1- "State" means the State of the United Arab Emirates.
2- "Minister" means the Minister of Health.
3- "Ministry" means the Ministry of Health.
4- "Pharmaceutical Profession" means the preparation, composition, separation, manufacturing, packing, selling or distribution of any medicine or pharmaceutical preparation for the

protection or treatment of humans or animals from diseases.
5- "Pharmacist" means every person holding a basic certificate in pharmacy from an accredited higher institute, college or university.
6- "Licensing Committee" means the committee mentioned in Article 6 of this Law.
7- "Licensed Pharmacist" means every person licensed to practise the pharmaceutical profession in accordance with the provisions of this Law.
8- "Pharmaceutical Establishment" means every public or private pharmacy, pharmaceutical warehouses and factories and scientific offices.
9- "Medicine" or "Pharmaceutical Preparation" means every compound that contains one or more substances with medicinal properties for treatment or protection of human beings or animals from diseases or for any other medical purpose such as disinfecting the environment from microbes.
10- "Chemicals" means the basic elements composing the medicine or pharmaceutical preparation.
11- "Medical Supplies" means the equipment, not entailing a medicine or a pharmaceutical preparation, used for medical purposes.
12- "Pharmaceutical Warehouse" means every establishment inside the State for the importation, storage and wholesale distribution of medicines.
13- "Pharmaceutical Factory" means the production unit inside the State, whose divisions cooperate to manufacture the medicine or pharmaceutical preparation.
14- "Scientific Offices" means the scientific centres that provide information about the medicine or pharmaceutical preparation or any other medical supplies or chemicals produced by factories, to which the scientific offices are affiliated.
15- "Poisons" means the substances listed in Table (1) attached hereto.

16- "Narcotics" means the substances listed in Table (2) attached hereto.
17- "Psychoactive Substances" means the substances listed in Table (3) attached hereto.
18- "Hazardous Drugs" means the substances listed in Tables (2) and (3).

Chapter 1
The Practice of the Profession of Pharmacist and Pharmacist Assistant

Article 2

No person may practise the pharmaceutical profession without obtaining a licence in accordance with the provisions of this Law.

Persons who apply to obtain the licence shall:
1- Be holders of a basic certificate in pharmacy from an accredited higher institute, college or university.
2- Have practised the pharmaceutical profession for a period of not less than two years after obtaining a basic certificate in pharmacy, for applicants who do not hold the citizenship of the State.
3- Not have been convicted due to a crime of misconduct or breach of trust, unless they have been rehabilitated or pardoned by the appropriate authorities.
4- Be fluent in Arabic and a foreign language, reading and writing.
5- Pass the examination administered by the Ministry in this regard according to the rules to be issued by a decision of the Minster upon consultation with the Licensing Committee.

Article 3

No person may practise the profession of pharmacist assistant without obtaining a licence according to the provisions of this Law.

Persons who apply to obtain the licence shall:
1- Be holders of an accredited pharmacist assistant certificate.
2- Have practised the profession for at least two years at a pharmaceutical establishment under the supervision of a Licensed Pharmacist.
3- Not have been convicted due to a crime of misconduct or breach of trust, unless they have been rehabilitated or pardoned by the appropriate authorities.
4- Be fluent in Arabic and a foreign language, reading and writing.
5- Pass the examination administered by the Ministry in this regard according to the rules to be issued by a decision of the Minster upon consultation with the Licensing Committee.

Article 4

The documents to be attached to the application for obtaining the licence mentioned in the two previous articles shall be determined by a decision of the Minister.

Article 5

The Licensed Pharmacist may appoint as an aide a pharmacist assistant who has fulfilled the conditions mentioned in Article 3 hereof. He may also engage in the pharmaceutical establishment students from pharmacy colleges or pharmacist assistants who have not completed the training period, after obtaining the Ministry's approval, provided that he assumes responsibility for their errors.

Chapter 2
Licensing Committee

Article 6

There shall be established at the Ministry a committee called the "Licensing Committee", which shall be formed and its work regulation determined by a decision of the Minister.

The Licensing Committee shall examine the applications for obtaining the licences mentioned in Articles 2, 3, 18, 34, 47 and 60 hereof.

The Committee shall submit its recommendations regarding the matters it examines to the Minister for his action.

Article 7

The Licensing Committee shall perform its responsibilities that are mentioned in the previous article giving priority to licences recommended for issuance to UAE nationals, Arab nationals and then applicants of other nationalities.

Article 8

The decision to refuse to grant a licence shall be justified, and the applicant whose application is rejected may appeal to the Minister within thirty days from the date that he is notified of the decision. The Minister's decision in this regard shall be final.

Article 9

There shall be established at the Ministry a register for registering the pharmacists and pharmacist assistants licensed to practise the pharmaceutical profession according to the provisions of this Law.

The Minister shall issue a decision determining the form of this register and the information and data to be entered therein.

Chapter 3
Provisional Licences

Article 10

By a decision of the Under-Secretary of the Ministry, Pharmacists and pharmacist assistants contracted by government bodies to work at their various departments and institutions shall be granted a provisional licence to work for the contracting bodies only.

Chapter 4
Medical Prescriptions and Dosage

Article 11

A Licensed Pharmacist may not dispense any Medicine or Pharmaceutical Preparation except on a medical prescription stating in clear handwriting the name of the physician who has issued the prescription, his seal, signature and issue date, provided that the physician is licensed to practise human or veterinary medicine in the State.

If the prescription includes any of the drugs listed in one of the tables attached hereto, the Licensed Pharmacist may not dispense it unless it satisfies the particulars referred to in the previous Paragraph , in addition to the following:

1- The medical prescription shall be numbered, stamped with the Ministry's seal and issued on the form prepared for this purpose.
2- It shall be written with an ineffaceable material.
3- The prescription shall include the amount of medicine in figures and letters, the directions of usage and the patient's name and address.
4- It shall not have been issued for a period exceeding two days.
5- The prescribed dose shall not be more than the amount stated in the Pharmacopoeia, and the period of usage shall not exceed three days.

The provisions of Paragraph one of this article shall not apply to the products sold by one pharmacy to another pharmacy or to a healthcare establishment.

Article 12

A Licensed Pharmacist may not give, dispense or sell poisons in amounts exceeding the medical doses stipulated in the Pharmacopoeia.

Article 13

A Licensed Pharmacist may not alter or change anything in the medical prescription except after consulting with the physician who issued the prescription.

physician, dispense refills of medicines containing narcotics or abortifacients, or medicines that can accumulate in the body or whose habitual consumption leads to addiction.

Article 14

If the Licensed Pharmacist discovers a mistake or omission in the medical prescription or becomes doubtful about some of its particulars, he must discreetly contact the physician who issued the prescription for clarification. He should return the prescription to the physician if he does not accept the latter's clarifications, in which case the physician shall underline the point of disagreement in the prescription and sign it.

Article 15

The Licensed Pharmacist shall enter the medical prescriptions, which he has dispensed, in a register designated for this purpose, and shall affix the pharmacy's seal thereon after writing on each prescription its number of entry in the aforementioned register and the price of the medication,which he has collected. He shall then return the prescription to the client or give him a copy under the same terms and conditions, if he is required to keep it.

Chapter 5
Pharmacist Duties and Unauthorized Actions

Article 16

The Licensed Pharmacist shall carry out his duties in conformity with professional norms and traditions and shall uphold the honor of the profession and keep its secrets. In particular, he:

1- Shall not perform any action that would degrade the honor of the profession such as illegal competition.
2- Shall not disclose to anyone the diseases that he becomes aware of from the medical prescriptions presented to him or by any means related to the practice of his profession.
3- Shall comply with the laws and regulations applicable in this profession.
4- Shall notify the competent authorities of the communicable diseases which are related to his work.
5- Shall perform full time duty at the pharmacy where he is in- charge.

Article 17

The Licensed Pharmacist shall be prohibited from committing any action involving breach of professional duties or departure from the requirements of honesty and honor in discharging these duties. This shall include the following, in particular:

1- Encouraging or enticing patients into buying medicine from his pharmacy through deals with persons or institutions.
2- Monopolizing, withholding, hiding or selling medicine for prices higher than those approved.
3- Changing the quantity or quality of the medicine contrary to the provisions of this Law.
4- Selling free medical samples or spoiled or expired medication.
5- Practising medical or nursing works, except for works related to first aid as necessary.
6- Dispensing medical prescriptions with a code or a sign not agreed upon scientifically.
7- Agreeing with a physician to write prescriptions in a special way or other signs agreed between them.
8- Criticizing or slandering the physician who has issued the

prescription in front of others.

Chapter 6
Licensing of Pharmacies and Related Provisions

Article 18

No person may open a pharmacy unless he obtains a licence according to the provisions of this Law.

Article 19

To open a pharmacy, the following shall be fulfilled:

1- The applicant for the licence shall be a citizen of the State.
2- The pharmacy shall be managed by a Licensed Pharmacist.
3- The nearest road between the pharmacy, subject of the licence, and the nearest pharmacy shall be not less than 200 metres.
4- The pharmacy shall fulfill the health and technical conditions to be determined by the Minister.

Article 20

A person who applies for a licence to open a pharmacy shall submit his application to the Licensing Committee, including the following:

1- Name, nationality and permanent address of the applicant.
2- Number and date of the licence for the practice of the pharmaceutical profession issued to the pharmacist who is responsible for the management of the pharmacy.

3- The documents to be attached to the application as determined by a decision of the Minister.

Article 21

The competent administrative authority at the Ministry shall inspect the place where the pharmacy shall be established to verify that all the conditions stated in the Law are fulfilled. It shall then submit its inspection report to the Licensing Committee.

Article 22

The licence for opening a pharmacy shall be personal and may not be assigned to others. The licence shall be considered expired by law if the ownership of the pharmacy is transferred to another person and a new licence has to be obtained.

In all cases, the licence for opening a pharmacy shall be for one year, renewable for a similar period or periods.

Article 23

The pharmacy may not be shifted from one place to another nor its design plan modified without obtaining the approval of the Ministry.

Article 24

The name of the pharmacy shall be written in big Arabic letters on a visible board.

Article 25

The licence of the pharmacy shall be considered expired by force of law in any of the following cases:

1- Transfer of the ownership of the pharmacy to another person.
2- Closure of the pharmacy for six consecutive months without excuse acceptable to the Licensing Committee.
3- Failure to commence work in the pharmacy within six months from the date of issue of licence.

Article 26

No person may be licensed to open more than two pharmacies in the State. No pharmacist who is employed by the government or any of its institutions may open, manage or work in a pharmacy.

Article 27

If the Licensed Pharmacist responsible for the management of the pharmacy is absent, the pharmacy responsibilities and supervision must be assigned to another licensed pharmacist. The period of absence shall not exceed 60 days in a year, whether consecutive or non-consecutive, provided that a pharmacist assistant who has worked in the pharmacy for at least three months is present.

Article 28

The pharmacy shall not be used as a medical clinic or for any purpose other than for storing, preparing and selling medicine and pharmaceuticals and for trading in cosmetics, perfumes, children's food, medical milk, domestic insecticides, medical, surgical, optical and laboratory equipment, dental equipment, toothpastes and brushes, shaving and similar items.

Article 29

No pharmacy shall have an entrance leading to a medical clinic, shop, apartment or any place not related to its activities.

Article 30

The emergency first aid equipment, basic medicine, scientific equipment, reference books and official records that should be available in the pharmacy shall be determined by a decision of the Minister. The Minster shall also determine the banned medicines and the ways of keeping and trading in psychoactive substances, narcotics and poisons.

Article 31

The medicines in the pharmacy shall be preserved in good condition according to the technical conditions in this respect. Medicines whose dates have expired shall not be displayed at the pharmacy.

Article 32

The Ministry shall regulate the night and morning shifts of the pharmacies that carry out their activities in each city or sector thereof.

Article 33

Licences may be granted for opening private pharmacies that are affiliated with a government body, a public authority, a public institution or association or private hospital, provided that these pharmacies are under the management of a full-time Licensed Pharmacist and serve only the bodies with which they are

affiliated.

The special conditions for opening these private pharmacies shall be determined by a decision of the Minister.

Chapter 7
Licensing of Pharmaceutical Warehouses and Related Provisions

Article 34

No person may open a Pharmaceutical Warehouse unless he obtains a licence according to the provisions of this Law.

Article 35

To open a Pharmaceutical Warehouse, the following shall be fulfilled:

1- The applicant for the licence shall be a citizen of the State.
2- The Warehouse shall be managed by a Licensed Pharmacist.
3- The Warehouse shall fulfill the health and technical conditions to be determined by a decision of the Minister.

Article 36

A person who applies for a licence to open a Pharmaceutical Warehouse shall submit his application to the Licensing Committee, including the following:

1- Name, nationality,age and permanent address of the applicant.
2- Number and date of the licence for the practice of the

pharmaceutical profession issued to the pharmacist who is responsible for the management of the Warehouse.
3- The documents to be attached to the application as determined by a decision of the Minister.

Article 37

The place selected as the premises of a Pharmaceutical Warehouse shall be inspected in accordance with Article 21 of this Law.

Article 38

The licence for opening a Pharmaceutical Warehouse shall be personal and may not be assigned to others. The licence shall be considered expired by law if the ownership of the Warehouse is transferred to another person and a new licence has to be obtained.

In all cases, the licence for opening a Warehouse shall be for one year, renewable for a similar period or periods.

Article 39

A register shall be set up at the Ministry for entering the names of the owners of licensed warehouses in accordance with the provisions of this Law. The Minister shall issue a decision determining the form of the register, the information to be included therein and the administrative body which shall supervise and organize it.

Article 40

No person may import medicines, pharmaceuticals or chemicals of any kind unless he is the owner of a licensed Pharmaceutical Warehouse and holds a permit to import the said items according to the provisions of this Law.

Imported medicines, pharmaceuticals or chemicals may not be cleared by customs unless the importation permit is attached to the clearance form.

The concerned customs department shall recover the importation permit at the end of the clearing process and return it to the Ministry noting that the medicines, pharmaceuticals or chemicals have arrived and have been delivered to their rightful owner.

Article 41

If the owner of the Pharmaceutical Warehouse is an agent for a party that produces medicines, pharmaceuticals or chemicals that he is importing, he may not be permitted to import these except from this same party and without mediation from others.

Article 42

The owner of the Pharmaceutical Warehouse shall keep a general record to enter incoming medicines, pharmaceuticals and chemicals, their supply date and the daily amounts dispensed.

He shall also keep a special record for poisonous, hazardous and psychoactive drugs.

These two records shall be kept by the pharmacist responsible for the management of the warehouse, who shall also be

responsible for their organization and for the validity of the data stated therein.

Article 43

Neither the owner of the warehouse nor the pharmacist responsible for its management may sell or grant as a sample to any pharmacy a medicine or pharmaceutical which is not priced or which has expired. They may not as well enter into deals with physicians or pharmacists to pursue personal interests in contradiction with the provisions of the Law.

Article 44

Neither the owner of the warehouse nor the pharmacist responsible for its management may sell any medicine to a pharmaceutical, medical or healthcare establishment. They are also prohibited from selling chemicals used for industrial or agricultural purposes to any person other than those licensed by the concerned authorities.

The provisions of Article 28 of this Law shall apply to warehouses.

Article 45

Neither the owner of the warehouse nor the pharmacist responsible for its management may sell, dispense or hand over poisons in amounts exceeding the medical dose determined in the pharmacopoeia, unless this is done by a Licensed Pharmacist responsible for the management of a pharmacy, or a physician licensed according to the provisions of this Law or a person permitted to use poisonous substances in their profession.

The number and price of any medicine or pharmaceutical preparation shall be written on the cover.

Article 46

The owner of the warehouse and the pharmacist responsible for its management shall observe the provisions of the applicable laws and regulations concerning the importation, storage, distribution and preservation of medicines.

Chapter 8
Licensing of Pharmaceutical Factories and Related Provisions

Article 47

No person may open a Pharmaceutical Factory unless he obtains a licence according to the provisions of this Law.

Article 48

Without prejudice to the provisions of Federal Law No. 1 of 1979 organizing industrial affairs, the following shall be fulfilled for obtaining a licence to open a Pharmaceutical Factory:

1- The factory shall include production sections and chemical, disinfection and bacteriological laboratories and shall fulfill the technical and medical conditions to be determined by a decision of the Minister.
2- The supervision of the factory with all its sections and laboratories shall be undertaken by a full-time manager licensed to practise the Pharmaceutical Profession according to the

provisions of this Law.
3- Every laboratory in the factory shall be supervised by licensed pharmacists and specialists in the medicines produced by the factory.

Article 49

To obtain a licence for opening a Pharmaceutical Factory, an application shall be submitted to the Licensing Committee, including:

1- The Memorandum or Articles of Association of the factory including names of the shareholders in its capital.
2- Number and date of the licence granted to practise the Pharmaceutical Profession, issued to the manager of the factory and the licensed pharmacists who will work at the factory.
3- Other documents to be attached to the application as determined by a decision of the Minister.

Article 50

The site and premises of the factory shall be inspected in accordance with Article 21 of this Law.

Article 51

The manager of the factory shall be responsible for preserving the hazardous drugs and keeping their records.

Article 52

In case of absence of the manager of the factory for a certain period, he shall be replaced by another person licensed to practise

the Pharmaceutical Profession. If the manager relinquished his work, a successor shall be appointed within a maximum period of 15 days from the date of the previous manager leaving work.

Article 53

The Ministry must be notified of the manager's absence or relinquishment of work and of the person who has replaced him. The Ministry shall also be notified of the names of the entire staff of the factory and those who are licensed to practise the Pharmaceutical Profession, as well as of any change to their status.

Article 54

The type and organization of the records to be kept by the factory and the party authorized to inspect these records shall be determined by a decision of the Minister while taking into account the following:

1- The records shall be stamped with the Ministry's seal, numbered and kept with the manager responsible for all the sections and laboratories of the factory.
2- All required information shall be registered in these records on a daily basis and shall be placed at the disposal of the inspectors in charge of controlling same at all times.
3- The records shall include all transactions concluded in the factory, in particular those related to raw materials, their issuance, preparation, manufacturing and distribution upon completion of production.

Article 55

Each Pharmaceutical Factory shall have the following warehouses:

1- Warehouse for raw materials, which shall include a special place for preserving the materials and substances that may be spoiled by heat, humidity or external factors.
2- Warehouse for hazardous materials, that is, the inflammable materials that may result in damage or harm and that shall be preserved in a place far from the main buildings of the factory.
3- Warehouse for the manufactured or ready compounds or preparations, where the conditions stated in the two previous paragraphs shall be fulfilled depending on the nature of the materials preserved therein.

Article 56

The Pharmaceutical Factories shall fulfill the following conditions:

1- The buildings shall be situated at a distance from each other and provided with all required precautionary measures to prevent any risks to their safety.
2- All sections shall include emergency exits in case of fire or any other danger.
3- The wastes shall be disposed of in a way to prevent environmental pollution and not threaten public health.
4- All the required technical and health conditions shall be maintained to secure the safety of their staff.

Article 57

The provisions of Articles 33 to 45 of this Law shall apply to the Pharmaceutical Warehouses of Pharmaceutical Factories.

Article 58

The licence for opening a Pharmaceutical Factory shall be considered expired by force of law if the share of UAE nationals in its capital becomes less than the percentage stated in Law No. 1 of 1979 on the Organization of Industrial Affairs.

Chapter 9
Licensing of Scientific Offices and Related Provisions

Article 59

No person may open a Scientific Office unless he obtains a licence according to the conditions to be determined by a decision of the Minister.

Article 60

In order to obtain a licence to open a Scientific Office, an application shall be submitted to the Licensing Committee.

Article 61

Scientific Offices may not import medicines or pharmaceutical preparations or store them for selling or promotion unless they are registered with the Ministry according to the provisions of this Law.

Article 62

The Scientific Offices shall keep samples of medicines and pharmaceutical preparations which they want to introduce. The

Offices shall also keep a record for these samples stamped with the Ministry's seal, provided that it each sample shall be marked as free and not for sale.

Chapter 10
Registration of Pharmaceutical Companies, Medicines and Pricing

Article 63

A committee for registering pharmaceutical companies and preparations and determining the prices of medicines shall be established in the Ministry, which shall be called "Medicine Companies and Pricing Committee". The Minister shall issue a decision on the formation of the committee and regulation of its work. The committee shall submit its recommendations on the matters considered by it to the Minister for his action.

Article 64

The Minister may, upon the recommendation of the committee mentioned in the previous article, decide the following:

1- To approve the registration of any pharmaceutical company or any medicine or pharmaceutical preparation which has proven to be suitable for circulation.
2- To ban the circulation of any medicine or pharmaceutical preparation which has proven at any time to be harmful to public health. In this case, the medicine or pharmaceutical preparation shall be deleted from the Ministry's records if registered, all quantities of such medicine or pharmaceutical preparation shall be confiscated and destroyed, and owners shall

have no right of recourse against the Ministry for compensation.
3- To fix the price of any medicine or pharmaceutical preparation and reconsider the price previously approved.

Article 65

No imported medicine, pharmaceutical preparations or children's food may be put into circulation except after registration thereof with the Ministry. Any pharmaceutical company desiring to market its products in the State must be registered.

Article 66

Any medicine or pharmaceutical preparation that undergoes modification of its constituents shall be re-registered.

Article 67

There shall be recorded on the outside label and inside leaflet of every medicine or pharmaceutical preparation the following information and data in at least Arabic and English:

1- Name of the medicine or pharmaceutical preparation and the number of its registration with the Ministry, with reference made to the Pharmacopeia according to which the medicine or preparation was prepared, if any.
2- Active compounds of the medicine and their amounts.
3- Expiry date of the medicine or preparation if its validity is time barred.
4- Name of the factory producing the medicine or preparation.
5- Directions of use and warnings in relation to the use of the medicine or preparation.

Chapter 11
Poisons and Hazardous Drugs

Article 68

The Minister shall issue the necessary directives to ensure protection from dangers posed by poisons and hazardous drugs and prevent exposure to their effects.

Article 69

Persons falling within any of the following categories have the right to possess hazardous drugs at the places where they practise their profession as hereunder:

1- The Pharmacist responsible for the management of the warehouse, by way of importation or purchase from another warehouse.
2- The Pharmacist responsible for the management of a pharmacy, by way of purchase from a Pharmaceutical Warehouse or a pharmacy.
3- The licensed physician for use for purposes related to his profession, provided that the Minister shall determine the quantities of hazardous drugs that the physician can possess.
4- Therapeutic establishments, by a special permit and pursuant to the conditions therein stated.
5- Pharmaceutical Factories, by way of importation or purchase according to the provisions of this Law.

Article 70

The Licensed Pharmacist responsible for the management of a pharmacy may not dispense hazardous drugs for medical use

except in the following cases:

1- To patients on a medical prescription issued by a licensed human physician.
2- To owners of sick animals on a medical prescription issued by a licensed veterinarian.
3- To physicians on a signed request certifying that the required amounts are for clinical use.

Article 71

Neither a Pharmaceutical Warehouse nor a Pharmaceutical Factory may import hazardous drugs except according to a request order signed by the Licensed Pharmacist responsible for the management of the warehouse or the manager of the factory, as the case may be. The order shall include all details relating to the hazardous drugs to be imported such as amounts, type, shipping methods, clearing station and the importing party and its address.

Import shall take place after obtaining a permit from the competent administrative body to be appointed by the Minister.

No customs clearance may be issued for these drugs unless the import permit is attached to the clearance form.

The concerned customs department shall recover the import permit at the end of the clearing process and return it to the Ministry after noting that the hazardous drugs have arrived and have been delivered to their rightful owner.

Article 72

The medical prescription issued by the licensed physician may include some hazardous drugs used in the composition of medicines or pharmaceutical preparations. The Minister shall issue a decision determining these medicines or pharmaceuticals.

Article 73

The Licensed Pharmacist responsible for the management of the pharmacy or Pharmaceutical Warehouse shall keep a special register for hazardous drugs, which shall observe the following, in particular:

1- The pages must be clearly numbered and sealed with the Ministry's stamp.
2- It shall include a detailed statement about the amount of hazardous drugs purchased or imported, the name of the supplier or exporter, the date of delivery or arrival, the amounts dispensed or sold and the name and address of the patient or the buyer.

Article 74

The Licensed Pharmacist responsible for the management of the pharmacy or Pharmaceutical Warehouse shall keep all medical prescriptions of hazardous drugs, dispensed or sold, for at least five years from the date of dispensation or sale.

Article 75

The Licensed Pharmacist responsible for the management of the pharmacy or Pharmaceutical Warehouse shall take a regular inventory to verify that the data stated in the hazardous drugs register tally with the actual stock. If any differences are

discovered, he shall inform the Ministry to take the necessary measures.

Article 76

Without prejudice to the provisions of international agreements to which the State is a party, the Minister may add to any of the Tables 1, 2 and 3 attached hereto, any medicines, pharmaceutical preparations or drugs proven to be poisonous or hazardous.

The Minister may also delete from any of these tables any medicines, pharmaceutical preparations or drugs proven not to be poisonous or hazardous.

The Minister's decision in this regard shall be published in the Official Gazette and shall come into force on the date that it is published.

Chapter 12
Persons with Judicial Authority

Article 77

The Minister of Justice, Islamic Affairs and Awqaf shall, after consultation with the Minister of Health, issue a decision determining the persons who shall have judicial authority to inspect Pharmaceutical Establishments and verify their compliance with the provisions of this Law and its implementing rules and regulations.

Owners of Pharmaceutical Establishments shall afford these inspectors all assistance to enable them to carry out their duty,

including the review of the records, documents and data as deemed necessary.

The Ministry's inspectors who are designated as judicial officers shall be authorized to inspect any establishment or store suspected to be dealing in drugs, medicines and poisons without a licence. They shall confiscate such substances and refer the offenders to the competent authorities for trial in accordance with the applicable procedures in the State.

Chapter 13
Disciplinary Accountability

Article 78

The Licensing Committee shall be competent to examine the occurrences committed by the Licensed Pharmacists or owners of Pharmaceutical Establishments, which constitute offenses against the provisions of this Law or its implementing rules and regulations.

The Committee shall notify the offender to appear before the Committee, at least three days prior to the Committee's meeting.

The notice shall include a statement of the offenses attributed to the offender. The offender must appear before the Committee on the specified date. If the offender fails to appear before the Committee on that date, the Committee shall have a right to decide on the offense in his absence.

Article 79

The Licensing Committee may impose one of the following disciplinary punishments on the Licensed Pharmacist in default:

a- Warning.
b- Suspension for a period not exceeding one year.
c- Withdrawal of the licence to practise the profession.

The Committee may impose one of the following disciplinary punishments on the owner of the Pharmaceutical Establishment:

a- Warning.
b- Closure of the Pharmaceutical Establishment for a period not exceeding sixty days. If the offense is repeated, the Establishment may be closed for several periods not exceeding six months in total in the same year. The Licence may also be withdrawn.

None of the disciplinary punishments provided in this Article may be imposed except after the offender is questioned and his defense made. If he fails to attend the punishment may be imposed based on the papers. The Committee shall submit its decisions to the Minister for approval.

Article 80

The person aggrieved by a disciplinary decision may appeal the decision to the Minister within fifteen days from the date the decision is notified to him.

The Minister's decision on the appeal shall be issued within thirty days from the date of submission, and his decision in this regard shall be final.

In all cases, punishments involving suspension from work, withdrawal of licence of the Licensed Pharmacist or closure of facility may not be imposed before the expiry of the period prescribed for submitting the appeal or deciding on it, as the case may be.

Article 81

The Licensing Committee may, if it finds that the ongoing operation of the Pharmaceutical Establishment will result in a gross harm, issue a decision ordering a precautionary shutdown of the Establishment until such time as a final decision is made concerning the disciplinary liability of its owner. This decision shall be approved by the Minister, and shall be enforced upon approval. The Establishment owner may appeal this decision to the Minister, and the appeal shall be subject to the provisions of the first and second paragraphs of the previous Article.

Article 82

The disciplinary accountability under this chapter shall not prejudice the criminal liability arising from the same occurrence of offense.

Chapter 14
Penalties

Article 83

Without prejudice to any more severe punishment provided in another law, a confinement sentence for a period of not less than six months and not more than one year, and a fine of not less than

one thousand Dirhams and not more than five thousand Dirhams, or either of these penalties, shall be imposed on:
1. Any person who submits false documents or data, or seeks illegal ways which result in him being granted a licence contrary to the provisions of this Law.
2. Any person who practises the Pharmaceutical Profession without fulfilling the conditions stated in this Law.

Article 84

Without prejudice to any more severe punishment provided in another law, a confinement sentence for a period of not less than six months and not more than one year, and a fine of not less than one thousand Dirhams and not more than three thousand Dirhams, or either of these penalties, shall be imposed on:

1. Every Pharmacist who fulfils the conditions for practising the Pharmaceutical Profession under this Law but commences practice of the profession before obtaining a licence.
2. Every Pharmacist who violates the provisions of Article 13 or Article 16 of this Law.

Article 85

Without prejudice to any more severe punishment provided in another law, a fine of not less than one thousand Dirhams and not more than five thousand Dirhams shall be imposed on every person who violates the applicable price list of medicines and pharmaceutical preparations. If the offense is repeated and a final judgment passed against the offender, the licence granted to him shall be considered withdrawn by force of law.

Article 86

Without prejudice to any more severe punishment provided in another law, an imprisonment sentence for a period of not less than one year and not more than three years, and a fine of not less than two thousand Dirhams and not more than ten thousand Dirhams, or either of these penalties, shall be imposed on every person who adulterates or imitates any medicine, pharmaceutical preparation or chemical substances or knowingly sells the same.

The court may, in addition to the penalties stated in Articles 83 and 84 and the previous paragraph of this Article, order the withdrawal of the offender's licence.

Article 87

Without prejudice to any punishment provided in another law, a fine of not less than one thousand Dirhams and not more than five thousand Dirhams, shall be imposed on any person who commits an offense against this Law or its implementing rules and regulations not falling under articles 83, 84, 85 and 86 herein.

Article 88

If the licence is withdrawn in accordance with the provisions of Article 83 or a final court judgment of withdrawal is passed in accordance with Articles 81, 82 and 84 of this Law, the Minister may permit the appointment of another full-time Pharmacist to undertake the management of the Pharmacy or Warehouse. He may also decide the final closure of the Pharmacy or Warehouse after liquidation and sale of its assets under the supervision of the Ministry.

Chapter 15
General and Transitional Provisions

Article 89

The Ministry may collect fees for the licences and registrations made according to the provisions of this Law, provided that the collected fee does not exceed ten thousand Dirhams for the Factory licence and two thousand Dirhams for other licences and registrations.

The Minister shall, upon the proposal of the Licensing Committee, issue a decision determining these fees.

Article 90

The obtaining of the licences stated under this Law shall not exempt from obtaining other licences provided for under the applicable laws, rules and regulations.

Article 91

If the agent of a preparation is changed, the new agent must notify the Ministry accordingly within thirty days from the date of transfer of the agency to him.

Article 92

Any medicine or pharmaceutical preparation and children's food to be determined by a decision of the Minister may not be advertised or promoted to the public through newspapers, radio, TV, pamphlets or booklets.

Article 93

With exception to the condition of distance stated in Article 19 of this Law, all existing Pharmaceutical Establishments must conform to the provisions of this Law within a period not exceeding six months from the date of this Law coming into force.

Article 94

Police force shall assist in implementing the final disciplinary decisions of closure or precautionary closure issued according to the provisions of this Law.

Article 95

The Minister shall issue the implementing decisions under this Law.

Article 96

Law No. 5 of 1974 hereinabove mentioned and every provision contrary to this Law is repealed.

Article 97

This Law shall be published in the Official Gazette and shall come into force thirty days after the date that it is published.

Zayed Bin Sultan Al Nahyan
President of the United Arab Emirates

Issued by Us at the Presidential Palace in Abu Dhabi
On: 25 Shaaban 1403 Hijri
Corresponding to: 6/6/1983

Table (1)
Poisonous Substances

Are the following substances that must be preserved in isolated and closed places:

- Arsenic / derivatives and compounds
- Mercury / compounds and derivatives
- Aconitum Lycoctonum / extracts and tinctures
- Bladona and its extracts

- Kinds of Estrophantos and its active glucoses
- Dionine
- Nicotine and its salts
- Strychnine and its salts
- Tiapine and its salts
- Pecacuanha and its extracts

- Barium and its salts
- Ouabain
- Codeine and its salts
- Cotarnine and its salts

- Homatropine and its salts
- Coca leaves, fruits, extracts or tinctures
- Tridione
- Oxalic acid and its salts
- Silver salts

Antimony / compounds and derivatives
Cyanuric acid and its salts
Contimin and its tinctures
Kinds of Estrophantos and its active glucoses
Jaborandi and its active alkaloids
Hyoscine and its salts
Papaverine and its salts
Urecholine and its salts
Tichorrhine and its salts
Barbituric acid and its salts and extracts
Cariacol
Picrotoxin
Conine and its salts
Amatine and its salts and derivatives
Yohimbine and its salts
Procaine and its salts

Adretaline and its salts
Iodine
Formalin

- Phenylenediamine	Chrysol and sodium chrysolate
- Aloin and its derivatives	Cinchophen and its derivatives
- Chaulmoogra oil	Colchium
- Colchicine	Datura and its extracts
- Saccharin and its extracts	Phenol
- Picric acid	Nux Vomica and its extracts
- Sulfanilamide and its derivatives	Sabin (Savin) and its volatile oil (sulfa compounds and derivatives)
- Lobelia and its extracts	Sadab and its volatile oil
- Curare	Lobeline and its salts
- Gelsemium (Yellow Jasmine)	Thallium salts and its active alkaloids
- Ergot and its active alkaloids	Sabadella and its active alkaloids
- 3-bromoethyl alcohol	Atropine and its salts
- Santonin	Zinc phosphide
- Lead salts	Local and general anesthesia
- Chloral hydrate	Brome
- Pyridine	Amyl nitrite
- Chenopodium oil	Acredin derivatives
- Jatroha Curcas oil	Hydnocarpus oil and its derivatives
- Cantharidin and its tinctures	Amidopirin and its salts
- Podophyllin	Cantharidin
- Calabar bean	Types of Digitalis lanata and its active glucoses
	Azirine and its salts

Table (2)
Narcotic Substances

1- Raw Opium of all kinds and names:
Medical opium
All opium preparations, whether listed of unlisted in the Pharmacopeia, which contain over 0.2% Morphine.
2- Morphine and all its salts. All Morphine preparations, whether listed of unlisted in the Pharmacopeia, which contain over 0.2% Morphine.
Morphine dilutants in an inactive liquid or solid substance, regardless of degree of concentration.
3- Diacetylmorphine, Aminomorphine, Diamorphine, Diaphor, Heroin and its salts, all preparations containing Diacetylmorphine or its salts.
4- Benzoyl-morphine and its salts and all other Morphine esters, and salts; all preparations containing Benzoyl-morphine or other Morphine esters.
5- Benzoyl-morphine (Peronin) and its salts, and all other Morphine –ether oxidates and their salts except for Ethyl-morphine (Dionin), Methylmorphine(Codeine), Benzoyl-morphine (Peronin) preparations and other Morphine – ether oxidates except for Ethyl-morphine (Dionin) and Methylmorphine(Codeine).
6- Dehydro Desoxy Morphine (Dezomorphine).
7- Thebaine and its salts; all preparations containing Thebaine or its salts or esters or the salts of these esters.
8- Oximorphine (neo- morphine) and its compounds as well as other morphine compounds with Pentavalent Nitrogen.
9- Dehydro-oxycodone and its salts (kolikodal), its esters and ester salts;Dehydrocodinone and its salts (kolikodal), its esters and ester salts;Dehydromorphine and its salts (kolikodal), its esters and ester salts;

Federal Law No (20) of 1995 Concerning Medicines and Preparations derived from Natural Sources

Federal Law No (20) of 1995 Concerning Medicines and Preparations derived from Natural Sources

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

Upon consideration of the provisional constitution,

And Federal Law No. (1) of 1972 , concerning the Jurisdictions of Ministries and the Powers of Ministers, as amended,

And Federal Law No. (4) of 1983, concerning the Pharmaceutical Profession and Establishments,

And Federal Law No (6) of 1986, concerning fighting narcotic and similar substances,

And Federal Law No (3) of 1987, concerning the issuance of the Penal Code,

And Federal Law No (35) of 1992, concerning the issuance of the Penal Proceedings Law,

And based upon the proposal of the Minister of Health, the approval of the Cabinet and the ratification of the Supreme Council of the Federation,

Have Promulgated the following Law:

Article (1)
In applying the provisions of this Law, the following words and expressions shall have the definitions set forth opposite each one,

Article 1

In applying the provisions of this Law, the following words and expressions shall have the definitions set forth opposite each one, unless the context requires otherwise:

State	: The United Arab Emirates
Ministry	: The Ministry of Health
Minister	: The Minister of Health
Concerned Directorate	: The Directorate of Drug Control at the Ministry of Health or any other directorate assuming its responsibilities under the law.
Concerned Committee	: The committee concerned with the registration of the medicines and preparations derived from natural source or sources at the Ministry of Health, whose establishment and work system shall be regulated by a decision of the Minister.
Medicine or preparation derived from a natural source or sources	: Every medicine or derived product containing active substances of vegetable or animal origin, or other natural sources, packed in a final package and intended for treating or preventing human or animal diseases, whether the medicine or product in its normal appearance is in the form of powder or extract or tinctures or juices, or any form that resulted from a process of purification, fragmentation, or concentration. There shall not be regarded a product derived from a natural source any medicine or preparation which contains

synthetic or quasi-synthetic chemical compounds.

Article 2

There shall be kept at the Concerned Directorate special registers for registering the medicines and preparations which are derived from natural source or sources.

The registration shall be restricted to the medicines and preparations intended for topical application, or administered orally or per rectum.

The registration shall be effected by a decision of the Minister upon the proposal of the Concerned Committee.

Article 3

The requirements and procedures of registration shall be issued by a decision of the Minister of Health upon the proposal of the Concerned Directorate.

There shall be taken into consideration, upon the registration of any medicine or preparation derived from natural source or sources, the information gained by the experience in using the plants and other natural sources of the popular medicine for an appropriate period of time, and the studies cited in the specialized scientific references and books and published researches.

Article 4

The Minister of Health may, upon the recommendation of the Concerned Committee, waive some registration requirements if

the medicines or preparations are listed in the international pharmacopoeia, or if the circulation of the medicine or preparation is for scientific purposes and not for treatment.

Article 5

There shall be clearly mentioned, on the outside package and inside leaflet of every medicine or preparation derived from natural source or sources, the following information and data in at least the Arabic and English languages:

1. Name of the medicine or preparation and its registration number in the Ministry with mention of the pharmacopia or scientific or cultural references according to which the medicine was prepared, if any.
2. Names and amounts of the active natural substances which are used in the composition of the medicine.
3. Date of production of the medicine or preparation, and expiry date if validity is time-barred.
4. Name of manufacturer of the medicine or preparation.
5. The instructions and warnings associated with the use of the medicine or preparation.

Article 6

The Minister of Health, upon the recommendation of the Concerned Committee, shall decide the following:

1. To approve the registration of any medicine or preparation derived from natural source or sources, when proven fit for circulation.
2. To prevent the circulation of any medicine or preparation if proven at any time to be harmful to health. In this case, the

registration of the medicine or preparation must be deleted from the Ministry's register, all their quantities everywhere must be seized and destroyed and the owners shall not have a recourse against the Ministry for compensdation.
3. To prevent the circulation of any medicine or preparation, if it was found that their components were modified and that they were were put in circulation before being re-registered.
4. To determine the prices of medicines and preparations that are derived from natural source or sources and reconsider these prices.

Article 7

There shall be no circulation of any medicine or preparation which is derived from natural source or sources except after its registration with the Ministry of Health.

There shall be a re-registration of the medicine or preparation if subjected to any modification to their components.

Also, there shall be a registration of every party manufacturing a medicine or preparation which is derived from natural source or sources and desiring to market same in the State.

Article 8

It shall not be permissible to import, manufacture, market or export medicines and preparations derived from natural source or sources except after obtaining a licence from the Ministry.
The conditions for licensing the import, manufacture, marketing or export and the procedures for obtaining a licence shall be determined by a decision of the Minister of Health.

Article 9

Any person having an interest in the case may appeal the decision to deny or revoke registration, or refuse to grant a licence. The appeal shall be submitted to the Minister within a maximum of thirty days from the date that the decision of rejection is received.

The Minister's decision on the appeal shall be final.

Article 10

The obtaining of licences under this Law shall not exempt from obtaining other licences as required by applicable laws, regulations and rules.

Article 11

The Concerned Directorate at the Ministry shall monitor the enforcement of this Law and its implementing decisions. The employees of this Directorate who are designated by a decision of the Minister of Justice in agreement with the Minister shall have the status of judicial officers. As such, they shall, in particular, be authorized to access the places whose activities fall within the scope of this Law, except for residential places. This shall be to ensure the enforcement of this Law and its implementing decisions and to catch violations. The local authorities in the Emirates shall facilitate the mission of these employees so as to enable them to do their job.

Article 12

Without prejudice to any more severe punishment provided in another law, a confinement sentence for a period of not less than

six months and not more than one year, and a fine of not less than five thousand Dirhams and not more than ten thousand Dirhams, or either of these penalties, shall be imposed on:

1. Any person who submits false documents or provides incorrect data or seeks illegal means which result in the registration of a medicine or a preparation derived from natural source or sources, or the granting of a license to import, manufacture, export, or circulate this medicine or preparation, contrary to this Law.
2. Any person who imports, exports, manufactures, or trades in a medicine or a preparation derived from natural source or sources, before obtaining a licence from the Ministry.
3. Any person who knowingly circulates a medicine or preparation derived from a natural source or sources whose circulation has been prohibited by the appropriate authority.
4. Any person who counterfeits or imitates a medicine or preparation derived from a natural source or sources, or promotes a counterfeit or imitated medicine, or sells it to others while knowing about the counterfeiting or imitation.

Article 13

Without prejudice to any more severe punishment provided in another law, a fine of not less than one thousand Dirhams and not more than five thousand Dirhams shall be imposed on any person licensed to trade in the medicines or preparations derived from a natural source or sources who violates the price prescribed by the Ministry for the medicine or preparation.

If the offense is repeated, the licence may be revoked, in addition to the imposition of a fine.

Article 14

Without prejudice to any more severe punishment provided in another law, a fine of not less than one thousand Dirhams and not more than five thousand Dirhams shall be imposed on any person who commits an offense against this Law or its implementing decisions not falling under articles (12) and (13) herein.

Article 15

There shall be no registration of a medicine or preparation nor issuance of a licence as provided for in this Law except after collecting the prescribed fees.

The fees for registration, reregistration and licensing shall be determined by a decision of the Cabinet.

The Minister may, upon the recommendation of the Concerned Committee, grant exemption from some or all the fees of the registration or licensing, and the exemption decision must be justified.

Article 16

The application of this Law shall not prejudice what other laws provide for in terms of the regulation of the pharmaceutical profession, or the ban on narcotic or similar substances, or toxic or hazardous substances.

Article 17

The Minister shall issue the required decisions for the implementation of this Law.

Article 18

Any provision contrary to, or inconsistent with, this Law is repealed.

Article 19

This Law shall be published in the Official Gazette and shall come into force six months after the date of its publication.

Zayed Bin Sultan Al Nahyan
President of the United Arab Emirates

Issued by Us at the Presidential Palace in Abu Dhabi
Date: 27 Jumada Al Akhera , 1416 Hijri
Corresponding to: November 20, 1995