Approval of the Council of Ministers

In Respect to the Enforcement of the Manufacture and Import of the Medicine and Medical Appliances Regulation

No: (39)

Date: 19th February 2007

I endorse the Regulation on Manufacture and Import of the Medicine and Medical Appliances, which was approved by the Council of Ministers in **6** chapters and **75** Articles.

This Regulation shall be enforced upon the date of approval and be published in the Official Gazette.

Hamid Karzai,

President of the Islamic Republic of Afghanistan.

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Chapter One

General Provisions

Basis

Article 1:

This regulation is established on the basis of the provision of paragraph (2) of the Article 16 of Medicine Law to regulate affairs related to manufacturing and import of medicine and all medical Appliances.

Legitimacy of Manufacturing and Import

Article 2:

Manufacture and import of all lawful medicine and medical Appliances shall happen in accordance with the provision of the Medicine Law, Private Investment Law and this regulation.

Chapter Two

Manufacture of Medicine and All Medical Appliances

Conditions for Manufacture License

Article 3:

License of Manufacture and Import of Medicine and all Medical Appliances is given to a natural or legal individual with the following criteria:

1-The natural individual shall [at least] be 18 years old.
2-Shall not have been deprived of civil rights.
3-Shall not have been involved in criminal acts.

License for Manufacturing

Article 4:

Individuals with criteria mentioned in Article (3) submit their applications for the establishment of Ltd (Company) manufacturing medicine and all medical Appliances. The individuals applying shall specify the following issues:

1. Primary investment
2. Application area
3. Number of items manufactured

4. Type of medicine supposed to be manufactured
5. Available logistics and technical tools
6. Available human resources
7. Criteria for recruitment of experts and administrative staff.

(2) The Office for Pharmacy Affairs shall evaluate the application mentioned in paragraph (1) of this article in a maximum period of three months and shall inform the applicant about the acceptance and rejection of the application with justified explanations.

(3) The license for medicine and medical manufactures will be issued by the Office of Pharmacy Affairs after evaluation and confirmation of the application by a delegation of Pharmacy Administration.

(4) The license mentioned in paragraph (3) of this article shall be issued by the Office of Pharmacy Affairs for a cost of (50000.00 Afs).

Conditions for Establishment of Ltd (Company)

Article 5:

Ltd (Company) shall be established under the following conditions:

1. Having a map for the Ltd (Company)
2. Owning machineries and technical instruments meeting the international criteria.
3. Owning well-equipped laboratories for qualitative and quantitative segregation of medicine.
4. Having pharmacists, pharmacists assistants and qualified staff members.
5. Having criterion and high-quality raw materials for production of medicines with high-quality and internationally acceptable norms.

Manufacture of Medicine According to International Norms

Article 6:

Companies, both governmental and private are under obligation to produce medicines and medical Appliances according to acceptable international norms.

Qualitative and Quantitative Test

Article 7:

(1) Medicine manufacturing company is under obligation to send its products, for qualitative and quantitative Test, to the Department of Quality Control and Preservation of Medicine and Foodstuff of the Ministry of Public Health before sending those products to the market.
(2) The Company mentioned in the paragraph (1) of this article may send medicine and medical Appliances to the market for sell after verification is

done by the Department of Quality Control and Preservation of Medicine and Foodstuff and official approval of Pharmacy Administration.

Packaging of Products

Article 8:

Companies producing medicine and all medical Appliances are under obligation to write the following issues on their products packages:

1. Generic Name of the Products
2. Unit weight or content feature of medicine
3. Production and expiration dates
4. Batch number
5. Price (not wholesale)
6. Name and address of the company
7. Brochure in one of the official languages of the country

Price Verifications

Article 9:

The price of the medicine or medical Appliances produced by a company, with a consideration of the related documents (of raw materials and other expenses), shall be verified by Pharmacy Administration.

Conformity of Unit Weight with Legal Medicine List

Article 10:

The weight for each unit or content of medicine or all medical Appliances shall match the lawful medicine list.

Import of Raw Materials

Article 11:

A company producing medicines and medical Appliances that is legitimate in accordance to the provisions of this regulation, may import the necessary raw materials after obtaining permission from the Pharmacy Administration.

Information Provided by the Company Owner

Article 12:

(1) The owner of the company is under the obligation to inform the Pharmacy Administration, in a written form, of any changes in primary investment, number of items of products and organizational structure [Tashkeel] or operational mechanism of the company.

(2)The Pharmacy Administration shall within a month examine the changes and decide regarding approval or rejection of such a change.

Renewal of License

Article 13:

The company manufacturing medicines and medical Appliances is under the obligation to renew its activity license after three years in accordance to the provision of Article 4 of this regulation.

Chapter Three

Import of Medicine and Medical Appliances

Conditions of Import License

Article 14:

(1) The license for import of medicine and medical Appliances is given to a natural or legal individual who has the following conditions:

1. The natural individual is at least 18 years old,
2. is not deprived of civil rights,
3. has not committed criminal acts

(2) The license mentioned in paragraph (1) of this article is issued for a cost of (40000.00 Afs) by the Pharmacy Administration:

Import and Procurement of the Necessary Medicine

Article 15:

(1) Import and Procurement of medicine and all medical Appliances (in the government sector) is a monopoly of the Pharmacy Administration of the Ministry of Public Health and shall be done in accordance with the provisions of this regulation.
(2) Aid NGOs may import all its necessary medicine and medical Appliances observing the provisions of Articles 19 to 23 and 27 of this regulation.

Conditions for Import of Medicine

Article 16:

Import of medicine and all medical Appliances by individuals, private import companies and Ltds shall take place in accordance with the provisions of this

regulation and the procedures of the Pharmacy Administration under the following conditions:

1. Obtaining of import license for medicine and medical Appliances.
2. Registration of foreign Ltd (Company).
3. Registration of medicine items with a consideration of lawful medicine list
4. Criterion norms for imported items

Necessity of Medicine out of Legal List

Article 17:

Import of medicine that is not included in the List of lawful medicine may take place when its necessity is verified scientifically by the National Board of Medicine and approved by the Ministry of Public Health.

Conditions for Registration of Foreign Manufacturing Companies

Article 18:

(1) A foreign manufacturing company shall be registered with the Pharmacy Administration under the following conditions:

1. If it has a good reputation in its respective country
2. If its manufactured medicines are according to the international norms
3. If its manufactured medicines have the same quality in the manufacturing country markets and outside
4. If the license for manufacture of medicine and medical supply of the company has been certified by three authorized entities (Ministries of Public Health, Commerce and Foreign Affairs) of the manufacturing country and sent by the Commerce Attaché of Afghanistan Embassy to the country.
5. If the company has the license for import of medicine in the country.
6. If it has the documents proving use of its products by consumers outside of the manufacturing country and export of its products to at least one more country.
7. If it has well-equipped laboratory for qualitative and quantitative Tests and can provide certificate for Test of each no. of package.
8. If it sends sample of medicine items for registration to Afghanistan through the Commerce Attaché of Afghanistan Embassy in the manufacturing country.
9. If it can provide specific documents related to the medicine including lists of ingredients of formulation medicine standards, price tag, packaging features, documents of [laboratory] Test, reference to the Test method, certificate for Test of processed materials.
10. If the price tag provided by the manufacturing company is according to the international prices.
11. If the GMP (Good Manufacturing Practices) and IOS (International Organization for Standardization) can be provided by the company,
12. If the DMF (Drug Master File) related to each manufactured item can be provided.

13. A payment of 5000.00Afs for each medicine item to the imports account of Afghan government in the state bank of Afghanistan.
14. Signature and stamp of the owner of the company on the documents.

(2) The company is registered after the completion of the requirements mentioned in the paragraph (1) of this article and endorsement of National Medicine Board and approval of the Ministry of Public Health.

Import Medicine from the Registered Companies

Article 19:

The import companies of medicines and all medical Appliances are under obligation to import the necessary medicine and medical Appliances from the companies registered with the Pharmacy Administration.

Obligation of Sampling

Article 20:

Sampling from each no. of batch, each item of medicine and all other medical Appliances for quality and quantity control is obligatory and it is done by authorized agents of Pharmacy Administration.

Criterion Test Result

Article 21:

Imported medicine may only be delivered to consumers when examined for quality and quantity norms by the Preservation of Medicine and Foodstuff Department and pass the required norms.

Elimination of Medicine and Medical Appliances

Article 22:

The Pharmacy Administration Affairs, after informing the responsible entities, is under the obligation to obliterate medicine and medical Appliances that fail to match with the acceptable norms. The obliteration shall take place according to the provisions of laws and accepted guidelines

Certification by the Authorized Laboratory

Article 23:

If imported medicine items and medical Appliances cannot be examined for quality and quantity norms inside the country [Afghanistan], the import company is under the obligation to provide certificate for Test of each package and type from a recognized laboratory.

Packaging of Imported Products

Article 24:

The import company is under the obligation to have the manufacturing company write the following specifications while packaging the imported products:

1. Generic Name of medicine (should be written clearly and with a lager font than that of Commercial Name)
2. Quantity of medicinal ingredients.
3. Production and expiration dates of the medicine
4. Batch Number
5. Name and address of the manufacturing company
6. Name and address of the importing company

Writing of Brochure in the Official Languages

Article 25:

Each batch shall contain brochure written in the official languages of Afghanistan. The contents of brochure shall be confirmed by the Expert Board of Pharmacy Administration at the time of document check.

Control of Writing on the Batch

Article 26:

Written materials on the batch/medicine packages shall be controlled by the Expert Board of Pharmacy Administration in accordance with the Article 24 of this regulation.

Import of Items According to Pro-form??

Article 27:

(1) Import permission of single items of medicine and medical Appliances shall be issued according to the Pro-form and shall include the following issues:

1. Writing of imported medicine in generic name and writing its commercial name under the generic name in parenthesis.

2. Writing of each item of medicine included in Pro-form in a clear and easy-to-read manner.

3. Mention of price included in Pro-form and according to packaging method.

4. Marking of validity duration of Pro-form

5. Marking of expiration date of medicine or medical Appliances in the Pro-form

6. Marking of transportation date from the origin [location] in Pro-form

7. Concurrent dispatch of quality control documents for each no. of package or batch.

8. Explanation of price payment conditions and transport of batches.

(2) If necessary, ingredients for formulation should also be provided attached to Pro-form.

Import of Narcotic Medicine

Article 28:

Narcotics medicine which is under control and its necessary amount has been decided by the National Board of Medicine, after primary Test by the Unit of Narcotics of Pharmacy Administration, may be imported.

Assignment of Expert Board

Article 29:

The Expert Board of Pharmacy has five members who are pharmacists with scientific credentials. The members are selected from the Pharmacy Faculty and Medical College who are assigned based on a suggestion of Pharmacy Administration and Ministry of Public Health approval for a period of one year.

Import Permission Based on Nature Inclusion of Medicine in the Legal List

Article 30:

The Export Board of Pharmacy Administration issues permission for the import of medicine in the Pro-form on the basis of the nature of its inclusion in the list of legal medicine of the country as well as dosage, formulation ingredients, comparative price,

registration of manufacturing company, toxicology, pharmacokinetics and all other scientific factors and types of use.

Calculation and Determination of Profit

Article 31:

Pharmacy Administration calculates and determines the price of medicine and medical Appliances on the basis of the provision of paragraph (10) Article 18 of this regulation and with addition of 4% for customs cost and 10% for profit.

Reconsideration of Price

Article 32:

Price of medicine may change with a consideration of international prices and changes in the rate of foreign currencies.

Demand on the Basis of Requirement

Article 33:

Pharmacy Administration with a consideration of facilities [of the company] may request the import companies for the import of medicine and medical Appliances when necessary.

HQ of Company and its Agencies

Article 34:

The HQ of import companies shall be in Kabul and its representations may be established in all provinces of the country when necessary.

Requirement for the Presence of Pharmacists

Article 35:

(1) An import company may not function without pharmacist.

(2) The pharmacist [working for the company] shall look after all the technical affairs of the company including transportation, preservation, and proper distribution of medicine and medical Appliances according to the accepted pharmacy rules and norms.

Observation of Physical Change

Article 36:

If the pharmacist observes physical changes [in medicine] in the process of import, storage and distribution, he/she is under the obligation to avoid distribution and inform the Pharmacy Administration in a written format.

Fair Distribution

Article 37:

The import company is under the obligation to distribute the imported medicine and medical Appliances in a fair way among all the drugstores and avoid selling to specific drugstores.

Trusted Preservation Conditions

Article 38:

The import company is under the obligation to set up trustable conditions for preservation of medicine and medical Appliances in accordance to the norms of pharmacy.

Import According International Norms

Article 39:

Import of all chemical and regents ?? shall take place in accordance with the provisions of Articles (27 and 28) of this regulation based on necessity and international norms.

Requirement of Sell Report

Article 40:

The import company is under the obligation to provide the Pharmacy Administration with the sell report of each imported item of each imported batch at the end of sells.

Customs Processing

Article 41:

The import company, after customs processing of the imported products. is under the obligation to provide the Pharmacy Administration with customs processing papers attached with the application for customs exit of the products and determination of the price.

Disallow of Reselling [sell directly to consumers] of Medicine

Article 42:

The import company is not allowed to resell its imported medicine and medical Appliances.

Import by Pharmacy Tenure

Article 43:

Import of medicine and medical Appliances by Pharmacy Administration tenure is influenced by the provisions of Articles (20, 29 and 33) of this regulation.

Import Based on Necessity

Article 44:

When highly necessary, the Pharmacy Administration may ask the import companies to import those medicine items that are exceptionally needed on a rotate basis.

Production and Expiration Dates

Article 45:

The import company is under the obligation to provide the Pharmacy Administration with a list of the medicine and all medical Appliances stored in the stock of the company, which will expire in three months. Such a list shall be provided in a written form and shall include information such as quantity, batch no., production and expiration dates.

Chapter Four

Wholesale of Medicine and Medical Appliances

Conditions on Wholesale License

Article 46:

(1) A license of wholesale of medicine and all medical Appliances is given to a natural or legal individual with the following criteria:

1. Be at least 18 years old
2. Shall not have been deprived of civil rights
3. Shall not have been involved in criminal acts

(2) A person with diploma or certificate in pharmacy shall be given priority for the license issuance.

License of Wholesale Activities

Article 47:

(1) Individuals mentioned in Article 46 of this regulation shall submit their application to the Ministry of Public Health for the wholesale license with observation of the following issues:

1. Owning at least an amount of (3000000.00Afs).
2. Owning a wholesale office with a size of at least 50 SM.
3. Owning a stock with a size of at least 50 SM.
4. Ability to preserve medicine from heat, cold, damp, light, and other effecting causes
5. Introduction of a pharmacist or pharmacist assistant to the MPH.

(2) The license for wholesale shall be issued for a cost of 25000.00Afs by the Pharmacy Administration.

Procurement of Medicines

Article 48:

(1) The wholesaler is under the obligation to provide medicine and medical Appliances from the import and manufacture companies that are registered with Pharmacy Administration.

(2) The wholesale profit of medicine shall not exceed an amount equal to 5% of the purchase price.

Chapter Five

Punitive Provisions

Medicine Having the Quality and Quantity According to the International Criteria

Article 49:

If at least three items of imported medicine from a manufacturing company is not according to the established international criteria, import from that company shall be prohibited.

Import of Medicine from the Registered Companies

Article 50:

Import of medicine and medical Appliances is only allowed from the companies registered with the Pharmacy Administration. If not imported form registered companies, the exit of medicine from the customs shall be disallowed; in such a case actions will be taken in accordance with the provisions of Article 39 of Medicine Law.

Suspension or Confiscation of License

Article 51:

If the activities of an import or manufacturing company of medicine is harmful to the public interests or contrary to enforced laws of the country, the Pharmacy Administration may suspend or confiscate their license.

Refusal the Provisions

Article 52:

If an import or manufacturing company of medicine refuse to implement the provision of Article 13 of this regulation, the Pharmacy Administration may suspend or confiscate their license.

Obtain of New License

Article 53:

If the import or manufacturing company, without a justified reason, does not commence import or manufacture of medicine within one year from the date of receiving the license, the license shall be confiscated. In such a case, the company may receive a new license according to the provisions of this regulation and commence its activities.

Chapter 6

Miscellaneous

Monitor of Company

Article 54:

(1) Monitor of an import of manufacture company shall take place only after issuance of license.

(2) Monitoring and evaluation of manufacture and import company (governmental or private) is a responsibility of Pharmacy Administration.

Fees

Article 55:

The Ministry of Public Health may determine a fee amount with consultation of Ministry of Finance for the Test of the qualitative and quantitative criteria of the

medicine mentioned in Articles 7 and 21 of this regulation. Such a fee can be established and obtained under a separate [from this regulation] procedure.

Taxes

Article 56:

The import and manufacture companies are under the obligation to pay a tax from their income according to the provision of the laws.

Enforcement Date

Article 57:

This regulation shall be enforced and published in the official Gazette from its approval date. Upon the enforcement of this regulation, the regulation enforced by the Decree no. (582), dated 6th October 2000 that was established to regulate import of medicine by individual traders, shall be dissolved.