



LAO PEOPLE'S DEMOCRATIC REPUBLIC  
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

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President's Office

No. 13/PO

**DECREE**  
*of the*  
**PRESIDENT**  
*of the*  
**LAO PEOPLE'S DEMOCRATIC REPUBLIC**

**On the Promulgation of the Law on Drugs and Medical Products**

Pursuant to Chapter 5, Article 53, point 1 of the Constitution of the Lao People's Democratic Republic;

Pursuant to Resolution No. 01/NA, dated 8 April 2000, of the National Assembly of the Lao People's Democratic Republic on the adoption of the Law on Drugs and Medical Products; and

Pursuant to Proposal No. 07/NASC, dated 17 April 2000, of the National Assembly Standing Committee.

**The President of the Lao People's Democratic Republic  
Decrees that:**

**Article 1.** The Law on Drugs and Medical Products is hereby promulgated.

**Article 2.** This decree shall enter into force on the date it is signed.

Vientiane, 22 May 2000  
The President of the Lao People's  
Democratic Republic

*[Seal and Signature]*

Khamtai SIPHANDON



LAO PEOPLE'S DEMOCRATIC REPUBLIC  
PEACE INDEPENDENCE DEMOCRACY UNITY PROSPERITY

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National Assembly

No. 01/NA  
8 April 2000

## **LAW ON DRUGS AND MEDICAL PRODUCTS**

### **Part I General Provisions**

#### **Article 1. Function of the Law on Drugs and Medical Products**

The Law on Drugs and Medical Products defines principles, rules and measures relating to the management of the cultivation, growing, preservation, exploitation, production, export, import, distribution, possession and use of drugs and medical products with the aim to ensure the supply of drugs and medical products that are of good quality, safe and appropriately priced, in order to prevent disease and provide treatment, ensuring the good health of the population.

#### **Article 2. Promotion of Potential Medical Resources**

The State promotes the expansion of potential medical resources through the cultivation, growing, preservation, exploitation, collection-purchase<sup>1</sup>, research, processing and production of modern medicines and traditional medicines for use within the country, for import substitution and for export.

#### **Article 3. Combination between Modern and Traditional Medicines**

The State promotes the wide and increasing production and use of modern medicines in combination with traditional medicines in the prevention of disease and the treatment of the multi-ethnic people.

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<sup>1</sup> The Lao word is a compound word meaning "to collect and purchase medical raw materials from individual growers in order to sell them in bulk". An alternative translation may be "consolidation purchase".

**Article 4. Supply of Drugs and Medical Products**

The supply of drugs and medical products shall ensure quality and safety, be timely, and be at an appropriate price, in order to fulfil the needs of society.

**Article 5. Use of Drugs and Medical Products**

The use of drugs and medical products shall be rational, in compliance with medical principles or under a physician's prescription.

**Article 6. Promotion of Investment**

It is the policy of the State to promote all economic sectors, including domestic and foreign sectors, to invest in the research, cultivation, growing, preservation, production, processing, and export of drugs and medical products with good quality and in compliance with standards.

**Article 7. International Cooperation**

The State opens wide to and supports international cooperation in the field of drugs and medical products through the exchange of experience, training, capacity building, cooperation, and assistance in the area of drugs and medical products.

**Part II  
Drugs and Medical Products  
Listing and Classification of Drugs and Medical Products**

**Chapter 1  
Drugs and Medical Products**

**Article 8. Drugs**

A drug is any substance, or any composite of substances, which may be active or non-active, and which is used for prevention of diseases, treatment, assisting in identifying and diagnosing diseases, relieving pain, modifying, improving, supporting, supplementing, curing or changing body functions, and rehabilitating physical and mental health.

**Article 9. Modern Drugs**

A modern drug is any pharmaceutical product, which is processed in accordance with certain scientific formulae and methods, which is packaged and labelled, and in which the active ingredients have been modified in a manner appropriate for the use of human beings.

**Article 10. Traditional Medicines**

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 establish a list of trees, plants, minerals and animals which are [sources of] traditional medicines, in order to manage them.

**Article 11. Counterfeit Drugs**

A counterfeit drug is any modern or traditional medicine that is a fake or is an imitation of a drug that is produced, distributed and legally registered.

**Article 12. Non-standard Drugs**

A non-standard drug is any modern or traditional medicine, the composition of which is consistent with the drug's registered formula.

**Article 13. Deteriorated Drugs**

A deteriorated drug is any modern or traditional medicine, the quality of which has deteriorated due to expiration or other impacts.

**Article 14. New Drugs**

A new drug is any modern or traditional medicine that results in positive effect, whose characteristics are not yet completely defined and mentioned in international medical documents, or that is not yet registered in its country of origin, has been registered for less than five years, or differs in formula, method of use, form and packaging from a drug that has been registered.

**Article 15. Medical Products**

A medical product is any thing or any substance that is used for medical purposes, including any product that is in general use in the society, but that can be harmful to human health, such as food supplements, cosmetics, and others<sup>2</sup>.

**Article 16. Pharmacists**

A pharmacist is a person who has completed a specialisation in pharmacy from a university and obtained at least a bachelor's degree.

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<sup>2</sup> The term "and others" is a literal translation and is not subject to further specificity.

## **Chapter 2**

### **Listing and Classification of Drugs and Medical Products**

#### **Article 17. List of Drugs and Medical Products**

The list of drugs and medical products is a list of the drugs and medical products that are legally permitted for sale and use in the Lao PDR, and a list of the drugs and medical products prohibited in the Lao PDR.<sup>3</sup>

#### **Article 18. Classification of Drugs**

In the Lao PDR, drugs are classified in accordance with their use for medical purposes, as follows:

1. Drugs sold under a physician's prescription;
2. Drugs sold under a pharmacist's control;
3. Drugs freely sold to the public without any medical prescription;
4. Toxic drugs.

Toxic drugs comprise:

- a. Toxic drugs;<sup>4</sup>
- b. Narcotic drugs that are specifically used for medical purposes in accordance with regulations on the control of narcotic drugs;
- c. Dangerous drugs.

All types of toxic drugs used for the purpose of treatment mentioned in the list established by the Ministry of Health shall be used and sold under medical prescription.

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<sup>3</sup> It is unclear whether there are one or two lists. See general Explanatory Notes, paragraph 6 (ii). Because the Lao language does not require nouns to signify whether they are singular or plural, it is not possible to resolve this provision.

<sup>4</sup> The translators are aware of the circularity of this listing.

**Part III**  
**The Management of Businesses Relating to**  
**Drugs and Medical Products**

**Chapter 1**  
**Conduct of Business Relating to**  
**Drugs and Medical Products**

**Article 19. Conduct of Business Relating to Drugs and Medical Products**

Any individual or organisation intending to conduct any business relating to the cultivation, growing, exploitation, production, distribution, sale, export, and import of drugs and medical products shall have an enterprise business license in accordance with the Business Law<sup>5</sup>.

**Article 20. Registration of Drugs and Medical Products**

Drugs and medical products to be sold in the Lao PDR shall be registered with the Ministry of Health and affixed with a stamp at the health sector<sup>6</sup>.

Before proceeding with registration, the Ministry of Health shall check and analyse the drugs and medical products in order to ensure conformity with standards.

**Article 21. Pre-conditions for Conducting Business Relating to Drugs and Medical Products**

In addition to the conditions mentioned in the Business Law, if any individual or organisation intends to conduct any business relating to drugs and certain medical products, its factory shall fulfil the following conditions:

1. Have a pharmacist with at least five years experience;
2. Have facilities necessary to ensure a good standard of drug production, such as laboratories, production facilities, and warehouses meeting standards that are determined by concerned sectors;
3. Have measures for the maintenance of safety and the protection of the environment.

**Article 22. Production of Drugs and Medical Products**

Before producing [any] drugs and medical products, the business enterprise shall submit an application to the Ministry of Health for permission

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<sup>5</sup> This is a reference to an older law which has since been replaced by the Enterprise Law.

<sup>6</sup> The term “sector” is used in many Lao laws to refer to the cluster of government ministries or agencies engaged in a particular activity.

to conduct production tests, together with a list of drugs and medical products, drug formulae, and production processes.

**Article 23. Export and Import of Drugs and Medical Products**

Any individual or organisation intending to export and import drugs and medical products shall, in addition to the conditions mentioned in the Business Law and as specified in the Articles 19 and 20 of this law, satisfy other specific conditions as follow:

1. Have a pharmacist. For the import of drugs and medical products, the pharmacist must be of Lao nationality;
2. Have conditions and necessary facilities to store and transport drugs and medical products in good condition.

Before any drugs and medical products are imported for distribution in the Lao PDR, they shall be registered with the Ministry of Health.

Before any drugs and medical products are exported or imported, they must be inspected by the health sector.

**Article 24. Acceptance of Donations of Drugs and Medical Products**

Drugs and medical products that are donated from abroad can only be imported into the Lao PDR when their quality is ensured and the Ministry of Health has been informed in advance of the objective of the donation and has approved it.

**Article 25. Wholesale of Drugs and Medical Products**

The wholesale of drugs and medical products can only be conducted by legally licensed business enterprises, specifically pharmaceutical and medical product factories, distributors for factories, and import-export companies, including their branches.

**Article 26. Retail Sale of Drugs and Medical Products**

The retail sale of drugs and medical products can only be conducted through legally licensed pharmaceutical stores.

**Article 27. Conditions for Conducting Wholesale Business Relating to Drugs and Medical Products**

Any individual or organisation intending to conduct any wholesale business relating to drugs and medical products must satisfy the following conditions:

1. Be or have a pharmacist;
2. Have no criminal record relating to drugs and narcotic drugs;
3. Have medical and business ethics;

4. Have good health, and no mental or communicable disease.

At the same time, the business must have the facilities necessary to ensure the quality of drugs and medical products such as: standardised warehouses.

**Article 28. Conditions for Conducting Retail Sale Business Relating to Drugs and Medical Products**

Any individual or organisation intending to conduct any retail sale business relating to drugs and medical products must satisfy the following conditions:

1. Be or have a pharmacist, have a diploma of pharmacy, or be a physician authorised by the Ministry of Health;
2. Be a Lao national, or, if a foreign individual or apatrid<sup>7</sup>, must have permanently resided in the Lao PDR for not less than five years;
3. Have medical and business ethics;
4. Have no criminal record relating to drugs and narcotic drugs;
5. Have good health, and no mental or communicable disease.

The retail sale of drugs and medical products must be conducted by<sup>8</sup> a pharmacist, a person with a diploma of pharmacy, or a physician authorised to sell drugs or to control the sale of drugs.

**Article 29. Possession of Drugs**

Possession of drugs is allowed in the following cases:

1. Drugs used for medical treatment by physicians, dentists, or obstetricians that are permitted for such treatment;
2. Drugs permitted for individual use by patients;
3. Drugs for individual use when travelling;
4. Non-narcotic traditional medicines;
5. Drugs mentioned in Article 18, paragraph 3<sup>9</sup> of this law for family use.

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<sup>7</sup> Readers may wish to refer to the Law on Lao Nationality for the distinction between aliens, apatrids (i.e. persons unable to certify their nationality) and foreign individuals.

<sup>8</sup> The literal translation of this term is “must have”.

<sup>9</sup> This is a reference to the third full paragraph in Article 18, not to the item numbered 3 in the first paragraph.

## **Chapter 2 Advertisement of Drugs and Medical Products**

### **Article 30. Advertisement**

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

### **Article 31. Conformity of Advertisement**

The advertisement must accurately state the quality of the drugs and medical products and be consistent with the contents and the form licensed by the health sector.

## **Chapter 3 Price Control of Drugs and Medical Products**

### **Article 32. Pricing**

The pricing of drugs and medical products must be rational and in accordance with the instructions of the health sector and related State organisations in order to allow all people in the society to be able to use drugs and medical products for the prevention of diseases and for treatment.

### **Article 33. Price Control**

The health sector and related State organisations have the duty to control the price of drugs and medical products in order to maintain the price at an appropriate level.

A retailer of drugs and medical products must label the price on the products and strictly follow the pricing guidelines.

## **Part IV Clinical Research Testing**

### **Article 34. Clinical Research Testing**

Clinical research testing of drugs and medical products refers to testing the use of drugs and medical products on human beings in order to prove their effectiveness and safety for consumers.

Clinical research testing of drugs and medical products can be undertaken only after it is licensed by the Ministry of Health.

### **Article 35. Report of the Results of Clinical Research Testing**

The result of any clinical research testing in the Lao PDR must be reported to the Ministry of Health.

In the event of any dangerous effect on human health, [such effect] must be immediately reported to the Ministry of Health in order to immediately modify or cancel such test.

**Part V**  
**Toxicology Information Centre**  
**and the Adverse Effects of Drugs**

**Article 36. Toxicology Information Centre**

The Toxicology Information Centre of the Ministry of Health has the function to conduct research, provide and disseminate information, and give recommendations on preventive measures and solutions in cases of toxicity occurring from drugs, chemicals and other substances to health profession personnel and personnel of different organisations through the country.

**Article 37. Collection of Information on the Adverse Effects of Drugs and Medical Products**

Besides the function provided for in Article 36 above, the Toxicology Information Centre has the duty to collect, assess and disseminate information to organisations and to people on the adverse effects of drugs and medical products that have been registered.

**Part VI**  
**Administration and Inspection of Drugs and Medical Products**

**Article 38. Authority<sup>10</sup> for the Administration and Inspection of Drugs and Medical Products**

The drugs and medical products administration and inspection authority comprises:

1. The administrative committee for food and drugs;
2. The Ministry of Health;
3. Provincial, prefecture and special zone health divisions;
4. District health offices.

At the same time, the Technical Committee on Drugs and the Pharmaceutical Council must be established to assist in the administration and inspection of drugs and medical products, and to administer professional pharmaceutical activities, including giving recommendations and consultation.

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<sup>10</sup> In the Lao language, the word roughly meaning “the entire organisation of responsible governmental agencies” is capable of being translated as any one of the following English words: “organisation”, “agency”, or “authority”. Here, the strong regulatory functions to be exercised by the institution suggested “authority” as the most appropriate translation but the reader should note the other possible meanings.

**Article 39. Primary Right and Duty of the Administration and Inspection Authority for Drugs and Medical Products**

The administration and inspection authority has the primary right and duty in the administration and inspection of trading in drugs and medical products to ensure safety, quality in accordance with defined standards, and proper and strict implementation of the laws and regulations relating to drugs and medical products.

**Article 40. Inspection of Drugs and Medical Products**

The inspection of drugs and medical products is the monitoring of activities relating to cultivation, growing, preservation, exploitation, collection-purchase, production, distribution, export, import, wholesale, retail sale, possession and use of drugs and medical products in the Lao PDR in conformity with laws, regulations, ethics and justice, to ensure that drugs and medical products are of good quality, safe and sold in accordance with the pricing guidelines, including [to ensure] the rational use of drugs and medical products.

**Article 41. Types of Inspection of Drugs and Medical Products**

Inspections of drugs and medical products are divided into three types as follows:

1. Regular inspection;
2. Inspection by advance notice;
3. Emergency inspection.

Regular inspection refers to an inspection performed regularly according to plans and at predetermined times.

Inspection by advance notice refers to an inspection that is not included in the plan and performed when deemed necessary and for which advance notice is given.

Emergency inspection refers to a sudden inspection performed without advance notice to the target persons.

In the course of the inspection of drugs and medical products, the inspection authority must duly and strictly obey the laws and regulations.

**Part VII**  
**Policies towards Persons with Outstanding Achievement**  
**and Measures Against Violators<sup>11</sup>**

**Article 42. Policies towards Persons with Outstanding Achievement**

Individuals or organisations with outstanding achievement in the implementation of this law will receive rewards and various policies as defined by the government.

**Article 43. Measures Against Violators**

Individuals or organisations that violate this law will be re-educated<sup>12</sup>, fined or punished depending on the gravity of their acts.

**Part VIII**  
**Final Provisions**

**Article 44. Implementation**

The government of the Lao People's Democratic Republic is assigned to implement this law.

**Article 45. Effectiveness**

This law shall be effective after ninety days from the date of the promulgating decree of the President of the Lao People's Democratic Republic.

All regulations and provisions that contradict this law are hereby repealed.

Vientiane, 8 April 2000  
President of the National Assembly

*[Seal and Signature]*

Samane VIGNAKET

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<sup>11</sup> The term “policies” is often used as an indirect way of referring to “incentives’ or “privileges” and the term “measures” is often used as an indirect way of referring to “sanctions”.

<sup>12</sup> Here, “re-education” does not mean the same as “re-education without deprivation of liberty” referred to in the Penal Law.