Law no. 127 of 1955

Concerning Practice of Pharmacy Profession

On behalf of the nation

Council of Ministers

Having considered the Constitutional Declaration of 10th February 1953;
Decree of 17th November, 1954 authorizing the Council of Ministers powers of the President of the Republic;
Law no. 5 of 1941 concerning practice of pharmacy profession and trafficking in toxic substances;
Law no. 163 of 1950 on mandatory pricing and defining profits;
Decree-law no. 351 of 1952 concerning trafficking and use of narcotic drugs;
As the Council of State has deemed it necessary;
and based on what was presented by the Minister of Public Health
Issued the following law:

Chapter One

Practicing the pharmacy profession

Article 1

No one shall practice the pharmacy profession in any capacity whatsoever unless he is an Egyptian or a country whose laws permit Egyptians to practice the pharmacy profession. His name is registered in the register of pharmacists at the Ministry of Public Health and in the Pharmacists' Syndicate.

The practice of the pharmacy profession in the provision of this law is deemed processing, combination or dissection of any medication, drug, medical plant or pharmaceutical substance used orally, topically or by injection, to protect or treat diseases either for man or animal, or described as having these properties.

Article 2

Registration in the Ministry of Public Health requires holder of a bachelor's degree in Pharmacology and Pharmaceutical Chemistry from an Egyptian university or a holder of an equivalent foreign degree or diploma and has successfully completes the examination provided for in Article (3).

Foreign degrees or diplomas are deemed equivalent to the Egyptian bachelor's degree by a resolution issued from a committee composed of four members designated by the Minister of Public Health; provided that two of them are at least Professors of Pharmacology at a College of Pharmacy and a pharmacist representing the Ministry of Public Health.

Article 3

Holders of foreign degrees or diplomas shall be examined as per the final examination curriculum for Bachelor's Degree in Egypt. Such examination shall be conducted in front of a committee composed of pharmacists selected by the Minister of Public Health prior to each exam from candidates nominated by the councils of pharmacy colleges and including a pharmacist representing the Ministry of Public Health.

A request shall be submitted on the form prepared for such purpose to the Ministry of Public Health for whoever wishes to attend the examination. Such form shall be accompanied by the original degree /diploma obtained or official copy thereof, and the certificate confirming study of the curriculum or any other relevant document; together with payment of L.E.10 against examination charge. Such charge will be refunded if examination is not attended willfully or not permitted to attend such exam. The exam will be conducted in Arabic and language and may be performed in a foreign language approved by the Minister of Public Health; provided that the student is fluent in Arabic both reading and writing. If the student fails to take the exam, he/she may not apply for it more than three times in two years. The Ministry of Public Health shall grant certificate stating completion of the exam successfully.

Article 4

Minister of Public Health may exempt Egyptians from performing the exam provided for in Article (3), if they have obtained the certificate of secondary education, relevant discipline, or equivalent, and along duration of their studies are well-behaved and punctual in receiving their practical lessons according to program of the institutes they graduated therefrom.

Article 5

Registration in the Ministry of Public Health requires application affixed thereto photo of the applicant and signature, indicating his/her name, surname, citizenship, and domicile.

Such application shall be accompanied by original certificate of degree / diploma, or official copy thereof; or certificate of exam or exemption thereof as the case may be, receipt of paying charge for registration in the schedule of Pharmacists Syndicate. The applicant shall also pay one pound against charge to be recorded in the Ministry. The pharmacist's name, surname, citizenship, domicile, date of the degree or diploma obtained and the issuing body, date of the exam certificate or exemption thereof as the case may be.

The Ministry shall inform the Pharmacists Syndicate to conduct the record in the register, and the licensee shall be given a free copy of this registration to practice the profession, with his/her photo affixed thereto. The licensee shall keep this extract in the institution where he/she practices the profession, to be submitted as requested by inspectors of the Ministry of Public Health.

Article 6

The pharmacist shall notify the Ministry of Public Health by virtue of a registered letter with acknowledgment of receipt for every change of domicile within one week from date of such change.

Article 7

Every registration in the pharmacists' register in the Ministry done by means of forgery, fraudulence, or other illegal means, will be deemed null and void by virtue of a resolution from the Minister of Public Health together with permanently writing off the name registered. The Pharmacists Syndicate and Public Prosecution shall be notified therewith; and the Syndicate shall notify the Ministry of Public Health with each resolution issued by the affiliated Council or Disciplinary Bodies in order to either suspend the pharmacist from practicing the profession or writing off his/her name.

Article 8

The Ministry of Public Health undertakes to publish the official schedule of pharmacist names licensed to practice the profession and shall annually publish the amendments that may arise thereto.

Article 9

The Minister of Public Health may, after taking the opinion of the Pharmacists' Syndicate, authorize a pharmacist who does not meet the conditions stipulated in Article (2) to practice the profession of pharmacy in Egypt for the period necessary to perform the duties entrusted to him by the government or the native pharmaceutical institutions; provided that such period does not exceed two years renewable only once, if such pharmacist is recognized for excellence in a branch of pharmacy and whose services were necessary due to lack of similar ones in Egypt.

Chapter Two
Pharmaceutical institutions
1- Definition

Article (10) [1]

In the application of this law provisions, the Pharmacy Institutions are deemed to be public and private pharmacies, pharmaceutical plants, drug stores, medical mediators' warehouses, commercial shops trafficking in medicinal plants and their natural products.

2- General Provisions for all Pharmaceutical Institutions

Article (11) [2]

A pharmaceutical foundation may not be established without a license from the Ministry of Public Health. The applicant must be at least 21 years of age.

If the license is transferred to ineligible or a disqualified person by any legal method on behalf of the original licensee, it shall be approved in name of the transferee associated with the guardian or trustee, and shall be liable for any violation of this law provisions.
This license shall not be given unless the health requirements are provided in the foundation, and a resolution is issued from the Minister of Public Health confirming the same, as well as the license special requirements as imposed by the health authorities on the stakeholder The license is deemed granted to owner of the foundation, if changed the alternative shall apply to the Ministry of Public Health to approve transfer of the license thereto; provided that such applicant meets the conditions prescribed in this law.

Article 12 [3]

The application for a license shall be issued to the Ministry of Public Health on the form prepared by the Ministry of Public Health and shall be sent to the Ministry by virtue of registered letter with acknowledgment of receipt to be accompanied by the following:

(1) Personal identification certificate, and police record.

(2) Birth certificate or any other alternative document.

(3) Three copies of engineering drawing of the institution to be licensed.

(4) The receipt verifying payment of the processing fees in the amount of five Egyptian pounds. If the application is completed will be listed in the register allocated thereof and the applicant will be given a receipt indicating number and date of application entry in the register.

Article 13 [4]

The engineering drawing shall be sent to the competent Health Authority for inspection. The Ministry shall notify the license applicant with opinion at the site of institution in a date not exceeding thirty days from date application is entered in the mentioned register. The application is deemed approved if the said date is lapsed without notifying the application with the opinion without prejudice to provisions of Clause two of Article 30 herein. If inspection proved that the health requirements as prescribed are met, the license will be ready within thirty days from d ate of inspection; otherwise, the applicant should be given sufficient term to complete the requirements, then inspection is repeated at end of such term - the applicant may be granted second term not exceeding half the first term. Thereafter, if the requirements are proven to be incomplete, the license application will be rejected permanently.

Article 14 [5]

Licenses of institutions subject to provisions of this law shall be cancelled in the following cases:

1. If the license is not used within six months from date of issuance.
2. If the institutions is closed for more than one continuous calendar year.
3. If the institution is transferred from one place to another (unless such transfer is due to demolition or fire; such transfer may be performed by the same license to another place as long as the health requirements prescribed are provided. cancellation or transfer shall be notated on the license and in the registers allocated thereof in the Ministry of Public Health.

Article 15

The license holder shall obtain approval of the Ministry of Public Health in advance for each change to be made in the pharmaceutical institution. An application shall be submitted accompanied by accurate description and drawing of the amendments required to be conducted. The license holder shall implement all requirements required as imposed as per the provisions of Article (11) and as long as the requirements required are completed.

The Ministry of Public Health shall notate to conduct the amendment on the license previously issued for the institution.

Article 16

The pharmaceutical establishments shall be subject to an annual inspection conducted by the competent health authority to ensure that the requirements stipulated in Article (11) are met. If the inspection shows that they are not available, the licensee must complete them within a period determined provided not

exceeding 60 days. If not completed within such term, the Ministry of Public Health has the right to implement such requirements at the expense of the licensee. The licensee shall pay L.E.1 against annual inspection fee.

Article 17

Name of the pharmaceutical institution, owner, and manager must be written in Arabic bold letters at façade of the institution.

Article 18 [6]

The pharmaceutical institution may not be used for any purpose other than that assigned thereto by virtue of the license granted, nor be directly connected with a private house, shop run for another industry, or outlets relevant to any of the above.

Article 19 [7]

Each pharmaceutical institution shall be run by a pharmacist practiced the profession in public or private pharmaceutical institution for a period of one year after graduation.

If the matter is related to private pharmacy or intermediary warehouse, management may be assigned to pharmacist assistant whose name is registered as such at the Ministry of Public Health. The director of the pharmaceutical institution is not allowed to run more than one institution.

Article 20

The Director of the Pharmaceutical Institution is allowed to outsource a pharmacist assistant under its responsibility. The pharmacist assistant may run the pharmacy on behalf of its director, in case no other pharmacist is available and the director is absent due to daily break, weekend, official holidays, sick leave, or due to compulsive condition; provided that period of absence does not exceed in the last two cases two weeks per year commencing from first of January. The director shall notify the Ministry of start and end of such assignment.

In such cases, the pharmacist assistant shall be subject to all the provisions of the pharmacy director.

Article 21

The Minister of Public Health shall issue a resolution to form a preliminary and appellate disciplinary panel for assistants of the pharmacists. Members of the panel, disciplinary penalties imposed, and procedures to be followed are designated in this resolution.

Article 22

Director of the Pharmaceutical Institution is responsible for non-pharmacists staff in relation to implementation of the provisions herein.

If the director quits management of the institution, shall notify the Ministry immediately by virtue of a registered letter with acknowledgment of receipt. Owner of the institution shall immediately appoint a new director whose name shall be notified to the Ministry of Public Health together with declaration of accepting management; otherwise the owner shall close the pharmacy, if not the health authorities shall close it administratively.

Director of the Institution shall, upon quitting management, deliver the drugs under custody to his immediate successor; provided that a record is edited in three copies signed by both and with a copy to be sent to the Ministry of Public Health, the second copy is maintained at the institution for reference when necessary, and the third copy is given to the director who quit work.
If a new director is not appointed for the institution, the director who will leave the work shall hand over what is in its custody from the drug entry book to the Ministry of Public Health's representative or to the health doctor in whose circle the institution is located and in all directions. Wheels containing such drugs shall be sealed by stamp of the Ministry representative and stamp of the manager who quit work.

Directors of pharmaceutical institutions must not be absent from their institutions during official working hours unless their employees are legally authorized to be directors.

Article 23

Each pharmacy applicant whose name is registered in this capacity in an Egyptian university and each pharmacy applicant who is legally registered in a recognized foreign pharmacy college is allowed to spend his training period as prescribed in the university regulations with one of the pharmaceutical institutions after approval of the college to which the applicant belongs and the Ministry of Public Health.

Article 24

Each pharmacist holder of a degree or diploma from abroad and wishes to apply for the exam stipulated in Article (3), may spend the period of training in a public pharmacy after approval of the Ministry of Public Health; provided that such training period does not exceed two years and such training is under supervision and responsibility of the director .

Article 25 [8]

Workers of both genders operating in the pharmaceutical institutions or in delivery of medicines must obtain a license therewith from the Ministry of Public Health after presenting personal identification certificate, and police record, being literate and shall be subject to health restrictions approved by the Minister of Public Health.

Article 26 [9]

Owners of pharmaceutical institutions, pharmacists and pharmacist assistants, pharmacology students under training shall notify the Ministry of Public Health by virtue of a registered letter with acknowledgment of receipt stating date of starting work in such institutions as well as notification upon quitting work. The directors of these institutions must send letter to the Ministry of Public Health including all the data required by virtue of registered letters with acknowledgment of receipt.

Article 27 [10]

If owner or director of the pharmaceutical institution wants to store medicines for the need of its institution in another place, a license must be obtained in advance against a fee of three Egyptian pounds and under the conditions issued by a resolution from the Minister of Public Health.

Article 28

All items found in the institution licensed under this law including medicines, neural proceeds, pharmaceuticals, medicinal plants or chemicals should be conforming to their specifications indicated in the medicine constitutions as prescribed, formulations registered, and are maintained in accordance with technical standards. These institutions shall be provided with medicines, tools and equipment required for work and preservation of medicines therein; together with scientific references and laws pertaining to the profession. Owner and director of the institutions shall take responsibility for implementation of the above.

Article 29

Owners of pharmaceutical institutions shall notify the Ministry of Public Health upon liquidation within at least two weeks before commencement thereof. The notice shall be accompanied by a statement of the narcotic items found in the shop, provided that the purchaser is a person authorized to trade in the items purchased within the limits of the license granted thereto. The license granted to such pharmaceutical institution is deemed canceled post the said liquidation. Owners of pharmaceutical institutions shall notify the Ministry upon inventory of the estate, occurrence of theft or damage in the medicines found therein for any reason whatsoever once such incident occurred.

[1] Article (10) is amended by law no. 91 of 1959

[2] Last clause of Article (11) is amended by law no. 253 of 1955

[3] Article (12) is amended by law no. 7 of 1956, then by law no. 360 of 1956

[4] Article (13) is amended by law no. 360 of 1956

[5] Article (14) is amended by law no. 253 of 1955, then by law no. 7 of 1956.

[6] Article (18) is amended by law no. 253 of 1955

[7] Article (19) is amended by law no. 7 of 1956

[8] Article (25) is amended by law no. 253 of 1955

[9] Article (26) first paragraph is amended by law no. 253 of 1955

[10] Article (27) is amended by law no. 253 of 1955

3- Special Provisions for each type of Pharmaceutical Institutions

First - General Pharmacies

Article 30 [1]

(Provision of Article 30 and 31 is unconstitutional according to the judgment of the Constitutional Court no. 51 of legal year 24 - Constitution, stating that pharmacist employed by the government is not allowed to own a pharmacy).

The license to establish a pharmacy shall be granted only to a pharmacist who is licensed to practice the profession, and has spent one year after graduation in practicing the profession in public or private institution. Such condition is not applied on the pharmacist who has acquired the pharmacy through transfer of inheritance or will. The pharmacist is not allowed to be owner or partner in more than two pharmacies, or being government employee. Taking into account that the distance between the pharmacy required to be licensed and the nearest licensed pharmacy should not be less than 100 meters.

Article 31 [2]

(Provision of Article 30 and 31 is unconstitutional according to the judgment of the Constitutional Court no. 51 of legal year 24 - Constitution, stating that pharmacist employed by the government is not allowed to own a pharmacy).

If owner of the pharmacy dies, the pharmacy may be run in favor of the heirs for a period not exceeding ten calendar years.

In the case the deceased has sons who did not complete their studies at end of the period referred to in the previous paragraph, this period extends until the youngest son of the deceased reaches the age of twenty six, graduated from the university, or any academic institute granting the same degree whichever is earliest. The heirs shall appoint an agent and notify the Ministry of Health; provided that the pharmacy is run by a pharmacist. The pharmacy shall be closed administratively after expiry of the time limit granted to the heirs unless it is sold to a pharmacist.

All licenses that have been cancelled as per provision of this Article prior to amendment thereof shall be renewed unless the pharmacy has been disposed of.

Article 32 [3]

The pharmacist may not dispense with the public any medicine prepared in the pharmacy except by a medical prescription except for the constitutional formulations that are used topically as well as the constitutional formulations that are used orally; provided not to include any of the substances mentioned in Schedule 1 annexed to this law. The pharmacist is not allowed to dispense any private pharmaceutical composition containing any of the substances listed in

Schedule (2) annexed to this law, unless prescribed medically and shall not be repeated except by written notation of the doctor.

Pharmacies may not sell wholesale medicines or medical compositions to other pharmacies, drug stores, intermediaries, hospitals or clinics, except for pharmaceuticals registered with the name of the pharmacy owner. Wholesale of medicine is exclusively confined to the pharmaceutical institutions.

Article 33

Any medical prescription shall not be dispensed from the pharmacies unless written by physician, veterinarian, dentist or midwife licensed to practice the profession in Egypt.

Article 34 · Every medicine composed in the pharmacies by virtue of medical prescription must conform to the specifications mentioned in the Egyptian Pharmacopoeia unless particular pharmacopoeia is stated in the medical prescription. In this case, the medicine shall be composed according to its specifications, and no change in the substances mentioned therein shall be made either in quantity or quality unless approved by the editor of the prescription prior to composition. It is not allowed to prepare any medical prescription written in terms or idioms known to the common, and the pharmacy director is responsible for all medicines composed therein. The pharmacist is responsible for all the minutes.

Article 35

Each medicine composed in in the pharmacy must be placed in a suitable container labeled with the pharmacy name, address, and owner's name, registration number in the medical prescriptions record book, date of composition, method of using the medicine as mentioned in the medical prescription, and name of medicine if dispensed without medical prescription.

Article 36

Each medicine composed in the pharmacy must be entered in the medical prescriptions book on the spot at the same day dispensed. Pages of this book shall be numbered serially and sealed y stamp of the Ministry of Public Health. Date of such entry shall be proven under serial number and in clear writing, neither indented nor written off. Each entry in this book should clarify names and quantities of the substances entered in composition of such medicine.

Article 37

No person other than those provided for in Articles 19, 20, 23, and 24 is allowed to intervene in composition, dispense of the medical prescriptions, or sale of pharmaceuticals the public.

Article 38

Working hours in the pharmacies, system followed in the annual leave, weekend, official holidays, and night service system are defined by a resolution issued by the Minister of Public Health after taking opinion of the Pharmacists Syndicate so that the working hours are not less than eight hours daily, so as to ensure that a number of pharmacies are open at all times.

[1] First Clause of Article (30) is amended by law no. 253 of 1955

[2] Article (31) is amended by law no. 44 of 1982

[3] First Clause of Article (32) is amended by law no. 253 of 1955

Second: Private pharmacies:

Article 39 [1]

Private Pharmacies are two types:

(1) Hospital pharmacies, polyclinics, comprehensive clinics and clinics of doctors authorized to dispense medicines to their patients or their equivalent. License may not be granted to open a private pharmacy of this type unless annexed to therapeutic institution licensed in accordance with the provisions of law No. 453 of 1954 concerning commercial and industrial shops, and subject to the provisions of public pharmacies, except for provisions of articles 30 and 32. Such pharmacies may dispense medicines by price in the outpatient clinics for patients in the countries where no public pharmacy exists. In this case, provisions of Article 32 shall apply.

(2)Pharmacies affiliated to notarized Cooperative Societies; whereby license is granted to open a private pharmacy of this type upon request of the Chairman or Manager of the Society. This type of private pharmacies is subject to provisions of public pharmacies except Article 30.

Article 40

The physician or veterinary licensed to practice the profession is allowed to dispense or compose medicines for its patients only; provided to obtain in advance a license to establish a private pharmacy in its clinic and is exempted from submission of the declaration set forth in Article (12), Clause (4).

This license is granted to the physician or veterinary as long as distance between clinic and the nearest public pharmacy or hospital with outpatient clinic including private pharmacy in the area is more than five kilometers.

Such license shall be cancelled upon opening public or private pharmacy in the area where the medical clinic obtaining such license exists. The doctor shall be granted a term of ninety days from date of opening the pharmacy to liquidate the drugs at the licensed clinic; otherwise the private pharmacy and clinic will be closed administratively with seizing the drugs found therein.

[1] First clause of Article (39) is amended by law no. 253 of 1955, law no. 7 of 1956, and law no. 61 of 1959 respectively.

Third: mediators of drugs

Article 41

Any person would like to engage as mediator of drugs, agent for plant, group of plants in the medicines and pharmaceutical or neural products should obtain a license from the Ministry of Public Health. The application for license should be submitted on the form prepared by the Ministry in this respect and accompanied by the following:

(1) Personal identification certificate, and police record.
(2) A certificate from the plant certified by the official competent authorities to prove agency of the applicant concerning the plant(s) and attached thereto a list of medicines and pharmaceuticals for plants under agency, together with clarification of their composition both in quantity and quality.
(3) Inspection fees of five Egyptian pounds.

Article 42

License for mediator is personal, and mediators shall update the Ministry by notification concerning each new plant they represent or waive such representation, and send each December a statement of the plant(s) represented.

Article 43

Mediators wishing to have warehouses for keeping medicines or pharmaceuticals under agency shall obtain license as per the general provisions of the pharmaceutical institutions.

Fourth: Medicine Warehouses

(Note resolution no. 151 of 2006 concerning conditions of license to establish medicine warehouses - attached to the file)

Article 44

Conditions of storage and sale of medicines from mediator warehouses are as follows:

(1) Medicines should be sold in their original covers.
(2) Sale shall be limited to the public and private pharmacies, medicine warehouses and scientific institutes.

Article 45 (1)

The warehouse manager shall maintain entry book for incoming and outgoing medicines. Pages of this book should be in serial number and sealed by stamp of the Ministry of Public Health. In the incoming section of the book, name of item, quantity, percentage of units, package shall be proven in the incoming date and price according to the price defined. In the outgoing section of the book, type of medicines dispensed from the warehouse, quantity, percentage of units, name and address of the person receiving the medicines, as well as date of sale. Entry should updated chronologically and in clear writing without indents between lines or writing off, sale should be by receipts from the purchaser.

Article 46

License to open medicine warehouse is not granted except in the governorates or capitals of provinces and centers containing pharmacies.

Article 47

Place of keeping medicines and pharmaceutical products in the warehouse should be separated from the rest sections, and warehouse manager is responsible for implementation.

Article 48

Medicine warehouses are open in the same working hours and dates defined for pharmacies during the day on the same area so that not less than eight hours daily and owner of the store and manager are responsible for implementation.

Article 49

Medicines shall be sold from the warehouse in their original packages; if divided should be inside firmly closed packages labeled with cards bearing name of warehouse, address, director, substance and density pharmacopoeia by which virtue the medicines are composed, quantity and plant imported from or manufactured therein as well as expiry date, if any, whether such medicines are prepared for veterinary use must be indicated on the card.

Article 50

The warehouse director shall keep a special book to enter the incoming and outgoing medicines of the substances listed in Schedule (1) annexed therewith, as well as the special or pharmacopoeia pharmaceuticals which contain only one active ingredient of these substances. Pages of this book shall be numbered serially and sealed by stamp of the Ministry of Public Health. Entry should be in clear writing, neither indented, written off, nor changed, without marginal writing, and should be chronologically with serial numbers. Concerning the incoming items, the entry should indicate name of item, density, quantity, source, and incoming date to the warehouse. With respect to the items dispensed, the entry should indicate name of item sold, density, quantity as well as name and address of purchaser, and date of dispense

[1] Article (45) is amended by law no. 253 of 1955

Fifth - Field of Trafficking in medicinal plants and proceeds

Article 51

Any person wants to open a shop for trading of medicinal plants indicated in the pharmacopoeia, in different parts of these plants, or in the proceeds produced naturally from the plants shall obtain a license in accordance with the provisions of the general provisions institutions of the pharmaceutical institutions. This provision does not apply to the shops selling medicinal plants as indicated in the Seventh Schedule annexed to this law.

Article 52

Medicinal plants are sold in sealed containers indicating conformity to specifications o Pharmacopoeia as well as date of collection, and expiry date for use, if any. Sale is limited to pharmacies, medicine warehouses, pharmaceutical plants and scientific bodies. Sale may be made to individuals licensed by the Ministry of Public Health.

Article 53

All items incoming to the shop trading in medicinal plants and outgoing items shall be entered on the spot in a special book which pages are in serial number and sealed by stamp of the Ministry of Public Health. Entry should be made in clear writing without indents or writing off. As to the incoming items, the entry shall indicate name of item, density, quantity, source and date incoming to the shop. As to the dispensed items, the entry shall indicate name of item sold density, quantity, name and address of purchaser and dispense date.

Sixth - Pharmaceutical plants

Article 54

All pharmaceutical plants shall contain laboratory equipped with tools and devices required for examination of raw materials and products. Such laboratory shall be supervised by one or more pharmacists other than those assigned to prepare the pharmaceuticals or proceeds in the plant. The pharmacist and plant director are responsible for quality of items produced and validity for use.

Article 55

The pharmacist may, post approval of the Ministry of Public Health, may process private pharmaceuticals; provided that the pharmacy is equipped with all tools and machinery required for manufacture and analysis of such pharmaceutical and meet the conditions developed by the Ministry.

Article 56

Each pharmacist prepares private pharmaceuticals in its pharmacy and Director of pharmaceuticals plant shall keep two books; one for composition of pharmaceutical in order to write down amount of quantity processed each time for every pharmaceutical, date prepared with serial number for each process to be signed by the pharmacist responsible for preparation and the pharmacist analyst . The other book is for recording the quantities dispensed, date and agencies dispensed to, the pharmacist director shall sign this book. Pages of each book should be numbered serially, sealed by stamp of the Ministry of Public Health, and entry should be clearly written without indentation or writing off.

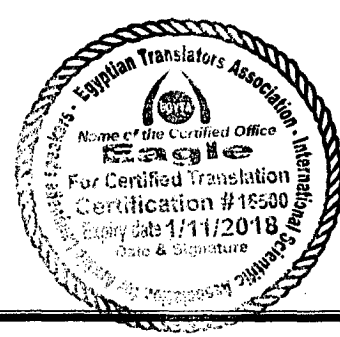
Article 57 [1]

Cards mentioning the following data should be placed on the pools containing pharmaceutical substances or pharmaceuticals and their external covers:

(1) If the medicine is among the private pharmaceuticals, the name should be mentioned, names and quantities of active substances in the composition should be mentioned in the known name and not in the chemical alternative.
If the medicine is sole or one of the pharmacopoeia, the name is mentioned as indicated in the pharmacopoeia, name and date of pharmacopoeia should be mentioned.
(2) Name of manufacturer or pharmacy handled the process of packing, processing, or composition, address and name of the country in which equipment is made.

(3) Method of use if the medicine among the private pharmaceuticals, amount per dose, within limits prescribed in the pharmacopoeia.

(4) Amount of medicine inside the package according to the percentage standards.
(5) The medical impact estimated if among the private pharmaceuticals.
(6) Serial number of the packing process, processing, or composition provided for in the preceding article.
(7) If among the medicines which effect changes by lapse of time, date of composition shall be mentioned and method of keeping density, expiry date, as well as how to preserve it against corruption when stored.
A statement of colored materials, preservatives and solvents should accompany the pharmaceuticals as well as proportion of each, if any.
In all cases, circulation of pharmaceutical products of any kind is not allowed unless number of registration in the books of the Ministry of Public Health is proven on the external card and the price defined for sale to the public.



[1] Article (57) is amended by law no. 253 of 1955

Chapter Three
Private Pharmaceuticals and Pharmacopoeia

Article 58 [1]

In application of the provisions of this law, the private pharmaceuticals, proceeds, and compositions containing or described as containing one or more medicinal properties in healing human diseases, or to prevent them, used for any other medical purpose even if not explicitly declared as long as prepared for sale, and are not indicated in any version of the pharmacopoeia and their official annexes.

The Minister of Public Health, by resolution, is allowed to regulate equipment or trading in any pharmaceuticals, medicines, or compositions that deemed relevant to treatment of man, or used as resistance against spread of diseases.

Article 59

It is banned to trade in private pharmaceuticals whether prepared locally or imported from abroad except after registration at the Ministry of Public Health. Such pharmaceuticals will not be registered unless application is submitted by a pharmacist, physician, veterinary, and dentist who are authorized to practice the profession in Egypt or owners of foreign plants abroad, their agents. Application to register the pharmaceutical is accompanied by fees of five pounds for each pharmaceutical against examination of applications and three samples of the pharmaceutical in their original containers each is sealed by red wax and stamp of the pharmacist who prepared them or sealed by stamp of the plant in which the pharmaceuticals are processed, and form in two copies for the card or prints to cover the pharmaceutical which is signed by the applicant, pharmacist, agent or director of the plant. The stakeholder shall submit all other data as required.

Article 60 [2]

Any private pharmaceutical will not be registered unless approved by the Technical Committee for Drug Control, which is formed by virtue of resolution from the Ministry of Public Health, and is composed of chairman and nine members as follows:

Undersecretary of the Ministry of Public Health or deputy ..... President

1 - Professor pharmacist from a College of Pharmacy

2 - Medical professor from a College of Medicine.

3 - Pharmacist delegate from the Ministry of Public Health

4 - Director of the Research Institute of Tropical Medicine at the Ministry of Public Health

or deputy .....

Members

5 - Pharmacist non - staff nominated by Pharmacists Syndicate

6 - a doctor from non - staff Guild nominated medical doctors

7 - Representative of the Standing Committee of the Pharmacopoeia

8 -Government Pharmacist specialist in analysis of drugs

9 -Government physician specialist in biological analysis

The Committee shall develop regulation to organize work by which virtue a resolution is issued from the Minister of Public Health. All resolutions of such Committee are final.
The Committee is not valid unless attended by seven members except the president. The committee is entitled to call for others to attend the meeting to take their opinion.

Article 61

The Technical Committee for Drug Control always have the right to refuse registration of any private pharmaceutical with giving reasons, and registration of private pharmaceuticals approved by the Technical Committee for Drug Control in the books of the Ministry of Public Health under serial number. The applicant shall be given an official extract of the entry and such extract is deemed a license for the pharmaceutical. It is not allowed, post registration of the pharmaceutical, to conduct any amendment as approved by the Technical Committee for Drug Control upon licensing registration; otherwise, the applicant shall repeat the application for registration.
If ownership of the pharmaceutical has been changed, both old and new owners shall inform the Ministry of this change within eight days from date of occurrence.

Article 62

The pharmacopoeia pharmaceuticals in the provisions of this law are deemed the proceeds and compositions mentioned in the latest editions of the pharmacopoeia by which a resolution is issued from the Ministry of Public Health, as well as pharmacopoeia fluids and sanitizers, which manufacture is allowed in the medicine plants or pharmacies with no need for registration. Processing of the pharmacopoeia pharmaceuticals is not allowed unless the Ministry of Public Health is notified prior to commencement of such processing, and be provided with the statement of pharmacopoeia mentioning the pharmaceutical, sample of package, card to be labeled thereon, and approval of the Ministry of Public Health.

Article 63

Private and pharmacopoeia pharmaceuticals should be sold closed inside their original covers; excluding ampoule if name & amount of medicine and plant name are printed thereon with static material difficult to be removed. The data mentioned on the pharmaceutical cards, handouts, and flyers distributed should be actually consistent with substances and therapeutic properties contained in such pharmaceuticals, and should not include phrases incompatible with public morals or that would mislead the public. Approval of the Technical Committee for Drugs Control at the Ministry of Health should be obtained on texts of such statements, handouts, or means of advertising prior to publication.

Article 64 [3]

Minister of Public Health is entitled, upon recommendation of the Technical Committee for Drugs Control, to issue resolutions to ban trading of any substance or pharmaceutical which circulation is deemed harmful to public health. In this case, the pharmaceutical shall be written off from the books of the Ministry if registered and quantities will be confiscated administratively wherever found without entitling owners to return to the Ministry for any compensation.

(1) Clause one of Article (58) is amended by law no. 253 of 1955, and then amended by law no. 360 of 1956.

(2)Article (60) is amended by law no. 253 of 1955

(3) Article (64) is amended by law no. 253 of 1955 and

Chapter Four

Import of medicines, pharmaceuticals, neural proceeds, medicinal plants and their natural proceeds

Article 65

Private pharmaceuticals are neither allowed to enter in Egypt, even if free medical samples, nor to be released unless the following conditions are met and after approval of the Technical Committee for Drug Control:

(1) Private pharmaceuticals should be registered in the books of Ministry of Public Health pursuant to Article (59) herein;

(2) Bear the same name known in the country of origin.

(3) Brought inside firmly sealed covers, and may not be brought without packages.

(4) The card labeled should read the data provided for in Article (57).

It is not permitted in any way to import pools of such empty pharmaceuticals, their empty covers without medicines, cards, or the like except post approval of the Ministry of Public Health.

Article 66

Pharmacopoeia pharmaceuticals, medicinal plants and their natural proceeds, or medical substances are not allowed to enter in Egypt unless name of the pharmacopoeia by which virtue such pharmaceuticals are processed, date of processing, or collection, and should be fully matching all requirements of this pharmacopoeia and are brought inside firmly sealed covers.

Article 67

The Minister of Public Health may issue a resolution not to allow entry of any medicines provided for in the preceding article to Egypt unless special qualities are provided and after testing and confirmation of their [illegible] of medical use.

Article 68 [1]

Pharmaceutical substances, neural proceeds, pharmaceuticals, or medicinal plants, and imported natural proceeds to which the conditions stipulated are available in this law are not allowed to be released except to persons licensed to trade in such substances each within limits of the license granted thereto; provided that such items are incoming from abroad especially for them, and third parties are not allowed to export such items abroad. However, individuals may import or export of those items; provided to be used in limited quantities, and with approval from the Ministry of Public Health.

Article 69

Substances listed in the first and third schedules annexed to this law, and the pharmaceuticals containing one or more substances should be placed in a separate place away from other goods upon arrival to the customs, and should not be delivered except to directors of pharmaceutical institutions within the licenses granted thereto by virtue of this law, governmental departments, and to persons obtaining license in advance from the Ministry of Public Health; without prejudice to provisions of Decree-law no. 351 of 1952 as mentioned. Vaccines and all medicines that require cooling should be placed in refrigerators once arrived at the expense of the importer to avoid damage. Explosive materials as listed in Schedule Six annexed thereto; should not be released except post obtaining approval of the General Security Department at the Ministry of Interior, taking into consideration the storage provisions set forth herein, when storing the materials indicated in the Schedule.
Upon sending any sample to the laboratories, it should be similar to the shipment and liquids should be in new, dry, and clean bottles.

[1] Article 68 is amended by law no. 253 of 1955

Chapter Five

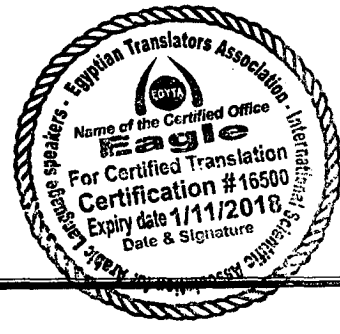
General Provisions

Article 70

The pharmacist is not allowed to combine between practicing its profession and that of the physician, veterinary, or dentist even if holds qualifications.

Article 71

It is not allowed to keep pharmaceutical substances, neural proceeds, pharmaceuticals, or medicinal plants and their natural proceeds, sale, offered for sale except in the shops licensed by virtue of this law each within limits of the license granted thereto. Trafficking in such products is only allowed for licensed persons, and may not be purchased except from such shops and people.



Article 72

Trafficking in medicine samples and pharmaceutical products intended for publicity or offer for sale is not allowed and may not be acquired for non - pharmaceutical institutions only licensed to import or manufacture. It is not permissible for the mediator to retain samples of drugs in any place other than the warehouse licensed thereby and the phrase (free medical sample) must be clearly printed on the cards of these samples internally and externally

Article 73

Trafficking of the pharmaceutical substances listed in Schedule (1) annexed to this law, and their pharmaceuticals is not allowed except by virtue of written request signed by director of the pharmaceutical institution and sealed by stamp reading (poisons).

Article 74

Books set forth in this Law and all relevant documents such as medical prescriptions, invoices, and applications are kept for five years period starting from last entry made in the books. Owners and directors of pharmaceutical institutions shall submit such invoices and documents to the inspectors of the Ministry of Public Health as requested.

Article 75

Drug stores, medicine mediators, pharmaceutical plants, shops trading in medicinal plants are prohibited to sell any medicine, pharmaceutical, medical plant, any chemicals, neural substance, offer for sale to the public, or grant as free. Such institutions are prohibited from processing any medicine or mediate therein.

Article 76

Pharmaceutical institutions may not abstain from sale of the items prepared for sale among the pharmaceuticals, pharmaceutical substances, neural proceeds, medicinal plants and proceeds thereof manufactured, imported, or stored to entities or persons licensed in accordance with the provisions of this law in exchange for payment of the price specified for each of such products.

Article 77

Customs release of imported drug shipments is only allowed post approval of the Ministry of Public Health - Such approval is required to be obtained prior to trading of each process of medicines locally processed - the Minister of Public Health develop the rules adopted in this respect based on proposals of the Technical Committee for Drugs Control.

[1] Clause One of Article (77) is amended by law no. 253 of 1955, then the Article is amended by law no. 360 of 1956.

Chapter Seven
Temporal Provisions

Article 86

Foreigners enrolled in an Egyptian university before enforcement of this law are excluded from the citizenship requirement provided for in Article (1).

Article 87

The Minister of Public Health may, post taking opinion of the Pharmacists Syndicate Council, authorize the Palestinian pharmacists refugees who were forced by the international force majeure to leave their country and resort to Egypt for residence until the situation of their country is settled, to practice their profession in Egypt for maximum period of one year renewable together with exemption from performance of the examination provided for in Article (3) provided obtaining the diploma set forth in Article (2).

Article 88 [1]

Provisions of Article 30 shall not apply to pharmacies existing at time of applying such law - provisions of article 19 shall not apply for a period of three years from date of enforcing provisions of this law on the shops trading in medicinal plants and their natural proceeds, private pharmaceutical institutions annexed to therapeutic unit affiliated to Charitable Society registered with the Ministry of Social Affairs and Labor, or recognized body.
Notwithstanding the provisions of Article 71, producers of medicinal plants and natural proceeds shall be licensed to sell, offer, present for sale, or export abroad as long as conformity to conditions and specifications for which a resolution is issued from the Minister of Public Health.

Article 89

No new licenses shall be granted to open simple drug stores - the simple drug stores existing at time of enforcing this law shall be cancelled if title is transferred from the licensed person to any other person for any reason whatsoever relevant to transfer of title. The license shall be also canceled if the store is moved from the current place to another, and the current license is deemed personal for the owners which title is not allowed to be shared.

Article 90 [2]

The provisions contained in this law regarding restrictions on customs clearance, registration, processing and trading concerning pharmaceuticals shall not apply concerning the pharmaceuticals except after a term of 24 months effective date of applying provisions of this law. The Minister of Public Health shall, during this period, define deadline to accept the registration applications for such pharmaceuticals. If the time limit referred is expired, the Minister of Public Health may issue, based on recommendation of the Technical Committee, a resolution to extend this deadline for pharmaceuticals whose application for registration are submitted in full to the Committee on time specified.

[1] Article 88 is amended by law no. 7 of 1956.

[2] Clause First of Article (90) is amended by law no. 253 of 1956, and the Article is amended by law no. 360 of 1956.

Chapter Eight
Final Provisions

Article 91

The Minister of Public Health may grant temporary licenses to open a pharmacy or more in summer resorts or temporary winter resorts as needed, and with the requirements deemed fit by the Ministry of Public Health.

Article 92 (1)

The Minister of Public Health shall issue resolution to state the foreign pharmacopoeia which is considered in Egypt as official Pharmacopoeia, until the Egyptian Pharmacopoeia is issued in Arabic.

Article 93

Schedules annexed are adopted by this law and are considered complementary. The Minister of Public Health may issue resolution to add any other article and is entitled to delete any article listed thereof. Amendments of schedules shall be published in the Official Gazette and are not considered part of the schedules mentioned except after 30 days from date of publication.

Article 94

This law is without prejudice to any of the provisions of Law No. 351 of 1952 referred to.

Article 95

Decree-law no. (5) of 1941 to practice the profession of pharmacy and trafficking in the toxic substances is cancelled as well as any provision conflicting with provisions of this law.

Article 96

Ministers of Public Health, Justice, Interior, Finance, and Economy shall implement this law each in its specialty and shall be applicable post lapse of sixty days from date of publication in the Official Gazette. The Minister of Public Health shall issue resolutions required for implementation thereof.

Promulgated at Office of Presidency on 14th Rajab 1374 A. H. (9th March 1955)
Prime Minister
Gamal Abdel Nasser Colonel (General Staff)
Minister of Justice
Minster of Public Health
Ahmed Hosny
[1] Article (92) is amended by law no. 253 of 1955, then amended by law no. 360 of 1956.

Law no. 81 of 1997 to amend some provisions of law no. 127 of 1955 concerning practice of pharmacy profession

On behalf of People
President of the Republic
The cabinet decided the following law and was enacted:

Article One

An exception to the provisions of Law No. 127 of 1955 regarding practicing the pharmacy profession, the General Authority for Veterinary Services of the Ministry of Agriculture is responsible for implementation of provisions relevant to the mentioned law in relation to the veterinary biological pharmaceutical (human and veterinary vaccines) in terms of registration, control and supervision, import, trading and pricing.

Article Two

Any provision contrary to the provisions of this law shall be canceled and the Minister of Agriculture shall issue the resolutions required for implementation.

Article Three

This law is published in the Official Gazette and shall apply from the day following date of publication.
This law shall be stamped with the seal of the State and shall be enforced as one of its laws.
This law is promulgated by the Presidency of the Republic on 17th Muharram 1418 A.H. (corresponding to 24th May, 1997 A.D.)