Lao People's Democratic Republic

Peace Independence Democracy Unity Prosperity

Ministry of Health No 1442/MoH

Regulation on Establishment
On Export-Import Drug and Medical Products Company

- Reference to: Drug and Medical Products Law No 01/NA, dated 08 April 2000;
- Reference to: Law on Business No 03/94/NA, dated 18/7/1994;
- Reference to: Prime Minister Decree on Ministry of Health Organization and Action No 020/PM, dated 19/03/99;
- Reference to: Prime Minister Decree on the Adoption on National Drug Policy of Lao PDR No 49/PMO, dated 13 March 1993;
- Reference to: Food and Drug Department Request Proposal and Study of Macro Departments and Leaders of Ministry of Health;

Minister of Ministry of Health issues Regulation on Establishment on Export-Import Drug and Medical Products Company as follows:

Group I
General Provisions

Article 1: Objective and Target.

1.1. Objective : To manage on the action of Export-Import Drug and Medical Products Company in accordance with rules of Law and specific technical principles, in order to ensure the service on Drug and Medical Products having the good quality, efficacy, fairness for consumers and at the same time is to encourage the business owners running their businesses effectively.

1.2. Target:

To protect the consumers in receiving drug and medical products having good quality, efficacy and safety only, contributing to the Development and Construction of the Nation .

Article 2: Definition

2.1. **Drug**: is any substance or any composition of substances which are active or inactive, used for the prevention and treatment of diseases, which assist in testing and diagnosing diseases, relieving pain, modifying, improving, supporting, protecting or changing the body functions, rehabilitating physical and mental health.

2.2. **Modern Drug or Western Drug**: is any drug product which is manufactured in accordance with its formula and accurate scientific technique, which is packed and labeled, including the active modified ingredients to appropriately use for human.

2.3. **Traditional medicine**: Traditional medicine is drug deriving from herb, tree, mineral, animal manufactured, packed and labeled, including the nature and dosage of its active ingredients are not yet identified by current scientific, but it should be approved by Ministry of Health.

Health sector shall organize the survey and list trees, herbs, minerals and animals considering as traditional medicine to be controlled.

2.4. **Medical product**: Medical product is any material or substance using in medical, including any product using in general society, which could be dangerous for human health such as: medical food supplement, cosmetic, chemical products using in the household, daily used medical product, according to attached table of contents.

2.5. **Whole sale**: Whole sale on drug and medical products is the sale in bulk in order to be re-sold, meaning that selling in its original packaging. Purchaser is the businessman who re-sales those products to consumers. People who has right to to perform the whole sale is individual who run the export-import company or brand of factory or company or sold agent of company and internal whole seller.

2.6. **Retail sale**: is selling in less amount or quantity, meaning that product shall be sold under the medical prescription or be sold by the patient request, aiming to treat diseases according to the medical prescription only, such as be sold in ampule, tablet, foil or piece……People who has right to perform the retail sale is retail pharmacy, revolving drug fund in hospital, health center and village drug kit.

2.7. **Importation**: is the importation of drug and medical products from abroad, to deliver to local consumers by correctly applying to rules of Law of Lao PDR.

2.8. **Exportation**: is sending goods to be sold by consumer's order in abroad by correctly applying to rules of Law of Lao PDR.

2.9. **Company**: is business unit running the importation, exportation and distribution of drug and medical products which is authorized by Ministry of Health.

2.10. **Branch or sold agent**: is business unit which is representing the mother company or factory to distribute drug or medical products.

Group II
Establishment on Export-Import Company, branch, sold agent on drug and Medical Products

Article 3. Conditions on establishment on Export-Import Company

3.1. Person who aims to run the business on Export-Import on drug and/or medical products in Lao PDR shall apply as follows:

- Individual or juristic person who is Lao citizen or foreigner aiming to establish the Export-Import Company on drug and/or medical products shall implement Law on Business, Law on Labor, Law on Accounting, Law on Drug and Medical Products and regulations of Ministry of Health.

3.1. Shall have Lao pharmacist with Diploma or Certificate on Pharmaceutical Sciences Education issued by related Educational Institution in both local and international institutions and receiving the Pharmaceutical Practice Authorization Certificate from Ministry of Health and shall have professional working experiences at least 5 years. If he/she is still the government officer, he/she has to have official permission.

3.3. Shall be person with no sanction period or no position escape or no discipline penalty due to pharmaceutical professional mistakes or narcotic trading.

3.4. Shall have good health with no mental health diseases and non-addiction.

Article 4. Conditions and necessary facilities

4.1. Individual or juristic person running the business on Export-Import drug and medical products is only an organization specifically carrying out on Export-Import drug and medical products, no mixing with other goods.

4.2. Every item of imported drug and medical product shall be inspected, analyzed (if necessary) and certified its quality by Ministry of Health.

4.3. The introduction sheet on every item of drug and medical product use shall be in Lao language.

4.4. The Export-Import drug and medical product company, which will be authorized to establish, is pending on its balanced plan by region, population and proportion of exported products more than the imported ones, which will be prioritized in its consideration.

4.5. Place for running the business on Export-Import, company/factory branch and sold agent shall be clean, with the space in at least over 20 m2; it should be specific room, no mixing with residence and other non-drug goods for selling and shall have standard warehouse system to store drug product such as ventilation system, lighting, temperature and humidity measurement equipment and others…..

4.6. Board of Company, Company Branch, Sold Agent.

Shall have a specific board and bearing clearly written information as followed:

- Name of company, above in Lao language and bottom in international language.
- Address, Tel. number, business registration number with picture of snake surrounding vase Logo.
- Board is in green color with white letter, wide in 80-100 cm, large in 200-250 cm, in general Lao letter shall be large than international one and approved by Provincial/Capital Health Department or Special Zone and information and culture sector.

4.7. Equipment to be used in the company, company/factory branch, sold agent.

Place for running the business shall completely have equipment using for storage and distribution as follows:

- Glass shelves to store and display selling drug.
- Special shelves to store the toxic substances and narcotic drug, such shelves shall be robust and locked with keys
- Refrigerator with temperature not more than 4 degree Celsius with Equipment measuring temperature, in case there are drug to be stored in cool temperature such as vaccine, suppository drug and others.
- Appropriate containers and packaging materials are available and in compliance with rules on the quality assurance and other necessary equipment.
- Having standard warehouse in accordance with Good Warehouse Practice.

4.8. Documents permanently available in company, branch of factory/company, sold Agent.

Company, branch of factory/company, sold agent shall have permanent documents such as:

- Pharmaceutical Professional License Certificate and Business License Certificate shall be hung at the visible position.
- Laws, Decrees, Regulations, rules and Notices on drug products
- Drug use Manual.
- Book on inspection monitoring of inspectors.
- List of drug available at store: in, out, remaining with expiry date and lot numbers.
- Copies of Bills on drug purchasing, drug selling in accordance with rules.
- Completed sets of invoices and drug delivery from the store.
- List of special controlled drug, narcotic drug and psychotropic drug and others.

4.9. Company, Branch of factory/company, sold agent shall have its own organization structure, at least it should be composed: Director and Directorate, essential

Divisions/units such as: accountant, warehouse keeper, marketing officer and others …….and shall have its internal specific rule.

4.10. For the establishment on local whole sale company, it shall be applied the same Conditions as Export-Import one, in exception items 4.2 in article 4 of this regulation.

Article 5. **Application documents applying to request for License or License Renewal for professional staff**

5.1. Documents to be submitted for license request for professional staff:

1. Application form on Pharmaceutical Professional Staff License.
2. Personal history certificate with photo (not more than 1 year).
3. Health Check Certificate (not more than 3 months).
4. Current Address Certificate (not more than 3 months).
5. Photo in size 3x4 in a number of 3 (not more than 1 year).
6. Diploma/Certificate.
7. Penalty Declaration Certificate.
8. Government Official Release Certificate or Appointment Certificate, in case State- Owned Company.
9. Location map of company, branch of company/factory, sold agent.
10. Facility Inspection Record issued by related officer before license release.

5.2. Application documents applying to request for License Renewal for Professional Staff.

1. Former Pharmaceutical Professional License Certificate nearly expired date or already expired date.
2. Application form on Pharmaceutical Professional Staff License Renewal request.
3. Health Check Certificate (not more than 3 months).
4. Current Address Certificate with photo (not more than 3 months).
5. Photo in size 3x4 in a number of 03 (not more than 1 year).
6. Facility Inspection Record for release of renewal license.

Article 6. Establishment of Sold Agent of Factory, Company or their branch in provinces.

Factory or Company shall apply as follows:

Compile documents in accordance with No 5.1 or 5.2 of this regulation and then submit such application form to Ministry of Health through Provincial/Capital or Special zone Health Department (Food and Drug Section) where sold agent or branch will be located.

Article 7. **The person who has right to perform the whole sale on drug and/or medical products**

Just only the export-import company, branch of company or branch of factory, sold agent, pharmaceutical factory and whole sale company have the right to carry out the whole selling on drug and medical products.

Group III
License authorization on Pharmaceutical Profession and Closing the business running

Article 8. License authorization on Pharmaceutical Profession

The person who intending to carry out the business on export-import, branch or sold agent on drug and medical products shall compile documents submitting to District Health Bureau (where the business will be located) to inspect its location and make comments and

then re-send to Provincial/Capital Health Department or Special zone to attentively and strictly consider and then forward them to Food and Drug Department, Ministry of Health to be considered in issuing the Professional License. (Time frame for its study /consideration on all documents within health sector is about 60 days).

In case of foreign investment, it shall be applied documents according to Regulation of Chairman of Board of Investment and International Cooperation and Local Investment on considering rule on foreign investment in Lao PDR No 013/BOI, dated 27/2/2002.

The Pharmaceutical Profession License has its validity in 01 year, 03 months before its expiry date, it shall be applied for its renewal.

Article 9. Closing Company, Branch of company/factory, Sold agent.

The closing shall be performed in cases as follows:

- Person who volunteer or intend to temporarily close his/her business due to any reason, shall submit the application form to related sector to be considered.
- In case, violation against rules of Law, the Government Official has the authorization to close it.

Article 10. Company, Branch and Sold agent Moving Location

The request on moving location of company, branch or sold agent shall apply the application form to District Health Bureau, Provincial/Capital Food and Drug Sub-division or Special zone to make comments and then submit to Food and Drug Department to be considered.

Group IV
The Quality Assurance

Article 11. Drug and/or medical products which will be imported for distribution in Lao PDR, shall be registered in accordance with rules in Food and Drug Department, Ministry of Health.

Article 12. The authorized drug and/or medical products, before its importation to distribute in Lao PDR, shall be inspected by Food and Drug Inspectors at the official entry point.

Article 13. Every registered drug, before distributing, shall be correctly stamped in accordance with determined rules of Ministry of Health.

Group V
Prohibition

Article 14. Due to drug is considered as a special good, company, branch or sold agent shall strictly apply against the prohibition as follows:

14.1. It is prohibited to any individual, juristic person or organization running the business on drug and medical products without permission from Food and Drug Department, Ministry of Health.

14.2. It is prohibited to import-export or distribute un-registered drug, un-authorized drug.

14.3. It is prohibited to distribute drug with no stamp.

14.4. It is prohibited to import and distribute the sub-standard drug, counterfeited drug, drug deriving from incorrect source of origin, incorrect packed drug (not in its original pack unit), expired drug, decomposed drug, drug specimen, all kind of officially prohibited drug.

14.5. It is prohibited to give or sale the Pharmaceutical Professional License to others

14.6. It is prohibited to export, import, re-export or distribute the narcotic drug, psychotropic drug, raw chemical for narcotic drug without permission from Ministry of Health.

Group VI
Rewards and measures towards violators

Article 15. Rewards

Individuals or juristic person correctly run business in accordance with the rules shall be appropriately rewarded from related sectors.

Article 16. Measures towards violators

The person who is violating this regulation shall be educated, warned, fined and punished depending on the gravity of violations as follows:

16.1. If there is infringe or violation against any article of this regulation such as: running business before receiving the license, expired license, running business in prohibited places mentioning in article 14.1 of this regulation, import-export unregistered drug, prohibited imported drug, do not import drug and medical products after officially establishing the company, shall be warned and stopped the business running.

16.2. If any individual give, sale, rent the pharmaceutical profession License mentioning in article 14.5 of this regulation shall be warned and stopped the business running.

16.3. If there is importation-exportation, re-exportation or distribution and using the narcotic drug, raw chemical for narcotic dug which are not authorized by Ministry of Health, shall be warned or not authorized the business running. If severe case, it shall be applied the article 135 of revised Criminal Law and Order No 14/PMO, dated 28/11/2000.

16.4. If there is 1st further violation such as: incorrect importation or exportation of drug, selling of counterfeited drug, non-qualified drug, prohibited drug, sub-standard drug shall be warned, fined in two fold of market goods value and seized or confiscated to be state -owned.

16.5. If any individual violates in 2nd time against article 16.4 of this regulation, shall be warned, fined in forth fold of market goods value, seized or confiscated such products to be state-owned. If refusing to apply the staff advice, it shall be temporally closed the business in period of 01 year.

16.6. If any individual violated in 3rd time against article 16.4 of this regulation, it shall be fined in sixth fold of market goods value, confiscated goods, permanently closed the business or be prosecuted according to the Law.

Article 17. In severe case, damage to the consumer health such as disability, mortality, despite of the 1st, 2nd or 3rd violation, the owner of company shall permanently close the business and at the same time he/she will be prosecuted to the court.

Group VII
Implementation

Article 18. The Food and Drug Department shall promulgate in detail and implement this regulation, in cooperation with Provincial/Capital or Special Zone Health Departments and other related sectors in the whole country.

All regulations, directives which have been previously promulgated and contradicted against to the provisions of this regulation, shall be entirely cancelled.

Article 19. This regulation shall get into force from the date of signature.

Vientiane Capital, date 13 August 2003
Signed and sealed

Dr PoneMek DALALOY