Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity

Ministry of Health No169 /MoH
Vientiane Capital, date 25th January 2022

REGULATION
ON TRADITIONAL MEDICINE REGISTRATION

- Reference to Law on Drugs and Medical Products No 07/NA, dated 21 December 2011;
- Reference to Prime Ministerial Decree on National Drug Policy Approval of Lao PDR, No 49/PMO, dated 13 March 1993;
- Reference to Decree on Organization and Action of Ministry of Health No 570/PM, dated 16 September 2021;
- Reference to Proposal Letter from the Food and Drug Department No 520/FDD, dated 17 January 2022.

The Minister agrees:

Section 1
General Provisions

Article 1 Objectives and purposes

This Regulation sets out principles, rules, and management measures to ensure the production, processing, import-export, circulation of traditional medicine in the market and in the health networks to ensure the quality, efficiency and safety in accordance with regional and international standards and regulations.

Article 2 Terms explanation

1 **Traditional medicine**: refers to medicinal product derived from plants, trees, animals, minerals and/or any part of medicinal plants, trees and animals which are used to produce, process into finished traditional medicine in the single and mixed forms with ingredients, strength, dosage according to container size, packaging and labeling, including the conventional traditional medicine and modern traditional medicine, 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.

2 **Traditional medicine formula**: refers to a formula that specify the composition and dosage of medicinal plants, animals, consisting of traditional medicine formula in a single form and traditional medicine formula in a mixed form with a mixture of other substances and modern drugs together as a traditional medicine formula, which is determined in the proportion of daily consumption and duration of use.

3 **Traditional medicine formula in a single form**: refers to traditonal medicine that contains a single medicinal plant, tree or animal species

4 **Traditional medicine formula in a special combination form**: refers to traditional medicine containing formulas from medicinal plants, trees, animals or/and any part of medicinal plants, trees, animals that are medicinal in the form of more than one or more medicines but not in combination with vitamins and minerals.

5 **Traditional medicine formula in combination with other substances**: refers to traditional medicine containing formulas from medicinal plants, trees, animals or/and any part of medicinal plants, trees, animals that are medicinated with vitamins, minerals.

6 **Traditional medicine formula in combination with modern medicine**: refers to traditional medicine containing combination formulas from medicinal plants, trees, animals or/and any part of medicinal plants, trees, animals in combination with modern medicines as specified in the Encyclopedia or certification from scientific research.

7 **Active ingredients:** refers to active substances according to the purpose of traditional medicine.

8 **Dosage form:** refers to forms of traditional medicine product such as: tablet, grain, granule, capsule, fluid, powder, cream, wax, inhalation form and others containing active ingredients in general.

9 **Traditional medicine category:** classified in 2 categories: conventional traditional medicine and developed traditional medicine (modern traditional medicine).

1. **Conventional traditional medicine**: refers to any traditional medicine derived from plants, animals, minerals derived from successional formula and/or have been used traditionally based on basic knowledge of succession or listed in any dictionary of traditional medicine.
2. **Developed traditional medicine (modern traditional medicine)**: refers to any traditional medicine that has been developed for use and that the drug has been modified in terms of formulas, methods of application, modifications of physical and chemical properties from standard traditional formulas, some of which have not yet fully developed, but the development of these properties must be based on scientific proof.

10 **Counterfeit traditional medicine**: refers to any traditional medicine intended to be counterfeit, imitate the registered traditional medicine products, including its formulas, packaging, logos and label contents.

11 **Substandard medicine:** refers to non-standard traditional medicine as registered due to standard conditions in cultivation, harvesting, production, processing, storage do not meet the specified conditions, causing the product to change.

12 **Medicinal resources:** refers to resources derived from nature, including planting, raising, mining, such as plants, trees, animals and minerals to be used as raw materials in production, processing into traditional medicine.

13 **Medicinal raw material:** refers to raw material derived from medicinal resources through planting, raising, excavating, havesting which has undergone the primary processes such as cutting, slicing, drying, extracting, separating the substances and others to produce traditional medicines.

14 **Packaging containers:** refers to materials used to contain and protect traditional medicine products, including the components of the first and/or second packaging. The components of the containers shall be panels, bottles, bogs, tubes or other materials.

15 **Medicinal labels**: refers to all information on traditional medicine products listed in all container sizes.

16 **Types of claims of traditional medicine:** refers to the classification based on the evidence cited for the purpose of use, which is divided into three categories:

1. Low category: is evidence of a claim to traditional, conventional, inheritaged health care.
2. Medium category: is evidence of a claim to traditional, conventional, inheritaged treatment to relieve symptoms or treat diseases or medical conditions according to the principles of traditional medicine (except for diseases that are prohibited).
3. High category: is a scientifically proven claim for treatment to relieve symptoms or treat disease, abnormalies or medical conditions that have been proven by scientific evidence that confirms traditional medicine into the principles that have been scientifically proven.

17 **Product Registration Owner:** refers to individual or legal entities that produce, process, import-export, distribute, which are authorized by Ministry of Health.

18 **Export-import Pharmaceutical Company:** refers to business unit that import, export and distribute traditional medicine, which is authorized by Ministry of Health.

19 **Pharmaceutical Factory:** refers to the place of production of traditional medicine production that meet the requirements of production processes, at least one process of the production to finished products that meets the standard of Good Manufacturing Practice, as well as other relevant standards issued by the Ministry of Health.

20 **Processing room:** refers to the basic facility of traditional medicine production that meets the requirements of production processes, at least one process of the production to finished products that meets the standard of Good Manufacturing Practice, as well as other relevant standards issued by the Ministry of Health.

21 **Sold Agent:** refers to company that has the right to conduct the pharmaceutical distribution business, which is assigned by manufacturer, processor or importing company after registration by giving a written assignment to the consignee to be responsible to the party with responsibility for quality and safety to the product equivalent to a factory, a company assigned to act on their behal.

Article 3 Scope of application

This regulation applies to individuals, legal entities, organizations that manage or conduct the production, processing, import-export, storage and circulation of traditional medicine in Lao PDR.

Section II
Principles of Registration

Article 4 Principles of Registration of Traditional Medicine

The general principle of registration of traditional medicine shall must be in accordance with the National Policy on Medicine, in accordance with the direction of health services, encourage the use of traditional medicine in combination with modern drug, in accordance with with Law on Drugs and Medical Products, Decree on Medicinal natural resources, list of medicinal plants, trees, animals, Official Risk Categorization List by Ministry of Health and Prohibited Plants List.

Article 5 Registration of Traditional Medicine

1. Traditional medicine registration shall indicate the name and formula from the manufacturer, processor and importer in writing, which refers to the display of a list of ingredients used in medicine, as well as clearly indicating the form, weight, packaging unit and packing quantity of each item.
2. The registration shall facilitate the management and inspection which can be controlled in the process of production, processing, domestic packaging or imported from abroad and distribution to be safe, efficient and of standard quality in treating diseases.
3. Traditional medicine distributing in Lao PDR shall be registered with the Food and Drug Department, Ministry of Health.

Article 6 Exemption from Registration of Traditional Medicine

Unregistered traditional medicine are for the following purposes:

- Traditional medicine produced, imported for study, analysis, research.
- Traditional medicine produced, imported for display or donation or as a sample for registration.
- Raw materials used as ingredients in traditional medicine.
- Traditional medicine produced, processed, imported to be used in individual and diplomatic treatment as recommended by a physician.
- Traditional medicine produced or imported for emergency use in the event of an outbreak, but shall be recognized by the Drug Regulatory Authority of the country of manufacture or export and shall be approved by the Food and Drug Department, Ministry of Health.

Article 7 Eligible Applicants

The eligible applicants are individuals, legal entities engaged in the business of manufacturing, processing and export-import pharmaceutical companies licensed by the Ministry of Health to conduct traditional medicine business. Registration application can be submitted directly to the Food and Drug Department, Ministry of Health or electronically.

Section III
Documentation Procedure and Principles of Consideration for Registration

Article 8 Documentation Procedure

Individuals, legal entities intending to apply for registration of traditional medicine shall submit an application form for registration, which consists of 03 steps:

Step 1 Traditional medicine produced, processed domestically is to apply for a sample drug from a traditional medicine manufacturer, processing room, shall submit the application form for sample drug production according to Form 1 (ຢຢພ 1) and include the following attachements:

1. Request letter from product owner 02 sheets
2. Application form 1 (ຢຢພ1) (details on the form) 01 sheet
3. Box, bottle, label of each container 02 sets

Remarks: The list of required documents may change from time to time.

Imported traditional medicine is to submit the application form 1 or (F1) and attach the following documents:

1. Request letter from product owner 02 sheets
2. Application form (F1)(details on the form) 01 sheet
3. Box, bottle, label of each container 02 sets
4. Drug reference documents (Lao/English) 02 sets

Remarks: The list of required documents may change from time to time.

Step 2 After obtaining the form 2 approval, an application for registration in form 2 shall be submitted for domestic traditional medicine (ຢຢພ2) and (F2) for imported traditional medicine and include the following attachments:

1. Request letter from product owner 02 sheets
2. Notice of permission to submit form 2 from the Food and Drug Department 01 sheet
3. Application form (ພຢຢພ2) or (F2) (details on the form) 01 sheet
4. Drug samples for inspection and monitoring of each container (lot number matching with the analysis certificate)

Remarks: The list of required documents may change from time to time.

Step 3 Apply for registration renewal for domestic traditional medicine according to application form 3 (ພນຢພມ3) and (F3) for imported traditional medicine and include the following attachments:

1. Request letter from product owner 02 sheets
2. Application form 3 (ພນຢພມ3) or (F3) (details on the form) 01 sheet
3. Drug samples for inspection and monitoring of each container (lot number matching with the analysis certificate)

Remarks: The list of required documents may change from time to time.

Article 9 Principles of Consideration for Registration

1 Application form for registration of traditional medicine shall be considered only unless article 8 is completely complied with.

2 The list of traditional medicines that are considered to be new ones specified in Article 3, item 3 shall be accompanied by documents confirming their safety and effectiveness by attaching complete information from scientific research studies.

3 Registration of traditional medicine is subject to research by the Drug Registration Committee appointed by the Ministry of Health.

4 The Food and Drug Department, Ministry of Health is the authority issuing the traditional medicine license.

5 The registered approved traditional medicine shall be issued a traditional medicne registration number and certificate, the lisencee then has the right to produce, process and import.

6 The timing of the process of research and consideration prior to the registration of traditional medicine is classified according to the classification of traditional medicne as follows:

1. Step 1: Set a time of 40 days: 30 working days for conventional traditional medince and 40 working days for developed traditional medicine (new traditional medicine).
2. Step 2: Set a time of 80 days: 50 working days for conventional traditional medicine and 80 working days for developed traditional medicine (new traditional medicine).
3. Step 3: Set a time of 40 days: 30 working days for conventional traditional medince and 40 working days for developed traditional medicine (new traditional medicine).

7 After the notice to submit the documents according to step 2, the application should be submitted not later than the period of 3 months, in case of exceeding the specified period, the documents will be received and the fee will be re-charged according to step 1

8 The submission documents for registration re-newal according to step 3 , the application must be submitted 3 months before the expiry date of registration, in

case of exceeding the specified period, the documents will be received and the fee will be re-charged according to step 2.

Article 10 Denial of Registration

1 Incompleted documents mentioning in the application forms ພຍ ພ 1, ພນ ພ 2, ພນ ພ 3, F1 and F2 and F3;

2 The traditional medicne products applied for registration are not as specified;

3 The traditional medicne products applied for registration are traditional medicine that have been removed or withdraw from registration;

4 The traditional medicne products applied for formulae registration with ingredients inconsistent with academic principles, boastful, unbelievable or unsafe to use;

5 The traditional medicne products applied for formulae registration with impolite name, not suitable for good culture or urgly wording for misunderstanding the truth;

6 The traditional medicne with prohibited ingredients of plant, tree, animal, mineral and chemicals based on prohibited list issued by the Ministry of Health and ASEAN and international prohibited plants list;

7 The traditional medicine with imitation characteristic on packaging and trade mark of previous registered traditional medicine.

Article 11 Withdraw the traditional medicine product registration

The registered traditional medicine shall be withdrawn its product registration in following cases:

1 The traditional medicine that has been modified to other purposes such as cosmetic use, narcotic drug, psychotropic medicine or food;

2 The traditional medicine advertising does not in line with determined principles, methodology and conditions;

3 The traditional medicine with no ingredients and property according to its registered formulae or as counterfeited or imitated traditional medicine from standard pharmacopia;

4 Lack of ethic, technical principles;

5 Do not perform the corrective action and do not monitor the safety after the marketing which is related to the efficacy, quality and safety of the product at risk to consumers;

6 The company that owns the product (manufacturer) declared to abolish/ the business was ordered to close;

7 There are regional and international alerts on consumer unsafety.

Article 12 Label

1 The contents determination of a label on container refers to all information on all sizes of container such as latent, bottle, bag, ampule or other things shall have following contents:

- Appropriate product name or tade name;
- Product form;
- Name and strength of active ingredients;
- Instructions for use;
- Indication or use purpose;
- Storage conditions;
- Registration number of manufacturing country;
- Name and address of manufacturer;
- Name and addess of authorized distributor/importer;
- Warning (if any);
- Content size;
- Special instruction;
- Lot or lot number;
- Manufacturing date and expiry date or expiry date only

Mini label: shall inform at least as follows:

- Appropriate product name and trade name;
- Name and quantity of active ingredients;
- Registration number of manufacturing country;
- Lot or lot number;
- Manufacturing date and expiry date or expiry date only

Label of latent / packaging sheet shall inform at leat as follows:

- Appropriate product name and trade name;
- Registration number of manufacturing country;
- Lot or lot number;
- Manufacturing date and expiry date or expiry date only;

The label information shall be in Lao language and English or Lao language and language of manufacturing country, it shall be clear and understainable.

2 The traditional medicine shall not be explained or presented on any label or any labeling with wording, picture or other materials claiming to or direct and indirect deceptive manner to misunderstand or persuade to create a false impression with the nature of the product in any way.

Article 13 Registration Number Code of Traditional Medicine

1 The registered traditional medicine shall have following signs as follows:

- Domestically produced traditional medicine bearing signs XX (month) TL XXXX (number) / year
- Imported traditional medicine bearing signs XX (month) TI XXXX (number) / year

2 For traditional medicine that is already licensed, the product owner such as: manufacturer, processor, importer shall print the registration number on container label or sticker.

3 For imported traditional medicine, if no condition to print the essential contents on label in Lao language, the company responsible for the import shall attach the medication sheet in Lao language on all sizes of box/bottle before the distribution.

Article 14 Variation after Registration:

The variation after registration shall be considered based on the determined variation conditions as follows:

1 Some minor variations "(Minor Variation)" refer to some variations of registered products, which are not affecting to the quality issue of such product such as: character modification, contents of packaging documents and others, but must be acknowledged and approved by the country Drug Management Authority;

2 Some major variation "(Major Variation)" refer to the significant changes related to the registered product, which are changes that affects the quality of product e.g.such as: modifying formulae, changes in some production techniques, change quality control techniques, the study of self-life, change of the production place and others , in the case of imported products, there must be proof of the change approved by the Drug Regulatory Authority of country concerned.

Article 15 Number of drug samples allowed to produce for registration

The drug sample produced for pre-registration which is authorized for sample production, in the lowest batch production package that the factory, processing room can produce.

Article 16 Number of drug samples brought for registration

The number of drug samples to be registered is determined according to the sampling techniques for testing or according to the form of all containers included in the registration.

Article 17 Acceptance of Application for Registration of Traditional Medicine

1 The acceptance of application for registration of traditional medicine steps 1, 2 and 3 (submission of forms 1, 2 and 3) is receiving documents every working day.

2 The application form must be the original with a red stamp, which is available to Food and Drug Department or download the application form on the Food and Drug Department Website.

3 The other documents are attached. If it is a copy, it must be signed and stamped with correct copy of the original from the company factory, processing room.

Article 18 Rights of the Registrant

1 Having exclusive rights to import, produce, process after registration.

2 Having rights to distribute, delegate distribution authority to the export-import company, domestic wholesale company being sole agent the registered drug based on the consent of product owner and obtained written permission from the Food and Drug Department.

Section IV
Cancellation and Validity of Registration Certificate

Article 19 Cancellation of Registered Certificate

The registered traditional medicine shall be cancelled in case the product has any of the following characteristics:

1 Not useful, does not conform to quality standards or do not both as registered;

2 Not safe for users related to the product quality with evidence from the inspector;

3 The company that owns the product (manufacturer) declared abolished / the business was ordered to close;

4 Medicine containing banned plant, tree, animal, mineral and chemical for traditional medicine based on ASEAN prohibitions;

5 Not imported throughout the life of the registration certificate;

6 If do not renew registration after one year.

Article 20 Validity of Certificate of Registration of Traditional Medicine Product

The validity of traditional medicine certificate valids for five years from the date of signing. The registrar must submit an application for renewal to the Food and Drug Department, Ministry of Health according to prescribed form (ພນ.ຢ.ພ 3 and F 3) within 90 days before the expiration date.

Section V
Collection of Fee

Article 21 Collection of Fee, Service Charge and Fee Payment for Traditional Medicine

1 **Collection of Fee and Service Charge**

The product owner who apply for registration must pay for the following fees and service charge for each item:

-Registration fee/renewal fee for domestic modern traditional medicine

1.000.000 Kip/01item/ 05 years

- Registration fee/renewal fee for domestic conventional traditional medicine

500.000 Kip/01item/ 05 years

- Registration fee/renewal fee for imported modern traditional medicine

2.500.000 Kip/01item/ 05 years

- Registration fee/renewal fee for imported conventional traditional medicine 1.500.000 Kip/01 item/ 05 years
- Fee for registration consideration 100.000 Kip/01 item
- Fee for quality analysis is based on actual calculations of the relevant analysis unit identified.
- Amendment fee in the traditional medicine registry 50.000 Kip/01time
- Fee for consideration on minor variation data after registration 100.000 Kip/01 time
- Fee for consideration on major variation data after registration 300.000 Kip/01 time

The above fees and charges are in accordance with the Fees Ordinanceamended time to time.

2 **Payment for Fee and Charge**

- Pay the service fee for consideration study at the time of submission Form 1
- Registration fee is paid 100% when submission Form 2 submission
- Renewal fee is paid 100% when submission Form 3, along with paying for study consideration at the same time.

For the traditional medicine items that are not registered, the owner of prduct can not be refunded.

Section VI
Prohibitions

Article 22 Prohibitions for traditional medicine business operator

1. Individual, legal entity produce, process, import and distribute the traditional medicine without registration at the Food and Drug Department, Ministry of Health;
2. Individual, legal entity falsify formulae under trade name or scientific name of registered traditional medicine;
3. Falsify documents and use fake documents to apply for registration;
4. Produce, process, import and distribute the sub-standard traditional medicine and mix prohibited compounds as prescribed by domestic and international standards;
5. It is prohibited to use the right to impersonate and intimidate employees and staff.
6. It is prohibited to do other acts that violate the rules.

Article 23 Prohibitions for Food and Drug Staff

1. Unfair, biased and illegal work is prohibited;

2. It is prohibited to suppress the registration process, demand bribes, demand compensation, abue the rights and officials duties for personal benefit;
3. It is prohibited to falsify documents and use false documents or disclose confidential information of individual and legal entity and unauthorized organization;
4. It is prohibited to conceal, swap, assist and conspire with traditional medicine business operator who do not meet the quality and safety standards;
5. It is prohibited to do other acts that violate the rules.

Section VII
Policies towards Persons with Outstanding Achievements and Measures against violators

Article 24 Policies towards Persons with Outstanding Achievements

Individual, legal entity or organization with outstanding achievements in contributing to the implementation of the promotion of traditional medicine to be registered before production, import and distribution shall receive rewards or other compensation policies from higher authorities as appropriate.

Article 25 Measures against violators

Individual, legal entity that violate this regulation shall be subject to disciplinary action, warned, educated, disciplined, fined according each time as follows:

1st time: Be warned, educated with record

2nd time: Be warned and fined 100% of the value of traditional medicine sold per item and close the business for one year.

3rd time: Be seized the product, warned and fined 200% of the value of traditional medicine sold per item and permanently close the business.

Section VIII
Final Provisions

Article 26 Implementation

1. It is delegated to the Food and Drug Department to be responsible for the strict implementation of this regulation.
2. All relevant organizations, both public and private, should cooperate and implement well.

Article 27 Effectiveness

This regulation shall enter in force 60 days after the date of signing.

Minister

Signed and sealed

Phd. Dr. Bounfeng Phoummalaysith