LAO PEOPLE'S DEMOCRATIC REPUBLIC
Peace Independence Democracy Unity Prosperity

National Assembly No. 07/NA
Vientiane Capital, 21 December 2011

LAW ON
DRUGS AND MEDICAL PRODUCTS
(Amended)

Part I

General Provisions

Article 1 Objective

This Law determines the principles, rules and measures relating to the use, management, monitor and inspection of drugs and medical products with the aims to ensure the supply of drugs and medical products of good quality, efficacy, safety with appropriate prices in order to prevent diseases and to provide treatment to all people for their good health, contributing to the national protection and development.

Article 2 Drug and Medical Product

A drug is any substances, or any composite substances with active and non-active ingredients, which is used for the prevention and treatment of diseases, identification and diagnosis of diseases, relief of pain, modification, improvement, support, supplement, cure or change of body functions, human physical and mental health rehabilitation. Drug consists of modern drug and traditional medicine.

A medical product is any things or any substances which is used for medical purposes, including any product of general use in society, such as medical devices, health supplements, cosmetics, controlled chemicals and dangerous chemicals for household use.

Article 3 Definition of terms

Terms used in this Law shall have the following meanings:

1. **Modern drug** refers to any finished pharmaceutical products which are processed, packaged and labeled in accordance with scientific formulae and methodology, and in which the active ingredients have been modified in a manner suitable to the use of human beings ;
2. **Traditional medicine** refers to a medical product derived from medicinal plants, trees, animals, minerals and/or parts of such medicinal plants, trees and animals which are processed, packaged and labeled, of which the characteristics and effective dose either have or have not yet been scientifically proven, but shall have been approved by the Ministry of Health;
3. **Counterfeit drugs** and medical products refer to any modern drugs, traditional medicines, medicinal natural resources, cosmetics, health supplement, medical devices, controlled chemicals and dangerous chemicals which are intentionally falsified or imitated or copied from the products which are produced, distributed and legally registered, for the trade benefit purpose ;
4. **Sub-standard drug** refers to a modern drug or traditional medicine, the composition of which is not consistent with its registered formulae ;
5. **Deteriorate drug** refers to a modern drug or traditional medicine, of which the physical or chemical characteristics have changed from its original forms before its expiration;
6. **New drug** refer to modern drug or traditional medicine which is newly produced or imported and which has never been sold, distributed and used in the Lao PDR;
7. **Medicinal natural resources** refer to any substances derived from natural resources, such as plants, trees, minerals and animals, which can be used as raw materials for the production of drugs or health supplement;
8. **Health Supplement** refers to any products derived from plants, trees, minerals, animals and various vitamins through processing, packaging and labeling, which are mainly used for supplement of certain body cellules and not for disease prevention and treatment;
9. **Medical device** refers to medical tools in the form of utensils, machines, materials in the liquid and solid form, gas and light, using for diagnosis or any similar materials to be used as prescribed by their producers and which may be used solely or in combination with other materials, for one or more time;
10. **Cosmetic product** refers to any substance or processed product to be used for smearing, massaging, rubbing, spraying on any parts of human body (skin, hair, tooth, nail, lip, mouth) for the cleanness, perfume and beauty;
11. **Dangerous chemical** refers to substance or toxic or dangerous substance components which have harmful effects to human beings, animals and environment, which to be used for the prevention, elimination or control of biting animals, termites and various insects in the household buildings, including chemicals using for sterilization, bactericide and for cleaning premises, clothes and other commodities;
12. **Controlled chemical** refers to chemical precursor and reserved chemical which is under the control of the Ministry of Health;
13. **Pharmacist** refer to a person who has completed pharmaceutical specialization and obtained at least a bachelor degree;

14. **List of essential drugs** refer to a list of essential drugs for disease prevention and treatment and for health care of all people. The drugs on the list shall be available in all time and at all levels of health facilities, based on the real situation of the disease outreach and economic conditions of the country. Most of the essential drugs are single ingredient with generic name;
15. **Generic name** refers to a name of medical products or active ingredients officially recognized by the World Health Organization which are worldwide used and no copyright owner;
16. **Business unit** refers to pharmaceutical manufacturer, export-import company, distribution branch, domestic wholesale company and retail pharmacy of drugs and medical products.

Article 4 Policy on Drugs and Medical Products Activities

The State promotes and encourages all people to access to drug and medical product affairs through the use of medicinal resource potential and encourages all economic sector, both domestic and foreign sector, to invest in cultivating, growing, protecting, conserving, exploiting, purchasing, researching, analyzing, testing, processing of semi-finished and finished drugs and medical products in good quality and standard for domestic use, substitution of import and for export, for creation favorable conditions for recruitment of employees and appropriated funding of such activities,

The State promotes the integration of the use between modern drugs and traditional medicines effectively and safely in disease prevention and treatment and encourages the integration, use and development of traditional medicines in the heath service system.

Article 5 Principles of Drug and Medical Product Activities

The drug and medical product activities shall be carried out in compliance with the main principles as follows:

1. Produce the drugs and medical products in accordance with the standards;
2. Ensure the quality, effectiveness, safety and appropriated prices for the supply and storage of drug and medical products;
3. Use of drugs and medical products rationally, in conformity with the medical principles and physician prescription;
4. Produce and use of drugs and medical products in junction with protection of environment and ensure the sustainability of medicinal natural resources.

Article 6 Scope of Application

This Law applies to individuals, legal entities or organizations that live and carries out drugs and medical products activities in the Lao PDR only.

Article 7 Internal Cooperation

The State contacts and cooperates with foreign countries, regional and international organizations on drug and medical product activities through exchange of experiences, information, science, technology, trainings, staff capacity building, assistance and other cooperation.

Part II

List and Classification of Drugs and Medical Products

Article 8 List of Drugs and Medical Products

The Ministry of Health is in charge of determination of the list of drugs and medical products which shall be produced, exported, imported, distributed, used and shall not be used in the Lao PDR.

Article 9 Classification of Drugs

In the Lao PDR, drugs are classified into the following types:

1. Drugs distributed, sold and used under medical' s prescription;
2. Drugs distributed, sold and used under a pharmacist's control;
3. Drugs generally sold to public without any medical's prescription;
4. Drugs for household use;
5. Toxic, narcotic and dangerous drugs as determined and listed by the Ministry of Health.

Article 10 Drugs in Possession

Drugs are allowed to be in possession in the following cases:

1. Drugs used for medical treatment by physicians, dentists or obstetricians who are permitted to use such drugs for medical treatment;
2. Drugs permitted for any individual use by patients;
3. Drugs for individual use when travelling;
4. Non-narcotic traditional drugs;
5. Drugs for household use.

Article 11 (New) Classification of Medical Device

Medical devices are classified into the following types:

1. Type A - Low risk, such as: rubber belt, cotton, non woven swab, wound plasters and others;
2. Type B - Low to medium risk, such as: neo-natal suction equipment, surgical gloves, gastro-catheter and others;
3. Type C - Medium to high risk, such as: endoscopic surgical equipment, anesthesia equipment, peritoneal dialysis equipment;
4. Type D - High risk, such as: cardio-logical catheter, craniotomy surgical equipment and others.

Part III

Drug and Medical Product Business

Section I

The management of Drug and Medical Product Business

Article 12 The management of Drug and Medical Product Business

Any individual or organization wishing to conduct a business relating to cultivation, growing, exploitation, production, storage, distribution, sale, export and import of drugs and medical products shall obtain prior approval and technically permission from the Ministry of Health and authorization to establish an enterprise as provided for in the relevant laws.

Article 13 Registration of Drugs and Medical Products

The drugs and medical products which shall be used, trafficked and distributed in the Lao PDR shall be subject to prior registration with the Department of Food and Drugs of the Ministry of Health.

Before allowing the registration of the drugs and medical products, the Department of Food and Drug of the Ministry of Health shall consider and proceed in accordance to the procedures, conditions, and regional and international standards requirements in order to ensure the quality, efficacy and safety.

The persons who are entitled to register the drugs and medical products shall be such pharmaceutical factories and companies operating the business on drugs and medical products and obtaining the authorization from the health sector.

The procedures of drug and medical product registration are determined in a specific regulation.

Article 14 Conditions for Business on Production, Export, Import and Wholesale of Drugs and Medical Products

In addition to the conditions stipulated in the Law on Enterprises, any individuals or organizations wishing to run the business on production, export, import and wholesale of drugs and medical products shall be subject to the following conditions:

1. Have a pharmacist with at least five years of experiences;
2. Have never been sentenced for the offenses relating to drugs or narcotic drugs or medical products;
3. Have an ethic on drugs and business;
4. Have personnel with knowledge and capacity;
5. Have a good health, no mental defects or communicable diseases;
6. Have measures on safety and environment protection;
7. Have an appropriate premises, necessary facilities, standardized warehouse and transportation vehicles.

For manufacturer, production and laboratory facilities with complete equipments shall be additionally required.

Article 15 Production of Drugs and Medical Products

Before proceeding to any production of drugs and medical products, the relevant enterprise shall submit an application for the permission to conduct a production tests together with the formulae, labels and production procedures to the Department of Food and Drug of the Ministry of Health in accordance with the procedure on drug and medical product registration and shall comply with the principles on the good manufacturing practices of drugs and medical products, which are approved by the Ministry of Health.

Article 16 Export and Import of Drugs and Medical Products

The drugs and medical products imported for distribution in the Lao PDR shall be subject to registration or notification with the Department of Food and Drug of the Ministry of Health.

The export and import of drugs and medical products shall be first subject to inspection by the health sector.

Article 17 Wholesale of Drugs and Medical products

The wholesale of drugs and medical products shall only be conducted by the authorized business units, such as: drugs and medical products production factories, factory distributor agencies, export-import companies and their branches, domestic wholesale companies.

Article 18 Retail of Drugs and Medical Products

The sale at retail of drugs and medical products shall be conducted by authorized retail pharmacies only.

The conditions and procedures of drugs and medical products retail business operation are determined in a specific regulation.

Section 2

Advertisement of Drugs and Medical Products

Article 19 Advertisement

The advertisement of the drugs and medical products can only be conducted after it has been authorized by the health sector.

Article 20 Conformity of Advertisement

The advertisement shall be accurately in conformity with the quality of the drugs and medical products; and shall be in consistent with such advertisement contents, forms and places authorized by the health sector.

Section 3

Prices of Drugs and Medical Products

Article 21 Pricing

The pricing of drugs and medical products shall be rational based on the regulated market mechanism and under the control of the health sector and other relevant State organizations in order to allow all people in the society to be able to use the drugs and medical products for disease prevention and treatment.

Article 22 Price Control

The health sector and other relevant State organizations have the duty to control the price of the drugs and medical products in order to maintain the prices at appropriate level, specifically in the cases of disasters and disease outreach.

Retailers of drugs and medical products, including the clinics and private hospitals shall show the prices in accordance with the State controlled prices.

Part IV

Supply, Acceptance of Donation and Intellectual Property

Section 1

Supply of Drugs and Medical Products

Article 23 Supply of Drugs and Medical Products

The supply of drugs and medical products shall ensure their quality, efficacy, safety, standards, appropriate prices, and drugs shall be in conformity with the list of essential drugs with generic name and registered in the Lao PDR, by using existing budget and resources appropriately to ensure cost-effectiveness and transparency.

Article 24 Procurement of Drugs and Medical Products

The procurement of drugs and medical products shall be complied with the State procurement principles based on the quantification of the needs from the grassroots and in consistent with the drugs and medical products list issued by the health sector.

Article 25 Budget Provision

The State shall be responsible to provide appropriate budget for the procurement of necessary and essential drugs and medical products.

Article 26 (New) Storage and Destruction

The health sector is responsible for determining the storage conditions of the drugs and medical products in order to ensure the quality and good conditions of the products and also responsible for determining the conditions for destruction of drugs and medical products in order to avoid harmful effects to health and environment.

Section 2

Acceptance of Donation of Drugs and Medical Products

Article 27 Acceptance of Donation of Drugs and Medical Products

The drugs and medical products that are donated from domestic and international organizations can be imported into the Lao PDR only if their quality is ensured, and such imported products shall meet the internal need, and shall be permitted by the health sector.

Article 28 (New) Sectors Accepted the Donation of Drugs and Medical Products

The hospitals or health facilities and relevant sectors that have accepted the donation of drugs and medical products shall collaborate with the relevant health sector before using or distributing of such products in order to be in accordance with the principles and objectives of the donation.

Section 3

Intellectual Property

Article 29 (New) Protection of Intellectual Property

The State protects and keeps the secret information of those persons who have duly registered their drugs and medical products in accordance with this Law and the Law on Intellectual Property, Agreements and Treaties of which the Lao PDR is a Party.

Article 30(New) Rights of Import and Production of Intellectual Property-related Drugs and Medical Products

The State shall have the right to import and produce the intellectual property-related drugs and medical products in case of necessity for the use for the disease prevention and treatment, but shall not for commercial purposes, for instance, in case of epidemic.

Part V

Clinical Trial Research

Article 31 Clinical Trial Research

The clinical trial of drugs or medical products is the test of the drugs and medical products on animals or human beings in order to prove their effectiveness and safety for the users.

The clinical trial of drugs or medical products can be conducted if only it is authorized by the health sector.

Article 32 Report of the Results from the Clinical Trial Research

The results from the clinical trial of drugs or medical products in the Lao PDR shall be reported to health sector and other relevant sectors.

In the case that harmful effects to health are found, the result shall be reported immediately to health sector and other relevant sectors in order to officially remedy or terminate such trial.

Part VI

Toxicology Information Centre and Collection of Adverse Effects of Drugs and Medical Products

Article 33 Toxicology Information Centre

The Toxicology Information Centre shall be established and shall have the duty to analyze, provide information, disseminate and advise the health technicians and various organizations throughout the country, on the preventive measures and solutions in case of toxicity occurring from drugs, chemicals and other substances, including the adverse effects of the medical products,.

Article 34 Collection of Adverse Effects of Drugs and Medical Products

In addition to the above mentioned duties in Article 33, the Toxicology Information Centre shall have the duty to collect, assess and disseminate the information on the adverse effects of the drugs and medical products to the health technicians, organizations and multi-ethnic people for their recognition and understanding.

Part VII

Rights and Obligations of Users, and Responsibility of Suppliers of Drugs and Medical Products

Article 35(New) Rights of Users

The users have the main rights as follows:

1. Receive the products with quality and safety for life and for health as desired by the users;
2. Receive clear and complete information on the contents, indications, side effects and the source of drugs and medical products, from the suppliers;
3. Make comments or recommendations on the prices, quality, performances on the service of the drugs and medical products;
4. Complaint the concerned sectors according to the law when received toxics and adverse effects from drugs and medical products.

Article 36(New) Obligations of Users

The users have the main obligations as follows:

1. Use of drugs and medical products by a physician prescription or physician and pharmacist's advice or as determined in the labels;
2. Declare or report on the substandard or/and unsafe drugs and medical products to the relevant sectors;
3. Actively participate in the dissemination on technical information of the drugs and medical products.

Article 37 (New) Responsibilities of Suppliers

The suppliers shall be responsible, by the laws, on any harmful effects to the health of users resulting from the use of poor quality, unsafe drugs and medical products, with inappropriate prices or from false advertisement.

Part VIII

Prohibitions

Article 38(New) Prohibitions for Pharmacists and other Health Technicians

The pharmacists and health technicians are prohibited to act as follow:

1. Give pharmaceutical license to others for use;
2. Produce, sell or provide substandard and unsafe drugs and medical products to others or without physician's prescription;
3. Misuse his/her own power and position and improperly, unlawfully induce others to do so in relation to drugs and medical products, for private gain;
4. Disclose secret information and formulae relating to drugs and medical products without permission;
5. Assign any persons who are not health technicians to sell the drugs and medical products;
6. Have other behaviors which contradict with the laws and regulations on drugs and medical products.

Article 39(New) Prohibitions for Business Operators

The operators of business on drugs and medical products are prohibited to take the following actions:

1. Operate the business in the non-authorized places;
2. Operate the business without officially authorization;
3. Sell drugs which not included in the relevant list, counterfeit drugs, substandard drugs, deteriorated drugs and expired drugs;
4. Advertise over the facts;
5. Transfer or lend the business license or pharmaceutical license;
6. Assign any person who has not officially permission and no knowledge of pharmaceutical principles to sell the drugs instead of his/her place;
7. Operate the business without medical ethics;
8. Have other behaviors which contradict with the laws and regulations on drugs and medical products.

Article 40(New) Prohibitions for Users

The users are prohibited to take the following actions:

1. Buy the drugs and medical products without physician's prescription if such drugs and medical products require physician prescription;
2. Use drugs and medical products by themselves without physician's prescription or without following the physician's prescription and medical instruction or as claimed in the labels as well as the expiry date;
3. Incite and encourage other persons to use the drugs and medical products in contradiction with the technical principles or without any medical diagnosis;
4. Have other behaviors which contradict with the laws and regulations on drugs and medical products.

Part IX

Management and Inspection of Drugs and Medical Products

Article 41 Management and Inspection Organizations of Drugs and Medical Products

The management and inspection organizations of drugs and medical products are comprised of:

1. Food and Drug Management Committee;
2. Ministry of Health;
3. Department of Heath of Province, City;
4. Office of Health of District, Municipality.

In case of necessity, a Technical Committee on Drug and a Pharmaceutical Council may be established to assist in management, inspection, advocacy and

consultation on drugs and medical products, including activities on pharmaceutical profession.

The organization and function of the Food and Drug Management Committee has been indicated in another specific regulation.

Article 42 Rights and Duties of Ministry of Health

To manage and control the activities on drugs and medical products, the Ministry of Health has the following rights and duties:

1. Develop the policies, strategic plans, laws and regulations on the management and control of drugs and medical products to submit to the Government for consideration;
2. Translate the above mentioned policies and strategic plans into its own detailed plans, programs and projects, and provide direction of their implementation;
3. Promote, disseminate the laws and regulations on drugs and medical products and educate people on their implementation;
4. Authorize to create, suspend or cancel the business units of drugs and medical products;
5. Register, determine the list, certify the good manufacturing practice standard, quality analysis and authorize to advertise, export and import the drugs and medical products;
6. Suspend or cancel the decisions, orders, instructions and notices from the organizations under its own responsibility on the management and control of drugs and medical products which are contradicted with the laws and regulations;
7. Consider and handle the propositions made by individuals, legal entities or organizations relating to the quality and standard of the drugs and medical products, and the management and control of drugs and medical products;
8. Coordinate with relevant sectors in management and control of drugs and medical products, including medicinal natural resources in order to render the effective implementation of the laws and regulations on drugs and medical products;
9. Cooperate with foreign countries and international organizations in order to facilitate the management and control of drugs and medical products;
10. Regularly summarize and report the results of the implementation of the drug and medical product activities to the Government;
11. Exercise other rights and perform other duties as provided for in the laws and regulations.

Article 43 Rights and Duties of Provincial, City Health Department

To manage and control drugs and medical products, the Provincial, City Health Departments have the following rights and duties:

1. Translate the policies, strategic plans, laws and regulations on drugs and medical products for implementation;
2. Promote, disseminate the laws and regulations on drugs and medical products and educate people on their implementation, within their responsibilities;

3. Propose the Ministry of Health to establish, suspend or cancel any business units of drugs and medical products in accordance to their roles;
4. Propose to register, to certify the good manufacturing practice standard, quality analysis and to authorize the advertisement, export and import the drugs and medical products, in accordance with their roles;
5. Suspend or cancel the decisions, orders, instructions and notices of the District, municipality Health Offices, which are contradicted with the laws and regulations;
6. Consider and handle the propositions made by individuals, legal entities or organizations relating to the quality and standard of the drugs and medical products, and to the management and control of drugs and medical products in accordance with their roles;
7. Coordinate with relevant sectors at their same level in management and control of drugs and medical products, including medicinal natural resources in order to render the effective implementation of the laws and regulations on drugs and medical products;
8. Cooperate with foreign countries and international organizations in order to facilitate the management and control of drugs and medical products as assigned by the higher levels;
9. Regularly summarize and report the results of the implementation of the drug and medical product activities to the Ministry of Health and the Provincial, City Government Administrations;
10. Exercise other rights and perform other duties as provided for in the laws and regulations.

Article 44 Rights and Duties of District, municipality Health Offices

To manage and control drugs and medical products, the District, municipality Health Offices have the following rights and duties:

1. Effectively implement the policies, strategic plans, laws and regulations on drugs and medical products;
2. Disseminate and educate people on the laws and regulations on drugs and medical products within their responsibilities;
3. Propose the Provincial, City Health Departments to consider the submission to the Ministry of Health for further consideration in relation to the establishment, suspension or cancellation of any business units of drugs and medical products;
4. Consider and handle the propositions made by individuals, legal entities or organizations relating to the quality and standard of the drugs and medical products, and the management and control of drugs and medical products in accordance with their roles;
5. Coordinate with relevant sectors in management and control of drugs and medical products, including medicinal natural resources in order to render the effective implementation of the laws and regulations on drugs and medical products;

6. Regularly summarize and report the results of the implementation of the medicine and medical product activities to the Provincial, City Health Departments and District, Municipality Government Administrations;
7. Exercise other rights and perform other duties as provided for in the laws and regulations.

Article 45 Monitoring and Inspection of Drugs and Medical Products

The monitoring and inspection of drugs and medical products are the monitoring and inspection of the activities relating to cultivation, growing, protection, exploitation, purchase, production, distribution, export, import, wholesale, retail, possession and use of drugs and medical products, including grant-in-aid, clinics, State and private hospitals to be in conformity with the laws and regulations, ethics and justice with the aims to ensure good quality and safe drugs and medical products , which are used rationally and sold at the determined prices.

Article 46 Forms of Inspection

There are three types of inspection of drugs and medical products as follows:

1. Regular inspection;
2. Inspection with prior notification;
3. Emergency inspection.

Regular inspection is an inspection carried out in regular manner in accordance with the fixed plans and time.

Inspection with prior notification is an inspection without included in the fixed plans, conducted when deemed necessary and with an advance notice.

Emergency inspection is an urgent inspection without any prior notification to the targets to be inspected.

In the course of inspection of drugs and medical products, the inspection authorities shall be duly and strictly complied with the laws and regulations.

Part X

Policies towards Persons with Outstanding Achievements and Measures against Violators

Article 47 Policies towards Persons with Outstanding Achievements

Individual, legal entities or organizations with outstanding achievements in implementing of this Law, such as: business operation of drugs and medical products with good quality; manufacturers, companies and model pharmacies shall receive rewards and other policies in accordance with the laws and regulations.

Article 48 Measures against Violators

Individual, legal entities or organizations that violated this Law, including the prohibitions as prescribed in Article 38, 39 and 40, shall be educated, disciplined, fined,

paid the compensation for damage or criminally punished depending on the gravity of their acts.

Part XI

Final Provisions

Article 48 Implementation

The Government of the Lao PDR is responsible for the implementation of this Law.

Article 49 Effectiveness

This Law shall enter into force, for the new contents, after ninety days from the date of the promulgating Decree of the President of the Lao People's Democratic Republic.

This Law replaces the Law on Drugs and Medical Products, No. 01/NA, dated 8 April 2000.

Any provisions and regulations which are contradicted with this Law shall be cancelled.

President of National Assembly

(Signature & Seal)
Pany Yathotou