

DECREE

Of

President of Islamic Republic of Afghanistan  
Regarding the enforcement





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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 1<sup>st</sup> 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 production, import, reserve and supply of medical equipments.

30. The selling place for medical equipments: is a place established in accordance to

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 medicines 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



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.

(1)

### 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 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

(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 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.

2. Second Degree Pharmacy
  - a. Having capital of at least 500,000 Afs.
  - b. Having an area of at least 43 m<sup>2</sup>
  - 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 m<sup>2</sup>.
  - 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

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 bodies, shall submit their aided medicine and 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.

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.

Publicity and Marketing

Article 36:

(1)



Suspension of Import License.

Article 40:

### 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: 6 October, 2000 shall be nullified.