Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity

Ministry of Health No 1820/MoH
Vientiane Capital, dated: 25 August 2017

Unofficial Translation

Regulation on Business Establishment for Medicine and Medical Product Company

- Reference to Law on Drugs and Medical Products (Amended) No 07/NA, dated 21 December 2011;
- Reference to Law on Business (Amended) No 46/NA, dated 26 December 2013;
- Reference to Prime Minister Decree on Ministry of Health Organization and Action No 178/PM, dated 05 April 2012;
- Reference to Proposal of Food and Drug Department , Review of Departments and Leaders of Ministry of Health.

Minister of Ministry of Health issues Regulation on Business Establishment for Medicine and Medical Product Company as follows:

Part I
General Provisions

Article 1 Objective, Target and Scope

1.1. Objective

This regulation determines the principles, rules, measures in order to manage business running on drugs or/and medical products is in compliance with the laws, rules and specific regulations.

1.2. Target

To ensure business running on drugs and medical products comply with laws, rules, and principles of Lao, and regional and international regulations.

To ensure consumers have access to quality, efficacy, safety medicines and fair to everyone, and to contribute to the development of the country.

Article 2 Scope

The scope of this regulation is used for individuals or organizations that manage or operate export-import and distribution business on drugs and medical products in Lao PDR.

Article 3 Definition of terms

1. **Drug** refers to any substance or any composition of substances, active or inactive which is used for the prevention and treatment of diseases, in testing and diagnosing diseases, relieving pain, modifying, improving, supporting, protecting or changing the body functions and rehabilitating physical and mental health.
2. **Medical product** refers to any material or substance which is used in medical services, including any product using in general society such as: medical devices, health supplements, cosmetics, controlled chemical products and household hazardous ..
3. **Company** refers to a business entity which imports, exports and distributes drugs and medical products that is authorized by the Ministry of Health.
4. **Exportation** refers to the delivery of drugs and medical products to foreign countries in compliance with the laws and regulations of Lao PDR.
5. **Importation** refers to the importation of drugs and medical products from abroad in compliance with the laws of Lao PDR.
6. **Branch or sales agent** refers to a business unit representing a parent company or factory for the sale of drugs and medical products supplied by a parent company or factory that is representing for.
7. **Wholesales** refers to sales in large quantities to domestic wholesale companies, pharmacies, public and private health facilities that are authorized according to the regulations. Wholesaler is a person or entity that runs export-import company or factory branch, company branch or sales agent of company and domestic wholesale company.
8. **Domestic wholesale company** refers to companies selling drug and medical products which are purchased from domestic manufacturing factories or Legally imported from export-import companies for the purpose of selling to retail customers.
9. **Retailing** refers to the direct sales to patients under the prescription of a physician, the doctor's recommendation or patient's need such as: ampoules, tablets, blisters and others.
10. **Repackaging** refers to changing the original packaging form to make it more appropriate for distribution or packaging improvement of drugs and medical products in compliance with the requirements on pharmaceuticals of Lao PDR.

Part II
Conditions of Establishment on Export-Import Companies, Branches, domestic wholesale companies on Drugs and Medical Products

Article 4 Personal Conditions for establishment of Export-Import Companies

Those who intend to export- import drugs and medical products in Lao PDR shall comply with the following requirements**:**

4.1. Individuals or juristic persons who are Lao citizen or foreigner aiming to establish the Export-Import Company on drugs and/or medical products shall implement Law on Business, Law on Labor, Law on Accounting, Law on

Drugs and Medical Products and all related regulations of Ministry of Health.

4.2. Shall have Lao pharmacist with Diploma or Certificate on Pharmaceutical Sciences Education issued by related Educational Institutions both domestic and international, and receive the Pharmaceutical Practice Authorization Certificate from Ministry of Health, and shall have professional working experiences of at least 5 years with the certification from relevant organization, if he/she is still a government officer, he/she has to have official permission.

4.3. Those companies who run business on medical products shall comply in addition to this regulation other related specific regulations particularly business on cosmetics.

4.4. Shall be a person with no sanction period or no position escape or no discipline penalty due to pharmaceutical professional misconduct or narcotic trading.

4.5. Shall have good health with no mental health diseases and no addiction to narcotics.

4.6. For certification of professional service, if the person is employed by the government he/she shall be certified by that relevant state agency. In case of serving in private sector, he/she shall becertified not only by that private sector but also recognized by relevant central provincial government authority.

Article 5 Personnel conditions for establishment of sales agents

Those who intend to operate sales agent on drugs and /or medical products in Lao PDR shall comply with the following requirements:

5.1. Individuals or legal entities shall be Lao or foreigners who intend to establish sales agent on drugs and /or medical products shall comply with business law, labor laws, accounting laws, law on drugs and medical products, and relevant regulations and rules on drugs and medical products of the Ministry of Health.

5.2. For a company's branch on medical products, it shall comply with the conditions set out in the specific regulations.

5.3. Shall have a pharmacist or pharmacist assistant (middle level pharmacist) who is a Lao citizen and has a diploma or certificate of completion on pharmaceutical professional issued by the relevant educational institution both domestic and international, and licensed by the Ministry of Health, and shall have experience serving pharmaceutical professional more than **4** years. If the person who still serves the government needs to be formally appointed.

5.4. Shall be a person with no sanction period or no position escape or no discipline penalty due to pharmaceutical professional misconduct or narcotic trading.

5.5. Shall have good health with no mental health diseases and no-addiction to narcotics.

5.6. For certification of professional service, if the person is employed by the government he/she shall be certified by that relevant state agency. In case of serving in private sector, he/she shall be certified not only by that private sector but also recognized by relevant central and provincial government authority.

Article 6 Personnel conditions for establishment of domestic wholesale companies

Those who intend to operate wholesale business on drugs and /or medical products in Lao PDR shall comply with the following requirements:

6.1. Individuals or legal entities Lao or foreigners who intend to establish domestic wholesale companies on drugs and /or medical products shall comply with business law, labor laws, accounting laws, law on drugs and medical products, relevant regulations and rules on drugs and medical products of the Ministry of Health.

6.2. A domestic wholesale company on drugs and medical products shall comply with the conditions set out in the specific regulations.

6.3. Shall have a pharmacist or pharmacist assistant (middle level pharmacist) who is a Lao citizen, and has a diploma or certificate of completion on pharmaceutical professional issued by the relevant educational institution both domestic and international, and authorized by the Ministry of Health, and shall have experience serving on pharmaceutical professional more than **4** years. If the person who still serves for the government needs to be formally appointed.

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

6.5. Shall have good health with no mental health diseases and no addiction to narcotics.

6.6. For certification of professional service, if the person is employed by the government he/she shall be certified by that relevant state agency. In case of serving in private sector, he/she shall be certified not only by that private sector but also recognized by relevant central provincial government authority. .

Article 7 Conditions of running business

7.1. Individual or legal entities running the business on Export-Import of drugs and medical products is an organization eligible to operate business specifically on Export-Import of drugs and medical products and no mixing with other goods.

7.2. Drugs and medical products which are to be sold shall contain packaging and drug and medical product leaflets in accordance with the principles and Lao Language contents must be available.

Article 8 Condition of location

Place for running business on Export-Import, company/factory branch and sales agent shall be clean, with the space of at least over 20 m^2; it should be specific room, no mixing with residence and other non-drugs and medical products.

Article 9 Condition of warehouse and storage

9.1. Import-export company on drugs and medical products

9.1.1. Shall have a place which is clean and appropriate and according to the standards the place shall be at least 6 meters wide, 12 meters long and the suitable height to store goods. Inside the warehouse, there shall be office for warehouse staff, inventory management systems, animal and insect protection systems, cooling systems, lighting, temperature and moisture monitoring equipment installed in the warehouse with regular monitoring and others...

9.1.2. Inside the warehouse, there are essential equipment such as pallets, shelves, cabinets, lifting and moving equipment, tools to track inventory and compliance with good storage practice principles, which are specified in regulations of Good Whole Selling Practice (GWP).

9.1.3. If there is no room to arrange in the warehouse, it is necessary to include the equipment required to manage the warehouse outside and to comply with Good Storage Practice Principle (GSP).

9.1.4. In case of selling narcotic, psychotropic drugs, they should be stored in a proper specific cabinet and a lock to protect those drugs.

9.1.5. Shall have a refrigerator with a maximum temperature of 2-8 degrees Celsius and a thermometer, in case of drugs to be kept in a cool place, such as: suppository and others.

9.1.6. In case of changes in the packaging to comply with the rules, the company must have the appropriate tools, appropriate packing equipment, other equipment which is deemed necessary, and follow the proper packaging principles which approved from relevant authorities to ensure the quality of the products.

9.1.7. If there is a business concern with vaccines and biological products, the operator must have the conditions to store and ship, maintain quality of those products in accordance with regional and international standards, such as a storage cabinet for each type of vaccine according to the requirements, including the vehicles with conditions to store during shipment.

9.2. For branch or company representative and factory branch

Branch or company representative and factory branch shall comply with the following storage conditions:

9.2.1. Shall have a place which is clean and appropriate and according to the standards the place shall be at least 4 meters wide, 8 meters long and the suitable height to store goods.

9.2.2. Shall have inventory management systems, animal and insect protection systems, cooling systems, lighting, temperature and moisture monitoring equipment installed in the warehouse and regular monitoring and others...

9.2.3. Shall have essential equipment such as pallets, shelves, cabinets, lifting and moving equipment, tools to track inventory, and in compliance with good storage practice principles, which are specified in regulations of Good Whole Selling Practice (GWP).

9.2.4. In case of selling narcotic, psychotropic drugs, they shall be stored in a proper specific cabinet and a lock to protect those drugs.

9.2.5. Shall have a refrigerator with a maximum temperature of 2-8 degrees celsius and a thermometer, in case of drugs to be kept in a cool place, such as:, suppository and others.

9.3. For domestic wholesale company on drugs and medical products

Wholesale company on drugs and medical products shall comply with the following storage conditions:

9.3.1. Shall have a place which is clean and appropriate and according to the standards the place shall be at least 4 meters wide, 8 meters long and the suitable height to store goods.

9.3.2. Shall have inventory systems, animal and insect protection systems, cooling systems, lighting, temperature and moisture monitoring equipment installed in the warehouse and regular monitoring and others...

9.3.3. Shall have essential equipment such as pallets, shelves, cabinets, lifting and moving equipment, tools to track inventory and in compliance with good storage practice principles, which are specified in regulations of Good Whole Selling Practice (GWP).

9.3.4. Shall have a refrigerator with a maximum temperature of 2-8 degrees Celsius with a thermometer in case of drugs to be kept in a cool place, such as: vaccines, suppository and others.

Article 10 Condition of shipment

The pharmaceutical export-import company, company branch, factory and domestic wholesale company on drugs and medical products shall comply with the principles of Good Distribution Practice (GDP). The vehicles and equipment used in shipment shall be complied with the principles of Good Storage Practice (GSP) of drugs and medical products, and taking into consideration the conditions for monitoring temperature, humidity and sunlight to ensure the quality of drugs and medical products during shipment.

Article 11 Board of Company, Company Branch, Sales Agent

The pharmaceutical export-import company, company branch, factory and-domestic wholesale company on drugs and medical products shall have a clear board with white letter on the green background , and the following written information:

- The company's name in Lao language is on the top with the English language underneath.
- Address, Telephone number, business registration number, and a logo of a white circle with green snake surrounding black vase in it.
- The background of the board is green with the size of at least 80-100cm wide and 200-250 cm long; the Lao letter shall be generally larger than the English language and the board shall be checked by the provincial, capital health department, and the information and culture sector.
- Company, branch or sales agent of company/pharmaceutical factory and domestic wholesale company can make larger board than the required standard, but the size of the board shall not be exceeded 2-3 times the above-mentioned standard. It shall be beautiful, and in compliance with the rules and principles of pharmaceutical and medical products; it shall not be shown as a sign in advertising of the product, and shall be authorized by Drug Regulatory Authority and other relevant authorities.

Article 12 Required documents in the business of pharmaceutical and medical products

The drug and medical products export-import company, factory, company branch, domestic wholesale company shall have the following documents:

- Pharmaceutical Professional License Certificate and Business License Certificate shall be hung at the visible position. There shall be an Organizational Structure consisting of director and manager, some necessary divisions such as financial accounting, inventory management , pharmacist, administrative, marketing and others. There shall be a detailed list of staff and specific rule for business
- Standard Operating Procedure (SOPs) for each of the tasks related to the operation of company, branch and agent.
- Legal documents such as laws, decrees, rules, regulations and notifications about drugs and medical products.
- Drug use Manual.
- Book on inspection monitoring of inspectors, and a report of each conducted inspection.

- List of drugs and medical products which have been submitted for registration/notification and list of registered/notified drugs and medical products.
- List of suppliers for drugs and medical products with detailed addresses, related person in charge, and contract for business partnership.
- List of available drugs and medical products in storage: incoming, outgoing and remaining quantities with expiry dates, lot numbers and sources of supply.
- Adverse Drug Reaction Report Form.
- Copies of Bills on purchasing and selling of drugs and medical products which shall be in compliance with the rules in pharmaceuticals, , and they shall be kept at least 5 years.
- Copies of all related documents for exported, imported and distributed drugs and medical products shall be kept at least 5 years
- There shall be regular reports on business activity and lists of exported, imported and distributed drugs and medical products every 6 months.
- List of special controlled drugs, narcotic drugs and psychotropic drugs and others.

Article 13 Business operations on drugs and medical products

- Business operation on drug and medical products shall comply with the following requirements:

1. Drug and medical product import-export company shall import and export only drugs and medical products which they registered or notified by themselves, and if they need to import and export the products of other company, they shall have the letter of authorization to be a representative agent.
2. Drug and medical product import-export company which makes package improvement or repackaging of drug and medical products shall have facilities and equipment standards, a system of quality assurance and safety for consumers, and shall be inspected by authorized personnel in order to comply with drug and medical product regulations.
3. Drug and medical product import-export, domestic wholesale companies shall have a contract of supply to ensure quality of drugs and medical product during distribution, a list of supply source and clients with clear information such as name of company, address, authorized person, telephone, fax, email and website (if available).
4. For selling of drugs and medical products to customers, it shall use the bill or shipping bill with full information in compliance with technical principles of the Food and Drug Department such as: brand name, INN name, batch number and expired date.
5. Drug and medical product import-export company shall have Quality Assurance and Pharmacovigilance systems which are the responsibilities of the company.
6. Drug and medical product import-export company shall be responsible to recall the products which have problems in the quality and safety after the market authorization.
7. Drug and medical product Company, branch, sales agent and domestic wholesale company shall have rule for business operation, and appropriate design clothing.

Part III
Application for License

Article 14. Application documents to request for License

Documents to be submitted for license request for professional staff:

1. Application form on Pharmaceutical Professional Staff License.
2. Personal history certificate (CV) 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. 3 Photos in size 3x4 (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, sales agent.
10. Letter of authorization of the company for whom to be hold a license.
11. Facility Inspection Record issued by relevant authority before license release.
12. An overview of how the company operates on drugs and medical products including providing details of products and source of suppliers of drugs and medical products.

Article 15 Application documents to request for License Renewal for Professional Staff.

Documents to be submitted for license renewal for professional staff:

1. Application form on Pharmaceutical Professional Staff License Renewal request.
2. Former Pharmaceutical Professional License Certificate nearly expired or already expired.
3. Health Check Certificate (not more than 3 months).
4. Current Address Certificate with photo (not more than 3 months).
5. 3 Photos in size 3x4 (not more than 1 year).
6. Penalty Declaration Certificate.
7. Report of company, branch, sales agent on business operation for the last year , and copies of 3 import records over the past year.
8. Facility Inspection Record for release of renewal license.

Article 16 Application documents to request for changing location

Drug and medical product export-import company, branch or sales agent and domestic wholesale company which needs to change location must notify the relevant authorities, follow the steps and shall apply the request with the following documents:

1. The request shall be indicated the reasons for changing the location from the company, branch with signatures of the directors and pharmacist who hold the pharmaceutical professional license.
2. The approved Pharmaceutical Professional License Certificate (original document).
3. Location map of company, branch of company/factory, sales agent of the new location where to move to.
4. Facility Inspection Record issued by relevant authority before approval.

Article 17 Application request and documents submission for establishment of export-import company, branch or sales agent and domestic wholesale company

Steps to request for new establishment, renewal of Pharmaceutical Professional License Certificate and changing new location of drug and medical product export-import company, branch or sales agent and domestic wholesale company shall be processed as following:

1. The documents identified in the Article 14 (new establishment) shall be submitted to the Food and Drug Department (Ministry of Health) through Food and Drug District Unit, Provincial Food and Drug Division, Provincial Health Department-Capital Health Department where the company, branch or sales agent and domestic wholesale company is located.
2. The documents shall be thoroughly evaluated, approved, signed and sealed from each authority level before submitting the request documents to each authority level following the steps.
3. Prior to submitting the request to the Food and Drug Department, the Ministry of Health, the Provincial Health Department shall have a transcript letter together with the list of the appropriate amount, and the documents shall be completed in accordance with the requirement of every business type.

Part IV
License authorization license renewal on Pharmaceutical Profession and closing the business

Article 18 License authorization on Pharmaceutical Profession

18.1. The person who intends to carry out the business on export-import, branch or sales agent on drugs and medical products shall be technical assessed at each level after getting business approval from relevant authority. The required documents shall be submitted through District Health Bureau (where the business will be located), provincial Health Department and Capital Health Department and the Food and Drug Department, and then submit to the Ministry of Health for its consideration in issuing the Professional License. (Time frame for its review /consideration on all documents within health sector is about 90 days).

18.2. For renewal of Pharmaceutical Professional License Certificate, the Food and Drug Department is responsible for approving after the documents already submitted by relevant district, provincial and municipal level.

In case of foreign investment, it shall be complied with law and regulations on Foreign Investment.

The Pharmaceutical Profession License has its validity for 2 years; 3 months before its expiry date, it shall be applied for its renewal.

Article 19 Shipping, Copying and Filling of pharmaceutical professional license

1. The pharmaceutical professional license approved by the MoH is available in two original certificates; one original certificate including all related application documents shall be kept at Food and Drug Department, and another one shall be kept by the authorized company. For provincial-capital and district authority level, a copy of certificate shall be kept for monitoring.

2. The pharmaceutical professional license certificates including introduction guidelines for business operation and notices for service fee will be shipphed to provincial food and drug departments for further delivering to authorized companies.

3. The pharmaceutical professional license certificates of those authorized companies shall be kept in business running venues and shall not be laminated.

Article 20 Closing of Company, Branch of company/factory, Sales agent

The closing shall be performed in cases as follows:

- Person who volunteers or intends to temporarily close his/her business due to any reason, shall submit the application form to the concerned sector for its consideration.
- In case of violation against the Law and Regulations, the official Government has the authority to close it.

Article 10 Moving Location for Company, Branch and Sales agent

The application form to request on moving location of company, branch or sales agent shall be submitted with the documents identified in article 16 through District Health Bureau, Provincial/Capital Food and Drug for assessment and comments, and then submit to Food and Drug Department for consideration. There will be no moving location if it is not necessary, and moving location shall be notified 3 months in advance to the relevant organization.

Part V
Rights and Responsibilities of Business owner for Drug and Medical Product Export-Import Company, Branch of company/factory, Sales agent

Article 22 Rights of business owner for Drug and Medical Product Export-Import Company

Business owner for Drug and Medical Product Export-Import Company has the following rights:

1. The right to contact and cooperate with a mother company who is the sources of providing Drugs and Medical Products from abroad in accordance with the agreed scope.
2. The right to be a representative to register/notify drug and medical products to the relevant authorities.
3. The right to import, export, monitor distribution point of any registered/notified drug and medical product which belongs to the company or authorized by a mother company under the regulations.
4. The right to do re-packaging or labelling on drugs and medical products which is authorized by drug authority.
5. The right to assign other companies to be a representative to import drugs and medical products that they registered or assign other companies to continue to register/notify any drugs and medical products that they owned or they are assigned from mother company.
6. The right to receive the assignment from other companies to be a representative to import any kind of drugs and medical products which have been already registered/notified by other companies, or the right to receive

assignment from other companies to continue to register/notify any kind of drugs and medical products as a representative with an official letter provided by those company.

7. The right to participate in drug and medical product bidding or prices comparison to supply drugs and medical products to public and private health networks both inside and outside countries according to the related regulations.
8. The right to request for advertising and disseminating drug information according to the regulations.

Article 23 Responsibilities of business owner for Drug and Medical Product Export-Import Company

Responsibilities of Drug and Medical Product of Export-Import Company are

1. To take responsibilities in implementing the law on Drugs and Medical Products in order to ensure the supply of quality, efficacy and safety drugs and medical products to consumers.
2. To facilitate and cooperate with relevant regulatory authorities.
3. To cooperate in monitoring, checking, pharmaceutical drug and medical product analysis in order to ensure the quality of drugs and medical products during the supply chain.
4. To receive and disseminate necessary information of drugs and medical products to the public, and to contribute to the monitoring of Adverse Drug Reaction (ADR).
5. The pharmacist shall be present in the company and provide services according to the code of ethics.
6. To renew Pharmaceutical Professional Licenses or other related licenses as required.
7. To pay the fees according to the regulations.
8. To request licenses from other sectors for the establishment of drugs and medical product export-import companies.
9. To participate as a member of the Drug and Medical Product Business Association which is established and officially recognized according to the regulations.

Article 24 Rights of drug and medical product branch of company /factory

Drug and medical product branch of company/factory has the following rights:

1. The right to contact and cooperate with a mother companies who are sources of providing Drugs and Medical Products abroad in accordance with the agreed scope.
2. The right to be a representative to sell only the registered/notified drugs and medical products (except narcotic, vaccine) that the mother company assigned to sell within the branch, and have the right to monitor every kind of medicines that are under their responsibilities.

Article 25 Responsibilities of drug and medical product branch of company /factory

Drug and medical product company branch/factory has the following roles:

1. To take responsibility in implementing the law on Drug and Medical Products in order to ensure supply of quality, efficacy and safety drugs and medical products to consumers.
2. To facilitate and cooperate with relevant regulatory authorities.
3. To cooperate in monitoring, checking, pharmaceutical drug and medical product analysis in order to ensure the quality of drugs and medical products during the supply chain.

4. To receive and disseminate necessary information of drugs and medical products to the public, and contribute to the monitoring of Adverse Drug Reaction (ADR).
5. The pharmacist shall be present in the company and provide services according to the code of ethics.
6. To renew Pharmaceutical Professional Licenses or other related licenses as required.
7. To pay the fees according to the regulations.
8. To request licenses from other sectors for the establishment of drug and medical product company branch/factory.
9. To participate as a member of the Drug and Medical Product Business Association which is established and officially recognized according to the regulations.

Article 26 Rights of Drug and Medical Domestic Wholesale Company

Rights of Drug and Medical Domestic Wholesale Company are following:

1. The right to contact and cooperate with companies that they contract to be representatives in supplying Drugs and Medical Products within country in accordance with the agreed scope.
2. The right to procure and supply registered/notified drugs and medical products (except narcotic, vaccine) which are correctly produced and imported by factories, export-import companies and branches .

Article 27 Responsibility of Drug and Medical Domestic Wholesale Company

Roles of Drug and Medical Domestic Wholesale Company are following:

1. To take responsibility in implementing the law on Drug and Medical Products in order to ensure supply of quality, efficacy and safety drugs and medical products to consumers.
2. To facilitate and cooperate with relevant regulatory authorities.
3. To cooperate in monitoring, checking, pharmaceutical drug and medical product analysis in order to ensure the quality of drugs and medical products during the supply chain.
4. To receive and disseminate necessary information of drugs and medical products to the public, and contribute to the monitoring of Adverse Drug Reaction (ADR).
5. The pharmacist shall be present in the company and provide services according to the code of ethics.
6. To renew Pharmaceutical Professional Licenses or other related licenses as required.
7. To pay the fees according to the regulations.
8. To request licenses from other sectors for the establishment of drug and medical product company branch/factory.
9. To participate as a member of the Drug and Medical Product Business Association which is established and officially recognized according to the regulations.

Part VI
Quality Assurance

Article 28 Drugs and/or medical products which will be imported for distribution in Lao PDR

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

Article 29 Importation inspection

The registered drugs 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 30 Quality Control Testing

All registered drugs and medical products which are distributed in Lao PDR shall pass quality control testing, and shall be officially certified by Ministry of Health or regional or international accredited regulatory authority.

Article 31 Registration number

All registered medicines before distribution, the number of registration issued by the Food and Drug Department, Ministry of Health shall be printed on its labels and containers.

Article 32 Stamping hologram

All registered medicines before distribution, if there are conditions for stamping of the holograms which are designed and controlled by the company, the company shall notify and request for approval to the Food and Drug Department, Ministry of Health.

Part VII
Prohibitions

Article 33 Company, branch or sales agent shall strictly apply against the prohibitions as follows:

1. It is prohibited to any individual, juristic person or organization running business on drugs and medical products without permission from Food and Drug Department, Ministry of Health.
2. It is prohibited to drug and medical product company, branch, and domestic wholesale company operating business without presence of technical staff who hold Pharmaceutical Professional License.
3. It is prohibited to import-export or distribute un-registered/un-notified drugs and un-authorized drugs which are not premeitted by relevant regulatory authorities.
4. It is prohibited to domestic wholesale company for export-import of drugs and medical products without a contract with the company who is a supplier.
5. It is prohibited to import and distribute sub-standard and counterfeit drugs and medical products, drugs and medical products derived from incorrect source of origin, incorrect packaging (not in its original packing unit), expired drugs, decomposed drugs, drug specimen and all kind of officially prohibited drugs.
6. It is prohibited to sell drugs and medical products in the place where is not approved by relevant regulatory authorities.
7. It is prohibited to rent, transfer or sell the Pharmaceutical Professional License to others.
8. It is prohibited to export, import, re-export or distribute narcotic drugs, psychotropic drugs, raw chemical for narcotic drugs without permission from Ministry of Health.

Part VIII
Rewards and measures towards violators

Article 34 Rewards

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

Article 35 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:

35.1. Shall be warned and recorded by the regulatory authority of Food and Drug Department if there is an offence or breach of Article 33 of this regulation.

35.2. Shall be fined 500,000 Kip and recorded by the regulatory authority of Food and Drug Department, if there is an offence or breach of Article 33.1, 33.2, 33.4, 33.6, 33.7 of this regulation for the 2nd time.

35.3. Shall be fined 2 times of the regular fine charge and recorded by the regulatory authority of Food and Drug Department, if there is an offence or breach of Article 33.1, 33.2, 33.4, 33.6, 33.7 of this regulation for the 3rd time, and business shall be temporary closed.

35.4. Shall be fined 3 times of the regular fine charge and recorded by the regulatory authority of Food and Drug Department, if there is an offence or breach of Article 33.1, 33.2, 33.4, 33.6, 33.7 of this regulation for the 4th time, and business shall be permanently closed.

35.5. Shall be fined 1 time of the value of the goods found, warned and recorded by the regulatory authority of Food and Drug Department, if there is an offence or breach of Article 33.3 and 33.5 of this regulation for the 2nd time. If there is an offence or breach of Article 33.8 of this regulation for the 2nd time, it shall be warned or not be allowed to run the business. If the case is severe, Article 89 and 144 of the Criminal Law (Amended) No. 12/NA, dated 09 November 2005 shall be applied.

3.5.6. Shall be fined 3 times of the valued of goods found and recorded by the Food and Drug Department, if there is an offence or breach Article 33.3 and 33.5 of this regulation for the 3rd time, and business shall be temporally closed.

3.5.7. Shall be fined 6 times of the valued found and recorded by the Food and Drug Department, if there is an offence or breach Article 33.3 and 33.5 of this regulation for the 4th time, and business shall be permanently closed.

35.8. The Pharmaceutical Professional License expired more than 2-3 years, write a wow and pay 3 times of the fee.

35.9. The Pharmaceutical Professional License expired more than 4 years, renewal shall not be considered, and business shall be permanently closed.

35.10. After the company has been authorized, but there is no business running within 2 years, the first time it shall be warned and approved the Pharmaceutical Professional License, and the second time, it shall not be considered for renewal.

Article 37 Seriously dangerous cases cause disability, death to consumers, despite the first, second or third offenses, the company must be permanently closed, and at the same time it shall be prosecuted to the court.

Part IX
Implementation

Article 37 The Food and Drug Department shall promulgate in detail and implement this regulation, in cooperation with Provincial/Capital Health Departments and other related sectors in the whole country.
This regulation replaces the regulation on Establishment of Drug and Medical Product Export-Import Company No 1442/MOH, dated 13 August 2003. All regulations, directives which have been previously promulgated and contradicted against to the provisions of this regulation, shall be entirely cancelled.

Article 38 This regulation shall get into force from the date of signature.

Minister

Ass. Prof. Dr. Bounkong Syhavong