LAO PEOPLE'S DEMOCRATIC REPUBLIC
Peace Independence Democracy Unity Prosperity

Ministry of Health No. 1441/MOH

Regulation Governing Drug Registration

- Based on:
  - The Law on Drugs and Medical Products No. 01/NA, Dated April 8th, 2000
  - The Decree of Prime Minister No. 020/PM, Dated March 9th 1999 on the organization and function of Ministry of Health
  - The Decree of Prime Minister No 49/PM, Dated March 13th 1993 on the adaptation of the National Drug Policy of Lao PDR
- Up on the request of the food and drug department and the consideration of the Macro Departments and the Steering Committee of Ministry of Health.

The Minister of Health hereby issued the regulation on Drug Registration as follows:

Section 1
General Provisions

Article 1: Definitions and explanations of some terminologies used:

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

Remark: The products which are intended to indirectly affect health and to support health, such as, medicinal food supplements and complementary food product consisting of vitamins of adequate strength as a drug, in this case, the consideration of drug regulatory authority (DRA) of the manufacturing countries.

1.2. Counterfeit Drugs: A counterfeit Drug is any modern or traditional medicines, which are fakes, an imitation of a drug product, which is produced, distributed and legally registered.

1.3. New drugs: A new drug is any modern drug or traditional medicines which is effective but its characteristics are not yet completely defined and mentioned in international medical documents, or not registered in its original country, or already registered but less than five years, or differs by its formula, dosage form, indication of the use and packaging from the registered drug.

1.4. Drug formula: A drug formula is a formula containing ingredients for drug preparation including active ingredients, which can be used for the production of any forms of finished medicine ready for use by human and in animals through manufacturing process following the standard of Good Manufacturing Practice (GMP)

1.5. Drug label: Drug labels are documents which give details of the respective drug and are affixed to the containers thereof; i.e. glass bottles, vials ampoules etc. and contain the following details:

- Name of Drug (Trade name and Generic name) dosage form and strength;
- Drug formula and quantity of the active ingredients;

- Package unit;
- Manufactured date and expiry date;
- Lot Number (Lot No), control number and registration number;
- Indication/instructions of the use;
- Precautions and contra[indication;
- In case of dangerous drug or drug using in special areas there shall be the wording “Dangerous Drug”, “For hospital use only” in red letter and also in a red bracket;
- Keeping condition;
- Name and full address of the manufacturing;
- The Contents of the label must be written in Lao and/or English, French.

Article 2: Registration of drug products is the notification of the name and medical formula in writing, which means the disclosure of the substances used in the drug clearly showing the dosage form, the weight, the package unit and the quantity of each substance.

Article 3: Drug registration is for convenience in supervising and controlling of each step of manufacturing process of repackaged drug within country or of imported drugs from other countries and to ensure the distribution of safe, efficacious and good quality drugs thereof for the treatment and prevention of illness.

Article 4: Every drug to be sold in Lao PDR shall have proper registration of drug at the Food and Drug Department (FDD) Ministry of Health.

Section 2
Principles of Drug Registration

Article 5: Registration of drug is in accordance with the National Medicines Policy, the Updated list of Essential Medicines which has already promulgated and the essential medicines list for specific usage in different level of hospitals with official certification by concerning sections.

Article 6: Drug products, which have no need to be registered, are the following:

1. Substances which are drug chemicals or quasi-drug chemicals which are not finished products i.e. chemicals which are raw materials;
2. Traditional medicines without further preparation; no specific package and no indicated formula, for example: roots, stems, bark, buds, leaves, flowers and other parts of plants;
3. Drug manually prepared including both modern drugs and traditional medicines, which are not officially permitted;
4. Drug permitted to be imported into Lao PDR for, analysis, research, donation and use in embassies; the said drugs shall have been registered and permitted for sale by the drug regulatory authorities in the manufacturing or exporting countries, and shall be controlled through the Food and Drug Department of Ministry of Health.

Article 7: Person entitled to apply for drug registration

1. Person legally permitted to manufacture, to import modern and traditional drug for selling in Lao PDR.
2. Manufacturing factories or the parent exporting companies holding proper license of the related countries through a representative which is a licensed local company for importing (Modern Drug or Traditional medicines) or an office of the representative of Mother Company in Lao PDR with the authorization for the performance as agreed by both mentioned parties.
3. Owners of formula of traditional medicines used for prevention and treatment of diseases, who can provide information on safety and efficacy of the drug product.

Section 3
Supporting Documents and Principles for Consideration of Drug Registration

Article 8: Supporting Document:

8.1. For drug locally produced within country:

Individual intends to manufacture drugs shall submit applications for producing drug sample in accordance to the form No.1 (LP1 or ຢຢ1). After the approval for manufacturing of drug sample, the manufacture shall submit the application for registration according to form No. 2 (LP 2 or ຢຢ2) within 3 to 6 months.

8.2. For drugs imported into the country:

Individual/person who intends to import drugs shall submit the application to import drug sample in accordance to the form No.1 (IP1 or ນຂ1). After the approval for manufacturing of drug sample, the manufacture shall submit the application for registration according to form No. 2 (LP 2 or ນຂ2) within 3 to 6 months.

Article 9: Principles for consideration of drug registration.

1. Application for drug registration will be considered only after **Article 5, Article 7 and Article 8** have been fully complied.
2. Application for drug registration will not be considered in the following cases:
   (a) Documents are not completed as prescribed in the application form No. LP1, LP2, IPI, IP2;
   (b) Notification has been given for correction of any errors, but no amendment is made;
   (c) Failure to submit application form LP2 or IP2 for drug registration within 12 months.
   (d) Drug listed in the list of banned drug of Lao PDR.
   (e) Drug withdraw by the manufacturing parent company or the registration of which is revokes;
   (f) New drug according to the definition prescribed in **Article 1.3**;
   (g) Drug with more than three active ingredients except for multi-vitamins and basic essential for body (amino acid, minerals, drug for external use, which is OTC drug and traditional medicines).
   (h) Drug with copied package and copied trade name that has already been registered in Lao PDR.

Article 10: Principles for consideration of drug registration.

- The drug registration committees appointed by the Minister of Health shall decide on the drug registration
- The food and Drug Department has authority to issue the certificate of drug registration for all drugs as prescribed in **Article 5.** For the other drugs that do not meet the condition as prescribed in **Article 5**, shall be considered by the drug registration committees;
- The Period for consideration of the issuance of each certificate of drug registration is within 180 days.
- The Food and Drug Department will issue a registration number and a certificate of drug registration for any drug which is approved for registration, thereof the license shall be entitled to manufacture, and import as well ;
- Any drug, which has never been imported into Laos or new drugs produced for the treatment of serious diseases i.e. AIDS, hepatitis cancer, cardiovascular…may be considered by the following conditions:
  (a) The drug shall be registered in some countries, such as:

- One of European Union Country;
- United States of America;
- Australia and
- Japan

(b) Additional necessary documents can be provided up on request e.g. Toxicology, Pharmacology, Pharmaco-kinetic, Bio-availability and clinical trials.

Article 11: Principles of receiving the application for drug registration

- Receiving application form for drug registration is conducted every Friday.
- The Documents on safety and efficacy with comprehensive information of the study shall be provided for the new drug as defined in **Article 1.3.**
- In the case that drugs are not needed to perform a laboratory test, before issuing the certificate of drug registration, the sample of drugs should be taken in time of importation. In the case of lacking of reference substances for analysis the related drug company should supply the reference substances for analysis the related drug company should supply the reference substance with other related documents.
- The application forms for drug registration shall be the original document with red mark of Food and Drug Department (FDD), and which are available at the Food and Drug Department.
- Other related certificates: if they are the copied documents, they shall be certified by the company to confirm of correctness to the original documents.

Article 12: Code number for drug registration

Registered drug shall be allotted the following number:

- Modern drug produced within the country shall have the following:
  XX (Month) LXX XX (Number)/year A.D
- Traditional drug produced within the country shall have the following:
  XX (Month)LTXXXX (Number)/year A.D
- Modern drug imported shall have the following:
  XX (Month) ixx xx (Number)/year A.D
- Traditional Drug imported shall have the following:
  XX (Month) ITXX XX (Number)/year A.D

For drug allotted with registration numbers, the respective product owners (i.e. manufacturers, importers or exporters sham print the registration number on the labels, boxes, containers, blisters, vials.

For every imported drug if there is no, possibility to print the necessary Lao content on the label, the related importing and distributing company shall prepare the leaflet in Lao version which shall be inserted into all different types of packages before distributing.

Article 13: The right of authorized applicant

For any drug registered in Lao PDR, only the authorized applicant shall be entitled to import that drug.

Section 4
Revocation and Validity of
Certificate of Drug Registration

Article 14: The registration of any drug may be revoked in any of the following events:

1. It is not effective and/or according to the quality standard as registered;
2. It is not safe for the consumers;
3. It is withdraw by the manufacturing parent company;

4. It is included in the list of banned drug of the Lao PDR;
5. No importation of the registered drug during the whole life of the registration certificate.

Article 15: the validity period of each certificate of drug registration is three years from the date of signature. The product owner shall submit application for renewal, not less than ninety days before the expired date, to the Food and Drug Department (FDD), Ministry of Health. Otherwise the registration thereof shall be revoked.

Section 5
Collection of fees

Article 16: The product owner applying for drug registration shall pay the following fees:

- Specific professional service fees, application forms and supporting documents;
- Quality control fees or fee for Post-marketing surveillance;
- Fees for drug registration:
  + Modern drug produced within country 30 US$/1 item;
  + Modern drug imported 100 US$/1 Item;
  + Traditional drug produced within country 15 US$/1 item;
  + Traditional drug imported 50 US$/1 item.

Note: Procedures of the fee collections are the following:

- 50% of the fee for drug registration and 100% of the fees for analysis shall be paid during the second submission of the application (Form No. LP2, IP2).
- The remaining 50% of the fees for drug registration shall be paid up on receipt of the registration certificate
- In the case that application is not approved for drug registration, the owner of drug product could not reclaim for the fees of drug registration.
- Any changing in any point of drug after registration such as: size of package, address of company representative and etc… the application for changing shall be submitted and 5% of the fees for registration shall be paid.

Section 6
Prohibition and Measures against Violations

Article 17: It is prohibited for individual and juristic persons to counterfeit the registered drug formulas, trade names or generic name.

Article 18: Individual and juristic persons not granted permit are prohibited from manufacturing, importing and selling drug without registration at the Food and Drug Department (FDD) Ministry of Health.

Article 19: Any individual and juristic persons violate the provision in **Article 17, 18** of these regulation shall face the following measure:

- First violation: The related products shall be confiscated and warning will be given;
- Second Violation: The related products shall be confiscated and warming will be given and a fine of 100% of the total value of each drug selling will be imposed and the business shall be temporary closed for 1 year.

- Third violation: The related products shall be confiscated, warning will be given and a fine of 200% of the total values of each drug selling in market shall be imposed and the business shall be permanently closed.

Section 7
Enforcement

Article 20: The Food and Drug Department shall be responsible for the strict enforcement of these regulations.

Article 21: All related governmental authorities and private organization shall fully co-operate and comply with these regulations.

Article 22: These Regulations shall be used to replace the regulation No. 613/MOH, Dated 6 April 1995

Article 23: These regulations sham be fully enacted as from date of signature.

Vientiane, 13th August 2003
Minister of Health

Dr. Ponmek DALALOY