Authentic in Lao only

Lao People Democratic Republic
Peace Independence Democracy Unity Prosperity

Ministry of Health **No: 1442 /MOH**
Vientiane Capital, 13 August 2003

Regulation on the establishment of drug and medical equipment import–export companies

- Pursuant to the Law on Drug and medical equipment No. 01/NA, dated 8 April 2000.
- Pursuant to Prime Minister Decree on the organization and function of Ministry of Health No. 020/PM, dated 19 March 1999.
- Pursuant to Prime Minister Decree on the adoption of the National Drug policy of Lao PDR No. 49/PM, dated 13 March 1993.
- Pursuant to Request of the Food and Drug Department and the consideration of the line Departments and the Steering Committee of Ministry of Health.

The Minister of Health hereby issued this regulation:

Part I
GENERAL PROVISIONS

Article 1: Objective and expectation

1. **Objective:** To control the activities of the companies that import–export drugs and medical equipment products in accordance with the law, regulation and technical principles in order to assure that the service for drugs and medical equipment products is of quality, effective, fair for consumers and in order to support to operation of the business effectively.
2. **Expectation:** To protect consumers so that they are served drugs and medical products of quality, efficiently and safely and to contribute to the development of the country**.**

Article 2. Definition

1. **"Drug":** A drug is any substance or any composition of substances which are active or inactive, used for the prevention and treatment of disease, which assists in testing and diagnosing diseases, relieving pain, modifying, improving, supporting, protecting or changing body functions, rehabilitation and mental health.

2. **Modern medicine:** A modern drug is any pharmaceutical product, which is processed in accordance with certain scientific formula and methods, which is packaged and labelled, and in which the active ingredients have been modified in a manner appropriate for the use by humans.

3. **Traditional medicine:** A traditional medicine is a drug derived from plants, trees, minerals, or animals, which is processed, packaged and labelled, and whose characteristics and effective active dose have not yet been scientifically proven, but have been approved by the Ministry of Health. The health sector shall organise surveys and register a list of trees, plants, minerals and animals which are sources of traditional medicines, in order to manage them.

4. **Medical products:** A medical product is any substance that is used for medical purposes, including any product that is in general use in society, but that can be harmful to human health, such as food supplements, cosmetics, household chemicals and medical products in daily use according to the details attached.

5. **Wholesale of Drugs:** The wholesale of drugs and medical products is the sale in big volume for future retail, that is sale in the original packaging.
   Buyer is the businessmen, who has intends to make future sales to other clients
   Person who has the right to be wholesaler: individual who runs an import–export company or branch of pharmaceutical factory or branch of the company and domestic wholesaler**.**

6. **Retail: Retail** is the sale not in big volumes, that is sale according to a doctor's prescription or sale to a patient for the purpose of treating a disease according to a doctor's diagnosis such as sale in ampoules, tablets**,** sheets
   Person who has the right be a retailer is the retail drug revolving fund in a hospital, health centre and village drug kitbag

7. **The Importation: The Importation** is the import of drugs and pharmaceutical products from abroad for distribution and sale to domestic clients in compliance with the laws and regulations of Lao PDR.

8. **The Exportation: The exportation** is goods to be sent for sale abroad following receipt of an order by a foreign client in compliance with the laws and regulation of Lao PDR.

9. **Company: Company** is the business unit which that conducts the import-export and sale of drugs and medical products that has permission from the Ministry of Heath.

10. **Branch or distributor: Branch or distributor** is the business unit which is the representative of the Mother Company or company for the sale of drugs or medical products**.**

Part II
Establishment of an import-export company, branch, distributor for selling drugs and medical products

Article 3: Requirements for the establishment of an import-export company

1. Any individual who conducts export and import of drugs and medical products in Lao PDR shall comply with the following:

- Individuals that are Lao Nationals or foreigners intending to establish an import–export company shall comply with the Enterprise Law, Labour Law, Law on accounting, Law on Drug and Pharmaceutical Products and other regulations of the Ministry of Health.

2. Obtained a pharmacist of Lao Nationality with a diploma in pharmacy or certificate of completion of education in pharmacy issued by an educational institute in Lao PDR or abroad and who has received the a license of pharmacy technician by the Ministry of Health and who must have permanently resided in Lao PDR for not less than five years. If he/she is a government official, he/she shall have an official authorization letter.
3. Shall have no criminal record or in the penalty relating to drugs and narcotic drugs;
4. Shall be in good health, have no mental illness, have no history of drug abuse.

Article 4: Conditions and necessary facilities.

1. Any individual conducting an import-export business for drugs and medical products shall only import-export drugs and medical products and they shall not be mixed up with other goods.

2. All the imported items of drugs and medical products shall inspected, analyzed (if necessary) and obtain a quality certificate from Ministry of Health.

3. The instructions for use of all imported drugs and medical product items shall be in Lao Language.

4. An import–export company for drugs and medical products needs to obtain a permit for establishment from the Department of Planning which will take into consideration the priorities for balancing the rate of exports versus imports and the population in the area.

5. The location where the import-export business is operated, or a branch of the company/factory and distributor shall have hygienic conditions, with an area of not less then 20 square metres, and shall be in a special building, not shared with other accommodation or with sale of other goods that are not drugs and shall have a storage system according to standards such as: cooling system, light, temperature measurement, moisture and other.

6. The company, branch, distributor shall have a special sign, clearly written with the following content:

- Name of the company in Lao on top and English below.
- Address, telephone, registration number and the sign of the snake embraced cup.
- The base color of the sign shall be green, the words shall be in white, with size of 80-100 cm wide, 200-250 cm long. In general, Lao language shall be bigger than English and it shall be inspected by the Provincial Health Office, Capital or Special Zone and Information–Cultural sector.

7. Equipment in the company, branch factory/distributor.

The place of the business shall have the following equipment as follows:

- Glass cabinet for storage of medicines in order to display and sale.
- Special cabinet for storage of poison drugs and narcotics. This shall be strong and sealed and refrigerated to a temperature of not more than $4^{o}C$ with thermometer in the case of medicines that need to be kept in cold conditions such as vaccines, medicines for enema or other medicines.
- Proper equipment for packing that complies with the requirement for assurance and other necessary equipment.
- Good warehouse systems that comply with standards according to good wholesale practice (GWP).

8. Documents that a company, factory/company branch, distributor must keep. A company, factory/company branch, distributor shall keep the following documents:

- Registration certificate for pharmacy and permit certificate to conduct a business for drugs shall be displayed in place of easy access,
- Law, decrees, regulations and notices on drugs.
- Guidelines on using drugs.
- Monitoring booklet for inspection by inspector.
- Monitoring booklet for monitoring drug in the store: receipts, sales, actual balance with expiry date and lot number.
- Copy of the purchase invoices and sale invoices of the pharmacy according to the requirements.
- The import–export document sets for the drugs available in the shop.
-Special control list for narcotic and psychotropic and other lists.

9. A Company, branch of factory/company, distributor shall have an organization structure comprising at least a Director and Deputy Directors, necessary divisions such as: accounting, warehouse accounting, marketing and others and shall follow the rules of conducting business.

10. In order to establish a wholesale company in the country, the conditions and requirements of establishment for import–exports shall be complied with, except point 4.2 of article 4 of this regulation.

Article 5: Documents for requesting a permit or renewing a technician permit.

1). Documents for permission of the technician

1. Application form for pharmacist
2. CV with photo (not older than 1 year).
3. Health certificate (not older than 3 month)
4. Certificate of Residence with photo (not older than 3 months)
5. 3 x Photos of size 3x4cm (not older than 1 year)
6. Diploma Certificate
7. Criminal Letter
8. The certificate of release from the government or the nomination of the department in the case of becoming a business
9. Layout of the company location, branch company/factory, distributor.
10. Certificate of the inspection of the establishment by a competent authority

2). The documents for renewal a technical permit

1. The old permit certificate of the pharmacy that is expiring
2. Letter of Request for renewal of the permit for pharmaceutical technician
3. Health certificate (not older than 3 months)
4. Certificate of Residence with photo (not older than 3 months)
5. 3 x photos of size 3x4cm each (not older than 1 year)
6. Report on the inspection for issue and renewal of permit

Article 6: Establishment of a distributor of a factory, company or a provincial branch.

The establishment of a distributor of a factory, company or branches in provinces shall be implemented as follows: submit documents according to article 5.1 or 5.2 together with the request to the Ministry of Health through the Provincial Health Department, Capital or Special Zone (Food and Drug section) where the distributor or branch is located.

Article 7: Persons who have the right to be wholesaler of drugs and medical products.

Only the import–export company, drug company/distributor and domestic wholesale company has the right to be a wholesaler of drugs and medical products.

Part III
ISSUING OF LICENSE
FOR PHARMACY BUSINESS OPERATION

Article 8: Issuing of pharmacy license

Individuals who intend to operate an import-export business, branch or distributor of drugs and medicine products, shall submit the documents to the District Health Office (where the business will be established) to be checked and for comment and then send them to the Provincial Health Office, Capital or Special Zone for consideration in detail and to the Food and Drug Department, Ministry of Health for consideration of issuing the license (the period of all consideration of the documents in the health sector is 60 days).

In the case of foreign investment, it shall comply with the regulation of the Chair of the Committee for the Management of Foreign Investment and Domestic Investment on the rule for the consideration of the permit investment project in Lao PDR No 013/CIC, dated 27 February 2002.

The Pharmacy license certificate is valid for 1 year and needs to be renewed 3 months before expiry.

Article 9: Closure of the company, Branch/factory, distributor

The closure takes place in the following cases:

- In the case of voluntary suspension for whatever reason. In this case he/she shall send a Letter of Request to the related agencies for consideration.
- In the case of violation of the law and a regulation having been issued by official staff ordering the closure.

Article 10: Relocation of a Company, branch or distributor

For relocation of a Company, branch or distributor a letter of request shall be sent to the District Health Office (where the business will be established) to check and receive comment and then to the Provincial Health Office, Capital or Special Zone for detailed consideration and to the Food and Drug Department, Ministry of Health for consideration.

Part IV
QUALITY ASSURANCE OF DRUGS

Article 11: Drugs and medical products which will be distributed and sold in Lao PDR shall be registered according to the requirements of the Food and Drug Department, Ministry of Health.

Article 12: Drug and medical products which have received permission prior to sale in Lao PDRshall be inspected by the Food and Drug inspector at the entry points as formally identified.

Article 13: All drug items which have been registered prior to sale shall be stamped according to the requirement of the Ministry of Health.

Part V
RESTRICTIONS

Article 14: Drugs are special goods for which a company, branch or distributor shall comply strictly with the following restrictions:

1. Individual or organization that have not received permission from the Food and Drug Department, Ministry of Health are prohibited from operating a business concerning drugs and medical products.
2. Import–export and sale of unregistered medicines is prohibited;
3. Sale of medicines without stamp is prohibited;
4. Import-export of unqualified drugs, counterfeit drugs, drugs from improper sources, incorrect packaging (not in accordance with the original packaging and all types of banned drug are prohibited.
5. Transfer the rights or sale pharmacy license is prohibited.
6. Export, import, transit or sale of narcotic-psychotropic substances, precursors is prohibited without permission of the Ministry of Health.

Part VI
Reward and Measures

Article 15: Reward for outstanding persons

Individuals or organisations that conduct business and apply regulations accordingly shall receive an award as appropriate form the related agencies.

Article 16: Measures against violators.

Individuals or organisations who have violated this regulation shall be educated, warned, fined and punished according to the seriousness of the case as follows:

1. If any article of this regulation was violated such as: operate a business before having received a permit, the validity of the permit, operate a business in a prohibited location according to article 14.1, import–export unregistered drugs, drugs without permit for import, not having imported drugs and medical products after getting permission shall receive a warning and stop their activity.
2. If an individual transferred rights, sold, rented the pharmacy license according to article 14.5 shall be warned and stoped the activity.
3. If an individual imports–exports, transits, sells or uses narcotics, precursors without the permission of the Ministry of Health shall receive a warning or not permitted to operate the business. If the case is serious, article 135 of the Criminal Law revised edition and order no. 14 /PM, dated 28/11/2000 shall apply.
4. For the first violation such as: smuggling import or export of drugs, sale of bad quality drugs, banned drugs, counterfeit drugs , poisonous drug, psychotropic drugs and drugs over the expiry date, illegal drugs, unqualified drugs, the individual shall be warned,

fined twice the market price of the goods and the goods shall be confiscated and belong to the state.

5. Any individual who has violated article 16.4 for the second time shall be warned, fined four times the market value of the goods, the goods shall be seized or confiscated and shall belong to the state. If the recommendation of the inspector were not followed the business shall temporarily be closed for the period of one year.
6. If any person violated article 16.4 for the third time he shall receive a warning, shall be fined six times the market price of the goods, the goods shall be confiscated, the business shall be closed permanently or the case shall be pursued according to the law and regulations.

Article 17: In the case of the most serious cases that can harm or put in danger clients such as disablement, death, even if the violation is for the first, second or third time, the company shall be closed permanently and the owner of the company shall be prosecuted according to the laws and regulations..

Part VII
Implementation

Article 18: The Food and Drug Department is empowered to issue in detail and implement this regulation with the cooperation of the Provincial Health Offices, Capital or Special Zones and other related sectors in the whole country.

All regulations, requirements, orders previously issued that are in contradiction with this regulation shall be terminated.

Article 19: This regulation is effective from the date of signature.

Minister of Health

Dr Ponemek DALALOY