DECREE

Of

President of Islamic Republic of Afghanistan
Regarding the enforcement of Medicine Law

Number: (116)
Date: 18th November 2008

Article 1:

I, hereby, enforce the Law on Medicine which is approved in 8 chapters and 53 articles, under decision number 103 date 04/11/2008 of compound bodies of both national councils, pursuant to the provision of paragraph (16) of Article 64 and Article 100 of Constitution.

Article 2:

This law is enforced from the date of approval and should be published in official gazette.

Hamid Karzai
The President of Islamic Republic of Afghanistan

Islamic Republic of Afghanistan
National Council
Approval of National Council regarding the
"Law on Medicine"

Number: (103)
Date: 04/11/2008

The Law on Medicine is approved by compound board of National Council (consisting of 5 members from each council) on 9th August, 2008, in accordance with provision of Article 100 of the constitution.

The Head of Compound Board
Dr. Bakhtar "Ainzai"
The Deputy of Compound Board
Dr. Niamatullah

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Chapter One

General Provisions

Law on Medicine

Chapter One
General Provisions

Bases

Article 1:

This law has been enacted pursuant to Article 29 of Public Health Law in order to manage the issues regarding to selection, production, import, distribution and supply of medications, medical equipments and instruments and the appropriate use of them in the country.

Terms

Article 2:

For the purpose of this law, the following terms shall apply:

1. Medicine: A chemical and physiological substance which is used for diagnosing and treatment of human and animal diseases and protection against them.
2. Effective substance: is used for the elements of the medicine which has desired effects.
3. Legal Medicine: is effective and safe medicine, the production, import or use of which is granted by ministry of public health.
4. Core Medicine: is effective, safe and quality medicine which tends to resolve most of the needs in respect of sanitary.
5. Traditional Medicine: is a medicine which has been prescribed and used by traditional doctors for long years and which is very popular based on oral traditions or old scripts.
6. Counterfeit Medicine: is a medicine which has been produced by one of the production enterprises without permission of the original production company or the medicine which has been produced by the company itself, with the same name, type, package and label but considering the approved criteria, the effective elements are used less.
7. Defective Medicine: is a medicine which is not in accordance with granted medical criteria for label and packaging, in terms of quantity, quality and content.
8. Side effects: are undesired effects caused by usage of medical doses, and are harmful for body.
9. Medical substances and Medical instruments: include substances and equipments used for dressing of wounds, surgery, artificial parts of body, determining instruments and chemical substances used in medical laboratories and equipments sued in dentistry which are used in health care.
10. Medical Equipments: are equipments which are designed based on approved safe criteria and used for diagnosing, vigilance, and/or treatment.

11. Reasonable use of medicine: the better use of medicine, according to clinical need and in a sufficient quantity as the personal need and for a specific period with reasonable price.
12. Generic Name: is the official and non-commercial, international name of the medicine.
13. Generic Product: is a medicine, the production of which is not limited to a specific company and can be produced by other companies as well.
14. Raw Materials: are effective and ineffective materials which are used for production of different medicine types.
15. Batch: is the result of quantity of the medicine or other medical equipments produced in the same production term under the same circumstances and in the same compound and quality.
16. Batch Number: is the special number of a batch product.
17. Label: is a card containing the name, medical type, terms of maintenance, quantity and medical ingredients, batch number, date of product, expiry date, name and address of producing company, and is planted on the vessel or package.
18. Package: the practice of putting final medical products and other medical equipments in certain packages in order to ensure the safe transportation and avoid demolition (contains some information).
19. Pharmacist: is a person who has a university degree in the field of Pharmacy.
20. Pharmacist Assistant: is a person has a degree of 2 years higher than 12^{th} class in the field of Pharmacy from vocational institutes.
21. Pharmacist Employee: is a person with High school degree and has got at least a six-month vocational training in any part of pharmacy through relevant courses.
22. Importer of medicine and Medical Equipments: is a person who has got the commercial license and privilege of importing medicine and other medical equipments and necessities in accordance to relevant legislative documents.
23. The whole seller of medicine and medical equipments: is a person who has been issued, in accordance to related legislative documents, the privilege of selling medicine and other medical equipments wholly,.
24. Medical Inspector: is a pharmacist who controls and inspects issues related to production, import, reserve and supply of legal medicine.
25. Pharmacy: is a place which has been established according to this law and related regulation, in order to procure and supply medicine and other medical necessities.
26. Technical Authority of Pharmacy: are the pharmacist and the assistant pharmacist, who are responsible of all technical issues of the pharmacy, according to the related legislative documents.
27. Prescription: is a printed paper on which the prescription of doctor is written to the technical authority in order to procure and distribute the medicine.
28. Secret Prescription: is a prescription written in a transient name or in an abbreviated manner, based on illegal communication between the doctor and pharmacy for the purpose of misuse.
29. Inspector of Medical Equipments: is the engineer of medical equipments who controls and inspects issues regarding to production, import, reserve and supply of medical equipments.

30. The selling place for medical equipments: is a place established in accordance to provisions of related law and regulation, in order to procure and supply medical equipments.

Chapter Two
National Medical Board

National Medical Board

Article 3:

The National Medical Board is the highest decision making authority regarding to Medicine, medical equipments and instruments and the problems caused by them, which consists of the following:

1. The Minister of Public Health as the head
2. General Director in Pharmacy as deputy
3. The Director of Ibn-e-Sina, as a member
4. 2 pharmacy teachers, elected by pharmacy faculty, as members.
5. one person from Pharmacology of Kabul Medical University, elected by Medical University, as a member.
6. The Director of Medicine Affairs, as a member.
7. The director of Pharmacy, as a member.
8. The Director of medicine and food laboratory as a member
9. One person Internal Medical Specialist, working in hospital, elected by the Minister of Public Health, as a member.
10. The Director of supervision of medical legislations, as a member.
11. a surgery specialist working in the hospital and elected by the Minister of Public Health, as a member.
12. A representative of the National Association of Medicine Importers, as a member.
13. A representative of the National Association of medicine Producers, as a member.

Duties and Jurisdictions of the National Board

Article 4:

The national Medical Board has the following duties and authorities:

1. To approve of the legal medicine list
2. To supervise the operations of Ibn-e-sina Pharmacy Institute, in accordance to relevant legislative documents.
3. To add or omit a specific medicine to the legal medicine list after having the professional opinion of the related department.
4. To review the medicine listed in prepared legal medicine, by elected committee of the National Medical Board, at the maximum, every 3 years.
5. To approve and ratify the National Afghan Formulary.

6. Appointment of committees for renewing national lists of core and legal medicines and national formulary of the country and also different scientific and professional committees relating to pharmacy issues.
7. Ratification of scientific and research programs related to pharmacy.
8. Ratification of TORs and procedures related to pharmacy.
9. to approve the annual medical need of the country that has been predicted by the relevant department.
10. To supervise collective medical services provision system all over the country.

Chapter Three
Afghan National Formulary

Collection of Afghan National Formulary

Article 5:

(1) Afghan National Formulary is a collection of legal medicine list, individual description of the certain medicine and additional information regarding to reasonable usage of the medicine, which is prepared by a committee, selected by National Medical Board, consisted of the pharmacy faculty and Kabul Medical University professors and professional members of Ibn-e-sina Pharmacy Institute.
(2) The Afghan National Formulary is reviewed every three years by the committee described in paragraph (1) of this article.
(3) The Ministry of Public Health is obliged to print and publish Afghan National Formulary.

Publication of Formulary Attachment

Article 6:

If a new needed medicine is added to the Afghan National Formulary during the 3 year period of publication, the necessary information is prepared separately and attached to the formulary as a complement and in the next publication, it is added to the formulary.

Excluding Commercial Name

Article 7:

The commercial name of medicine is not to be written in Afghan National Formulary.

Chapter Four
Production and Import of Medicine and other Medical Equipments

Issuance of License

Article 8:

The Ministry of Public Health is the authorized body for issuing licenses to producing companies, importers and wholesalers for production, import and sale of medicine and other legal medical equipments listed in the law.

Production, import and supply of medicine which are not in the legal list

Article 9:

(1) Production, import and supply of medicine and medical equipments which are not in the legal medicine list, is not allowed.
(2) Production, import and supply of medicine and medical equipments which are not in the legal medicine list, can be allowed in special cases with proposal of Pharmacy Affairs Department and approve of National Medical Board.

License for Operation

Article 10:

A person can commence production, import or wholesale of medicine and other legal medical equipments, only when he/she achieve a license from Pharmacy Affairs Department.

Medical Procurement Body for Governmental Health Entities

Article 11:

(1) Procurement planning for medicine and medical equipments included in legal medicine list, considering related legislative documents, is created through Pharmacy Affairs Department.
(2) In special cases when the quantity of medicine and other medical equipments included in legal medicine list, is not sufficient to address the needs of public health entities, the permission for importing more medicine is proposed by the pharmacy affairs department and approved by National Medical Board.

Import and Supply of Medicine by non-governmental organizations

Article 12:

Non-Governmental Organizations working in medical services and humanitarian activities, in accordance to provisions of this law, can import and supply legal medicine and other medical equipments after attaining license from Ministry of Public Health.

Import of Medicine by Scientific and Research Organizations

Article 13:

(1) Scientific and Research Organizations can import medicine and other necessary medical equipments, after approval of National Medical Board and other related department.
(2) Production companies and importers cannot produce or import medicine and other legal medical equipments, more than the need specified by relevant departments of Ministry of Public Health. Medicine and other medical equipments tended for export, are exception to this provision.

Chemical Materials

Article 14:

Chemical Materials used in medical laboratories are provided in accordance to relevant legislative document, by pharmacy affairs department or importers of medicine.

Procurement of Medicine in use in special cases

Article 15:

(1) Importers and the Pharmacy Enterprise is obliged to provide medicine which is restricted to special and rare cases and has vital value, according to specific quota prepared by Pharmacy Affairs Department.

(2) The pharmacies in Kabul and other provinces are obliged to obtain the medicine afore-mentioned in paragraph (1) of this article from importers or pharmacy enterprise and provide them in accordance with relevant legislative documents to people in need.

Price Determination of Medicine

Article 16:

(1) The price for medicine and other legal medical equipments are determined by Pharmacy Affairs Department, based on official documents.

(2) Issues regarding to production and import of legal medicine and other medical equipments are managed by a separate regulation.

Chapter Five
Sale of Medicine and Other Medical Equipments

Establishment of a Pharmacy

Article 17:

(1) A pharmacy is established for the purpose of selling legal medicine and other medical equipments in accordance to this law.
(2) The privilege of pharmacy is issued by Ministry of Public Health and the Operation License is issued by Pharmacy Affairs Department.
(3) The sale and distribution of legal medicine and other medical equipments are only permitted to pharmacies having operation license.
(4) The interest of the pharmacy cannot be more than 15% of the whole price of medicine and medical equipment.

Operation License of Pharmacy

Article 18:

(1) The operation license for pharmacy is granted to a person who:
    1. has Afghan National ID card.
    2. is over 18 years old.
    3. is not divested from civil rights.
    4. has not committed any crime.
    5. has introduced the official name of the pharmacist to the Ministry of Public Health.
    6. has paid the fees for establishment of pharmacy to the bank account of government incomes.

(2) A person having diploma or certificate in the field of pharmacy will be preferred in issuing of license.

Categorization of Pharmacy

Article 19:

(1) Pharmacies are categorized regarding their income, location and area, as follows:
    1. First Degree Pharmacy:
        a. Having at least 1 million Afghani of capital.
        b. Having an area of at least 53 m^2.
        c. Having location in the center of cities, populated areas and near hospitals in 500 meters of distance.

2. Second Degree Pharmacy
    a. Having capital of at least 500,000 Afs.
    b. Having an area of at least 43 m2
    c. Having location in other areas of Kabul or provinces.
3. Third Degree Pharmacy:
    a. Having capital of at least 300,000 Afs.
    b. Having an area of at least 38 m2.
    c. Having location in remote areas, suburbs and villages.

Fees of Establishment of Pharmacy

Article 20:

(1) the fees for establishment of a pharmacy, considering the category, is as follows:
    1. First degree pharmacy, 15000 Afs.
    2. Second degree pharmacy, 10000 Afs.
    3. Third degree pharmacy, 5000 Afs.
(2) the fees concluded in paragraph (1) of this article is paid to the bank to the account of government income.

Sale and Ownership of Pharmacy

Article 21:

(1) The sale of a pharmacy to a person described in Article 18 of this law is permitted. The new owner has to renew the license and pay the fees stated in Article 20 of this law to the bank account of government income.
(2) Ownership of the pharmacy can be transferred to people qualified in this law, in accordance to provisions of law, considering the followings:
    1. When the right holder is dead.
    2. When the right holder is suffering from a severe disease which prohibits him from working.
    3. in the cases described in paragraph (2) of this Article, the name of pharmacy license is changed to inheritor (without paying the fee for renew).

Sale of Medicine according to prescription of the doctor

Article 22:

(1) The medicines are sold according to the prescription of the doctor, in the pharmacies.
(2) Legal medicine, the sale of which is allowed without prescription of the doctor is approved and announced by National Medical Board.
(3) Pharmacy employee is obliged to provide the medicine according to written prescription of the doctor, and also write the usage method of the medicine to the

patient and has to write the price of each medicine separately in a signed and stamped bill.

Preservation and Transportation of Medicine

Article 23:

(1) Preservation and Transportation of Medicine is not allowed, except for the following cases:
    1. The medicine of pharmacy, production and import companies having legal license.
    2. Registered medicine used for professional activities (human, animal and dental) of doctors and nurses.
    3. Legal medicine for personal use of patients.
    4. Medicine which is used by foreigner people during their trip.

(2) Temporary preservation of unregistered medicine for specific medical purposes is permitted by National Medical Board.

Receiving Body for aided Medicine

Article 24:

Non-governmental organizations and other assisting entities, shall submit their aided medicine ad other medical equipments, considering the provision of aided medicine, to Pharmacy Affairs Department in Kabul or Public Health Agencies in provinces and districts and in some special cases, directly to the people in need under the supervision of Pharmacy Affairs Department.

Prescription for purchase

Article 25:

The doctor cannot prescribe the patient in a public hospital, to purchase medicine which is distributed free of cost by the government.

Restriction of Medicine sale in Doctors' Office

Article 26:

Doctors do not have the right to sell or distribute medicine inside their personal office.

Operation Method of Pharmacy

Article 27:

The operation method and other issues related to Pharmacies is managed by a separate regulation.

Chapter Six
Reasonable use of Medicine and other Medical Equipments

Reasonable use of Medicine

Article 28:

It is the duty of Ibn-e-Sina Pharmacy Institute to expand and develop the context of reasonable use of medicine, with cooperation of Medical University and Pharmacy Faculty.

lack of prescription of illegal medicine

Article 29:

A doctor cannot prescribe or advice a medicine which is not included in the list of legal medicine to the patient.

Writing Method of Prescription

Article 30:

(1) A doctor is obliged to write the prescription in a clear, separated, bold Latin characters and shall prevent writing secret prescriptions.
(2) A doctor can write the commercial name of the medicine, inside parenthesis, beside the Generic name which is written in Latin.
(3) The doctor shall give information about the ingredient and side effects of the medicine to the patient.
(4) Medicine containing Alcohol in its ingredients, shall be prescribe according to instructions of the doctor, only for the purpose of effective treatment.

Specifications of a Prescription

Article 31:

A Prescription shall contain the following points:
1. Name and address of the doctor (Official Logo)
2. Name, age and sex of the patient

3. The Date
4. Name and medical type of the medicine, quantity of effective substances in each unit and total of it.
5. In case needed, written instructions for technical in-charge of pharmacy.
6. Necessary instructions and information including the usage of medicine, in a clear manner, for the patient.
7. Diagnoses of the disease.
8. The signature of the doctor.

Assessment of Prescription

Article 32:

(1) The technical in-charge of pharmacy, in accordance to provisions of this law, is obliged to assess the prescription of doctor regarding the name, quantity, medical type and type of harmony.
(2) in case the technical in-charge of the pharmacy notices a mistake in prescription, he/she shall distribute the medicine after agreement with the prescribing doctor and clearing the mistake.

Teaching the Generic Name of Medicine

Article 33:

Medical University, Pharmacy and veterinarian faculties and other Medical Institutes are obliged to teach the medicine using their generic names.

Including Basic Concepts of Medicine in Curriculum.

Article 34:

Medical University, Pharmacy and veterinarian faculties and other medical institutes are obliged to include basic medicine concepts and reasonable usage of medicine, into their teaching programs.

Publication of Medical Reactions

Article 35:

Ibn-e-Sina Pharmacy Institute is required to collect medical reactions reports and publish the results of its research after assessment of the report.

Publicity and Marketing

Article 36:

(1) Publicity and marketing of medicine and medical equipments are permitted, provided that the contents of the ads are approved by Pharmacy Affairs Department.
(2) Publicity and marketing for children's foodstuff and medicine are not allowed without permission of the Ministry of Public Health.

Prohibition of medicine application on body

Article 37:

Application of materials the use of which is not approved by traditional or current medical resources is prohibited.

Abolition of Medicine

Article 38:

Expired and deficient medicine shall be eliminated in accordance with WHO directions, by Pharmacy Affairs Department.

Chapter Seven
Provisions on Penalty

Cash Payments

Article 39:

(1) When people, enterprises or companies tend to sell, produce or import medicine without a license from the Ministry of Public Health, they will be charged as follows:
    1. If the medicine is included in the legal medicine list, it shall be restrained.
    2. If the medicine is not in the legal medicine list, it shall be restrained and in addition, the price shall also be obtained from violator.
(2) When people violate the provision of paragraph (4) of Article 17 of this law, the right holder shall pay 50 Afs for every single extra Afghani paid to him.
(3) For the violator of provision of article 23 of this law, the available medicine shall be restrained and the violator is obliged to pay the equivalent price, as well.

Suspension of Import License.

Article 40:
The importers of medicine are required, according to the provision of Article 15 of this law, to import the amount of medicine specified by Pharmacy Affairs Department during one year after the date of specification. In case they fail, their privilege to import shall be suspended for one year.

Production and import of counterfeit Medicine

Article 41:

(1) People, organizations or companies that produce or import counterfeit medicine, in addition to restraining the medicine, the violator shall be referred to relevant authorities for judicial pursue.
(2) If the violation stated in paragraph (1) of this article is repeated, the privilege of production or import shall be deprived for ever, in addition to application of penalty stated in the above mentioned paragraph.

Sale of Aided Medicine

Article 42:

Sale of aided medicine is not permitted for public or private pharmacies. If an employee of public pharmacy commits this action, he shall be suspended from duty for one year decided by court.
If a private pharmacy employee commit this action, the court shall issue an order to restrain the medicine and suspend the pharmacy license for one year.

Publicity and Marketing

Article 43:

If a production or importing company violates the provision of Article 36 of this law, the violator shall be charged from 5000 Afs to 100,000 Afs, considering the spread of the publicity and advertisement.

Deprival of pharmacy operation

Article 44:

If a pharmacy sells narcotics, alcoholic drinks, counterfeit and deficient medicine, the violator shall be subjected to judicial pursue and the privilege of operation will be deprived for ever.

Obstruction and suspension

Article 45:

If a doctor violates the provision stated in Article 30 of this law, the office and related pharmacy shall be obstructed or suspended as follows:

1. The first time, Obstruction of doctor's office and the pharmacy for 2 weeks.
2. The second time, Obstruction of doctor's office and the pharmacy for one month.
3. The third time, suspension of doctor's and pharmacy license for one year.

Money Delivery

Article 46:

The amounts stated in provisions of this chapter shall be prepared by a separate regulation and paid to the bank account of government income.

Violation of Provisions

Article 47:

If the owner or technical in-charge of a pharmacy violates provisions stated in pharmacy regulation, the violator shall be dealt with, according to the provisions of the mentioned regulation.

Chapter Eight
Miscellaneous Provisions

Medical Inspectors

Article 48:

Medical Inspectors are obliged to control the application of provisions of this law and regulation related to pharmacies and sanitary organizations.

Traditional Medicine

Article 49:

The issues regarding to production, import and use of traditional medicine shall be handled by a separate regulation.

Maintenance and Reserve of Medicine

Article 50:

The importers of medicine, wholesalers and owners of pharmacies are required to import, maintain and reserve the medicine under standard conditions.

Responsibilities of Customs Authorities

Article 51:

The authorities of customs are obliged to provide standard conditions for maintenance of Medicine and other medical equipments, considering sensitivity of medicine and conditions (e.g. heat, frigidity, humidity, and direct sunlight), and prioritize them in customs issues.

Establishment of Toxicology Center

Article 52:

The Ministry of Public Health shall establish a center for toxicology, in order to collect information and documents regarding to diagnoses and treatment of toxics and poisons.

Enforcement

Article 53:

This law shall be effective from the date of its endorsement and published in the Official Gazette. From the effective date of this law, the law on medicine published on Official Gazette, No. 916 year 2006 and Generic Law approved by decree No. 582 dated: 6th October, 2000 shall be nullified.