

**The Approval  
Of  
Ministerial Council of Islamic Republic of Afghanistan  
Regarding  
Enforcement of Pharmacy Regulation.**

**Number: 34**

**Date: 8<sup>th</sup> January 2007**

The Regulation of Pharmacy which is approved within 5 chapters and 37 articles is enacted.

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

Hamid Karzai

President of Islamic Republic of Afghanistan

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**In the Name of Almighty Allah, the most merciful and compassionate**

## **Pharmacy Regulation**

### **Chapter one**

#### **General provisions**

##### Basis

##### **Article 1:**

Following the provision of article 27 of Medicine Law, this Regulation is enforced for regulating the related affairs of governmental and personal Pharmacies.

##### Pharmacy establishment

##### **Article 2:**

A Pharmacy is established based on provisions of law to sell medicines and other authorized medical equipments, useable materials for personal sanitation and providing necessary information regarding reasonable usage of medicines.

##### Presence of Professional In Charge

##### **Article 3:**

A drug store, in accordance with provisions of this Regulation, can only operate in presence of a Professional In Charge (pharmacist or Assistant pharmacist).

##### Sale of authorized medicines

##### **Article 4:**

The responsible person of Pharmacy has the right to only sell the medicines from the authorized list of medicines in the country.

### Sale of medicines as per prescription

#### **Article 5:**

Sale and usage of authorized medicine take place based on prescription and in accordance with recommendation of physician doctor and pharmacist by considering scientific percepts. Sale of authorized medicines without prescription of doctor mentioned in paragraph (2) of article 22 of medicines law is exceptional from this provision.

## **Chapter 2**

### **Operations procedure of Pharmacy and owner's liability**

#### Responsibility of governmental hospital Pharmacy

#### **Article 6:**

Ministry of public health is obliged to give over the responsibility of governmental hospital Pharmacy to a person who holds graduate degree (diploma) from pharmacy faculty.

#### Map of Pharmacies (koroky)

#### **Article 7:**

- (1) The map of Pharmacy will be verified by Pharmacy Affairs Department in capital of country and in provinces by relevant departments of Public Health Directorate.
- (2) Rooms of Pharmacies shall be constructed as per guideline mentioned in pharmacy affairs department procedures.
- (3) Distance between new Pharmacy and old one shall be at least 200 meters.

#### Providing list medicines and other medical equipments

#### **Article 8:**

The list of medicines and other authorized medical equipments and useable materials for personal sanitation by considering capital and needs of Pharmacies will be provided based on implementation of health laws by departments of monitoring and pharmacy affairs.

## The Professional In Charge of Pharmacy

### **Article 9:**

Professional In Charge in Pharmacy will be appointed as follow:

- (1) For first and second class of Pharmacy, Pharmacist
- (2) For third class of Pharmacy, Assistant Pharmacist
- (3) In case of unavailability of Professional In Charge of Pharmacy in remote areas, a pharmacy worker can handle the responsibility of Pharmacy
- (4) A Pharmacy cannot be used as medical examination clinic

## Shifting requirements of Pharmacy

### **Article 10:**

A Pharmacy cannot be shift from one location to another. The following circumstances are exceptional from the provision:

- 1- In case of implementing urban plan
- 2- In case of destruction of Pharmacy in the event of unexpected incidents which is confirmed by the body of men from monitoring of health law implementation department.
- 3- In case the proprietor of Pharmacy, based on provisions of law, is obliged by the owner of property to shift the Pharmacy

## Inauguration of Pharmacy

### **Article 11:**

The owner, after obtaining work permit and completing medicines and other medical equipments according to relevant list, can inaugurate the Pharmacy. In case owner of Pharmacy after obtaining work permit, without a justified excuse, doesn't inaugurate his/her Pharmacy within six months, the work permit will be taken away. In such case a person can obtain a new work permit by making repayment.

### Providing medicines

#### **Article 12:**

The owner of Pharmacy is responsible to provide medicines and other necessary authorized medical equipments based on the list of pharmacy affairs department by considering the class of Pharmacy from the importers and wholesaler of medicines.

### Lack of having number of licenses

#### **Article 13:**

No one can have licenses of Pharmacy, import and wholesaler of medicines at a time.

### Notice about absence of Professional In Charge

#### **Article 14:**

- (1) In case of absence of professional person, owner is responsible to notify the Monitoring of health laws implementation department in capital, public health directorate in provinces and relevant departments of ministry of health in districts.
- (2) The owner of Pharmacy, during absence of professional in-charge, is responsible to hire another eligible person by considering the provisions written in this Regulation as Professional In Charge and inform through a written notification the authorities mentioned in paragraph (1) of this article, otherwise the Pharmacy will be suspended till recruitment of Professional In Charge.

### Presenting report on using narcotic medicines

#### **Article 15:**

- (1) The professional in charge is responsible to keep record of executed prescription of controlled and narcotic medicines, in addition to record in medicines book, in a separate book which is specially provided for controlled and narcotic medicines and keep the original copy of prescription and submit the copy by mentioning price, signing and stamp to customer.
- (2) Owner is responsible to provide the report every quarter on the usage of controlled and narcotic medicines with all original executed prescriptions in accordance with description to pharmacy affairs department.

### Requirements for keeping the medicines

#### **Article 16:**

Owner is responsible to put and compose the medicines by consideration of their relevant category in boxes of cabinet containing the following colors:

- 1- Severe poisons and narcotic medicines in the box of cabinet which contains red glass.
- 2- Light poisons in the box of cabinet which contains green glass.
- 3- Other controlled (under control) medicines in box of cabinet which contains blue glass.
- 4- Emergency medicines in cabinet with white glass
- 5- Other groups of medications in cabinet with transparent glass.

### Secured protection of medicines

#### **Article 17:**

- (1) Owner is responsible to provide necessary conditions for the secured protection of medicines from light, temperature, humidity and soil as per enacted scientific standards by pharmacy affairs department and monitoring of health laws implementation department in consultation of designated professional in charge in Pharmacy.
- (2) Owner is responsible to provide (electrical, run by fuel or gaseous ) refrigerator for keeping biological medicines and products in Pharmacy.

### Responsibility of Pharmacy owner

#### **Article 18:**

The owner of Pharmacy will have the following responsibilities:

- 1- Observing the cleanliness and sanitation terms
- 2- Lack of storing non medical equipments and taking actions for the sale of them
- 3- Making payment of salary and allowances of professional in charge as agreed between parties
- 4- Respecting the provisions written in medicines law and this Regulation

### 24 hours duty shift

#### **Article 19:**



- (1) Professional in charge shall perform the 24 hours duty shift based on the list
- (2) The list of night duty shift will be provided by monitoring of health law implementation department in capital, in provinces by public health directorate and in districts by relevant authorities of ministry of public health.
- (3) Owner is responsible to put the list written in paragraph (2) of this article on the entrance part of Pharmacy.

#### Posting of documents

##### **Article 20:**

The owner of Pharmacy is responsible to post the work permit, Identification of professional in charge of Pharmacy, price list of medicines and other authorized medical equipments which are stamped by pharmacy affairs department and monitoring of health law implementation department on visible location of Pharmacy.

#### Purchasing medicine

##### **Article 21:**

The owner of Pharmacy is responsible to purchase the medicines and other authorized medical equipments from the the incumbency of pharmacy, importers, and wholesaler against receipts and invoices.

### **Chapter 3**

#### **Requirements for recruiting and responsibilities of Professional In charge**

##### Requirements of employment

##### **Article 22:**

A person can be recruited as professional in charge (pharmacist or assistant pharmacist) who is eligible for below requirements:

- 1- Shall hold Afghanistan citizenship
- 2- Pharmacist shall hold B.Sc degree or higher for universities and Assistant Pharmacist shall at least hold graduate degree of two years from educational institute
- 3- Shall not be deprived from civil rights
- 4- Shall not be convicted of crime

### Employment requirements of Professional In charge

#### **Article 23:**

- (1) The employment of professional in charge of Pharmacy shall be contracted by confirmation of monitoring of health law implementation department.
- (2) A copy of employment contract and other documents of Pharmacy shall be kept in monitoring of health law implementation department and identification document of owner and professional in charge will be given to owner.

### Execution of compound medicines

#### **Article 24:**

The professional in charge of Pharmacy is responsible to execute the combined medications under required conditions as per prescribed by the physician considering pharmaceutical standards.

### Supply of medicines

#### **Article 25:**

The professional in charge is responsible to provide the medications to customers which are packaged based on the principles of pharmacy profession.

### Responsibility of professional in charge

#### **Article 26:**

The professional in charge of Pharmacy is liable for below instances:

- 1- Keeping medicines as per pharmacy standards
- 2- Observing cleanliness of Pharmacy and wearing professional uniform
- 3- Recording prescription in special book
- 4- Writing the price of medicines on prescription with signature and stamp
- 5- Providing understandable instructions and necessary information regarding recommended medicines to patients

### Professional In charge notification

### **Article 27**

Whenever owner of Pharmacy in absence of professional in charge take actions for selling medicines or violates the Pharmacy Regulation, the professional in charge shall report the issue in writing to monitoring of health laws department.

### Providing a constructive idea

#### **Article 28:**

The professional in charge of Pharmacy can provide his/her constructive ideas regarding insufficiencies of Pharmacy in two copies and send one copy for owner and the other one to monitoring of health laws implementation department in capital and in provinces to public health directorate. The owner of Pharmacy after confirmation of mentioned ideas by monitoring of health laws implementation or public health directorate is responsible for implementation of it.

### Medicines without label

#### **Article 29:**

The professional in charge of Pharmacy cannot keep or sell medicines without label.

## **Chapter four**

### **Correctional Provisions**

### Lack of observing sanitation

#### **Article 30:**

Whenever owner doesn't observe the sanitation of Pharmacy, will be treated as follow:

- 1- First time, advise
- 2- Second time, written warning
- 3- Third time, monetarily fined 3,000 AFN
- 4- Fourth time, monetarily fined 10,000 AFN
- 5- Fifth time, suspension of work permit reportedly up to one year

### Lack of reporting for night duty

**Article 31:**

In case of not reporting for night duty of 24 hours, the violators will be treated as follow:

- 1- First time, advise
- 2- Second time, written warning
- 3- Third time, monetarily fined 3,000 AFN
- 4- Fourth time, monetarily fined 10,000 AFN
- 5- Fifth time, suspension of work permit reportedly up to one year

**Lack of using Pharmacy as examining clinic****Article 32:**

Whenever a doctor uses Pharmacy as examining clinic , the owner of Pharmacy will be treated as follow:

- 1- First time, advise
- 2- Second time, written warning
- 3- Third time, monetarily fined 2,000 AFN
- 4- Fourth time, monetarily fined 3,000 AFN
- 5- Fifth time, suspension of work permit reportedly up to one year

**Renew permit for operation/work****Article 33:**

The ones, whose work permit is suspended, can renew their work permit of Pharmacy after passing the suspension period and by making payment of ten thousands (10,000 AFN)

**Payment****Article 34:**

The amount written in this chapter, based on a separate procedure from responsible figures, shall be paid to revenue account of government in bank.

## Chapter five

### Miscellaneous provisions

#### Having record book

##### **Article 35:**

Pharmacy shall contain stamp, standard board, medicines record book, and controlled and narcotic medicines record book that the format shall be verified by the monitoring of health laws implementation department and shall be provided by the owner of Pharmacy.

#### Implementation of Regulation provisions

##### **Article 36:**

Monitoring of health laws implementation department of ministry of public health will take care of implementing the provisions of this Regulation.

#### Enforcement

##### **Article 37:**

This Regulation from the date of approval of ministerial council is enforced and should be published in official gazette and by enforcement of this Regulation, the Pharmacies Regulation published in official gazette, numbered (513) in the year of 1361 and the enforced Regulation by the decree, numbered (582), dated 14/6/1422, are counted dissolved.