| MINISTRY OF HEALTH<br>--- | SOCIALIST REPUBLIC OF VIETNAM<br>Independence - Freedom - Happiness<br>--- |
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Number: 21/2018/TT-BYT *Hanoi, September 12, 2018*



# CIRCULARS

REGULATIONS ON REGISTRATION OF CIRCULATION OF TRADITIONAL MEDICINES AND PHARMACEUTICALS

*Pursuant to Pharmacy Law No. 105/2016/QH13 dated April 6, 2016;*

*Pursuant to Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government detailing a number of articles and measures to implement the Pharmacy Law ;*

*Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government regulating the functions, tasks, powers and organizational structure of the Ministry of Health;*

*At the request of the Director of the Department of Traditional Medicine and Pharmacy Administration,*

*The Minister of Health promulgates a Circular regulating the registration of circulation of traditional drugs and medicinal materials.*

## Chapter I

## GENERAL PROVISIONS

### Article 1. Scope

This Circular stipulates in detail the following contents:

1. Criteria to determine whether traditional drugs are exempt from clinical trials, exempt from some stages of clinical trials, must have stage 4 clinical trials, must have full clinical trials of all stages in Vietnam and data requirements clinical practice to ensure safety and effectiveness as a basis for granting registration for circulation of traditional drugs.

2. Documents and procedures for granting, extending, changing, supplementing and revoking registration certificates for circulation of traditional drugs and medicinal materials.

### Article 2. Subjects of application

1. This Circular applies to the following cases:

a) Traditional medicine;

b) Traditional medicine is prepared in traditional or modern form;

c) Medicinal ingredients on the list of medicinal ingredients that must be registered for circulation issued by the Minister of Health according to the provisions of Article 93 of Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government regulating costs. details a number of articles and measures to implement the Pharmacy Law .

2. This Circular does not apply to the following cases:

a) Traditional drugs specified in Point b, Clause 1, Article 47, Clause 2, Article 60 and Clause 1, Clause 2, Article 70 of the Pharmacy Law ;

b) Medicinal ingredients specified in Clause 2, Article 54 of the Law on Pharmacy and semi-finished medicinal products.

### Article 3. Explanation of terms

In this Circular, the following terms are understood as follows:

1. *Semi-finished medicinal products* are products from medicinal herbs that have gone through one, several or all stages of processing and production, except the final packaging stage.

2. *Ancient medicine (ancient remedy)* is a traditional medicine recorded in books on traditional medicine of Vietnam and China from before the 19th century, including the number of medicinal herbs, the content of each flavor, and the remedy. Preparation method, effects, indications, route of administration, dosage, usage and indications of the remedy.

3. *Reduced traditional medicine* is a traditional medicine that increases or decreases the number of ingredients and the content of each ingredient in accordance with the disease or illness according to the theory of traditional medicine but does not change the method of preparation. , the route of administration, dosage, method of administration and the ingredients in the formula are not incompatible.

4. *Registration facility* is the facility that submits an application for issuance, extension, change, or supplementation of the registration certificate for circulation of traditional drugs and medicinal materials.

5. *Traditional medicine disease* is a patient's disease condition that is diagnosed and determined according to the medical theory of traditional medicine.Additional

**Article 4. Language, form, and legality of dossiers requesting issuance, extension, change, and supplementation of registration papers for circulation of drugs and medicinal materials.**

1. Language used in dossiers requesting issuance, extension, change, and supplementation of registration papers for circulation of drugs and medicinal materials:

a) Registration dossiers for traditional drugs and domestically produced medicinal materials must be written in Vietnamese;

b) Registration dossiers of traditional drugs and imported medicinal materials must be written in Vietnamese or English. If written in English, the Product Instructions for Use and Summary of Product Characteristics must be written in Vietnamese. Documents proving that traditional medicine meets safety and effectiveness requirements with an additional copy written in the language of the country of origin issued by a competent agency of the country of origin.

2. Registration dossier must be prepared on A4 paper size, bound in a sturdy set; Arranged in the correct order of the table of contents, with separation between sections; The separating parts must be numbered for easy reference and have the registration or manufacturing facility's confirmation stamp on the first page of each part in the entire dossier; Particularly, quality standards, testing methods, and testing certificates for traditional drugs and medicinal materials must have the manufacturer's confirmation stamp.

3. Traditional medicine and herbal medicine labels: Each traditional medicine or medicinal herb must have 02 (two) sets of label design samples; Traditional medicines and imported medicinal herbs must also have 01 (one) set of actual labels. These labels are mounted on A4 paper with the stamp of the registration facility or manufacturing facility. When receiving applications for renewal of circulation registration, the registration facility must only submit a copy of the approved label sample if there are no changes compared to the first registration.

4. Instruction sheet of traditional medicine (not including traditional medicine) according to the regulations on labeling of drugs and medicinal ingredients of the Ministry of Health, with the seal of the registration facility. The content of indications and usage must clearly show the type of traditional medicine disease. In case of renewing the circulation registration, the establishment does not have to re-submit the drug's instruction sheet if there are no changes compared to the first registration and renewal of the previous registration.

5. Other documents:

a) The registration application must be signed directly by the head of the registration facility or an authorized representative of the registration facility and affixed with the seal (if any) of the registration facility; stamp signatures are not allowed. ;

b) In case of authorization, the application must be accompanied by an original authorization letter or a copy certified as a true copy of the registration facility or representative office in Vietnam and be carried out in accordance with the following regulations: following cases:

- Authorization to register in the name of the registered facility according to Form No. 09A issued with this Circular in case the registered facility is not a traditional medicine, medicinal herb, or traditional medicine manufacturer. Foreign infusions and medicinal materials do not have a representative office in Vietnam;

- Authorization to sign the registration dossier when the registration facility authorizes the representative office of the facility registering traditional drugs and medicinal herbs in Vietnam according to Form No. 09B issued with this Circular;

- Authorization to use names of traditional drugs or medicinal materials with registered trademarks when the trademark owner is not the establishment registering traditional drugs or medicinal materials according to Form No. 09C issued with the Circular This.

c) In case the registration facility is different from the manufacturing facility, the certificate of eligibility for pharmaceutical business of the registration facility can be a certified copy or a copy stamped by the manufacturing facility itself;

d) Certificate, protection title, ownership transfer contract of relevant industrial property object in the drug registration dossier (if any) issued by competent industrial property agencies or confirmation must be a certified copy or a copy with the seal of the registration facility.

6. Legal documents of foreign enterprises must also meet the following regulations:

a) Pharmaceutical product certificate (referred to as CPP Certificate), Pharmaceutical production and trading license issued by a competent foreign state management agency, certificate of meeting good manufacturing practice standards medicine (referred to as GMP), license to establish a representative office in Vietnam, the original or copy can be submitted, specifically as follows:

- In case of submitting the original: The original must have the full signature, name, title of the signer, date of issue and seal of the competent state agency; The signature, name, title of the signer and seal of the state agency competent to issue the CPP paper must be

consular legalized according to the provisions of law on consular legalization, except in the case of legal documents. The reason why competent state management agencies of issuing countries have signed Mutual Legal Assistance Agreements with Vietnam;

- In case of submitting a copy: The copy is duly authenticated by a competent Vietnamese state management agency according to the provisions of Vietnamese law on authenticating copies from originals or copies issued from master books. . In case of necessity, the facility shall present the original for comparison at the request of the dossier-receiving agency;

- Validity period of the license or certificate: The validity period must be specifically stated on the certificate and must be valid at the time of application submission; Do not accept official letters to renew licenses and certificates.

b) CPP paper must meet the regulations in point a of this clause and meet the following regulations:

- Issued and issued by a competent pharmaceutical management agency *(according to the WHO list on the website http://www.who.int)* according to the form of the World Health Organization (WHO) applicable to the System. quality certification of pharmaceutical products circulated in international trade;

- There is confirmation that the drug is allowed to circulate in the manufacturing country. In case the drug is not licensed for circulation in the manufacturing country or is licensed but the drug is not actually circulated in the manufacturing country, the registration facility must provide a CPP Certificate certifying that the drug is circulated in one of the countries. that the drug is actually in circulation.

c) A pharmaceutical production and trading license issued by a foreign competent state management agency, in addition to meeting the provisions at Point a of this Clause, must also fully contain the following contents:

- Name and address of the competent state management agency;

- Name and address of the drug business establishment;

- Scope of operation;

- The validity period must be specifically stated on the certificates and must be valid at the time of application submission. In case the validity period is not specified, the foreign drug business establishment must provide a certificate from the licensing authority certifying that the establishment is still operating in the pharmaceutical field at the time of application submission. .

d) Certificate of compliance with good manufacturing practice standards (GMP-WHO), ISO or certificates of compliance with equivalent standards must be issued by a competent authority in the manufacturing country, with the name and address of the manufacturer. manufacture.

7. Each traditional medicine and medicinal herb must have a separate registration dossier, except in the case of traditional medicines (not including traditional medicines) with the same formula for a dosage unit, the same content but different specifications. pack.Additional

**Article 5. Fees for registration of traditional drugs and medicinal materials**

Establishments registering traditional drugs and medicinal materials must pay fees in accordance with the law on fees and charges.

**Article 6. Inventions and confidentiality related to registered traditional medicines**

Traditional medicine registration establishments need data security for new traditional medicine registration dossiers according to the provisions of Circular No. 05/2010/TT-BYT dated March 1, 2010 of the Minister of Health. Instructions for security of testing data in drug registration must clearly state the request in the application for issuance, extension, change, and supplementation of circulation registration according to Form No. 03 , Form No. 04 and Form No. 05, Appendix Appendix I is issued together with this Circular and provides legal documents related to the status of exclusive intellectual property protection (invention patent).

**chapter II**

**CRITERIA FOR DETERMINING TRADITIONAL MEDICINES THAT ARE EXEMPT FROM CLINICAL TRIAL, EXEMPT FROM SOME CLINICAL TRIAL PHASES, MUST BE IN PHASE 4 CLINICAL TRIAL, MUST BE IN FULL PHASES OF CLINICAL TRIAL IN VIETNAM AND CLINICAL DATA REQUIREMENTS TO ENSURE SAFETY AND EFFICIENCY AS A BASIS FOR ISSUING TRADITIONAL MEDICINE REGISTRATION CERTIFICATE**

**Article 7. Criteria for determining traditional drugs exempt from clinical trials in Vietnam**

1. Traditional medicine.

2. Traditional medicine is recognized by the Ministry of Health when it meets one of the following criteria:

a) Ancient;

b) The traditional medicine has been certified according to the provisions of law, has effects and indications that clearly demonstrate the traditional medicine disease and has been approved by the Science and Technology Council or the Professional Ethics Council.

Traditional medicine sector at provincial level or equivalent or higher must have a document accepting and evaluating the finished product of the traditional medicine when circulating to ensure safety and effectiveness;

c) Drugs that have been used for treatment at provincial or higher traditional medicine medical examination and treatment facilities for 10 (ten) years or more and for 200 (two hundred) patients or more as of date. Submit a registration application with a stable route of administration, dosage, process, and dosage form; has effects and indications that clearly demonstrate the traditional medicine disease and has a written acceptance and safety assessment from the Science and Technology Council or the Traditional Medicine Ethics Council at the provincial or equivalent level or higher. safe and effective;

d) Traditional drugs that have been exempted from clinical trials have changed their dosage forms but have not changed their ingredients, content, indications, effects and routes of administration, and have been approved by the Science and Technology Council or the Professional Ethics Council. The traditional medicine branch at the provincial level or equivalent or higher has a document accepting the assessment of clinical safety and effectiveness in treating diseases and illnesses according to original prescriptions;

d) Traditional remedies are added to increase the main effect of the remedy, the added ingredients do not contain medicinal herbs on the list of toxic medicinal herbs issued by the Minister of Health; have documents and data to prove or analyze and explain the safety and clinical effectiveness of the drug after reduction;

e) Traditional medicines are products that are part of scientific research projects at provincial level or equivalent or higher; has effects and indications that clearly demonstrate the traditional medicine disease and has a written acceptance and safety assessment from the Science and Technology Council or the Traditional Medicine Ethics Council at the provincial or equivalent level or higher. complete and effective.

3. Traditional drugs have been granted circulation registration before the effective date of Pharmacy Law No. 105/2016/QH13 as prescribed in Point b, Clause 2, Article 72 of the Law on Pharmacy , except for the cases specified in Clause 3, Article 8. and Clause 2, Article 9 of this Circular .

**Article 8. Criteria for determining cases of exemption from some stages of clinical trial of traditional drugs in Vietnam**

1. Traditional drugs are exempt from phase 1 and phase 2 clinical trials in Vietnam when they meet one of the following criteria:

a) Drugs that are exempt from clinical trials but have changed or supplemented indications based on the main effects of the drug without changing the drug formula ingredients, dosage, or dosage form;

b) A family medicine that has been granted a certificate according to current regulations does not fall into the cases specified in Point b, Clause 2, Article 7 of this Circular ;

c) Drugs that have been used for treatment at district-level traditional medicine examination and treatment facilities or equivalent for 10 (ten) years or more and for 200 (two hundred) patients or more up to now. At the time of submitting the registration dossier, there is a route of administration, dosage, process, and dosage form that is stable, effective, and has indications that clearly demonstrate the form of traditional medicine and is approved by the Council of Science and Technology or the National Assembly. Ethical council specializing in traditional medicine at the grassroots level at a traditional medicine hospital at the provincial level or equivalent or higher has written acceptance and assessment of safety and effectiveness.

2. Traditional drugs are exempt from phase 1 and phase 2 clinical trials in Vietnam, but must undergo phase 3 abbreviated clinical trials when they meet the following criteria: Drugs that are exempt from clinical trials, with changes change the dosage form, do not change the ingredients, indications, effects and routes of administration, except in the case of traditional drugs specified in Points a and dd, Clause 2, Article 7 of this Circular . The Biomedical Research Ethics Council specializing in traditional medicine in the field of traditional medicine and medicinal materials considers and decides on the scale and methods of phase 3 abbreviated clinical trials.

3. Traditional drugs that have been granted circulation registration before the effective date of Pharmacy Law No. 105/2016/QH13 are exempt from phase 1 and phase 2 clinical trials at the request of the Advisory Council for issuance of registration certificate. circulated when falling into one of the following cases:

a) There are formula ingredients that do not meet the regulations in Clause 2, Article 7 of this Circular and additional unwanted effects and/or adverse reactions of the drug are discovered compared to the licensed drug instruction sheet. circulation registration;

b) There is not enough clinical, safety and effectiveness data for hepatitis, cancer and some other diseases as requested by the Advisory Council for issuance of marketing registration certificate.

**Article 9. Criteria for determining traditional drugs subject to phase 4 clinical trials in Vietnam**

Traditional drugs that have been granted registration for circulation in Vietnam must undergo phase 4 clinical trials when they meet one of the following criteria:

1. There is a request from a competent state pharmaceutical management agency in case additional information must be provided to continue evaluating the safety and treatment effectiveness of the drug.

2. Traditional drugs that have been granted circulation registration before the effective date of Pharmacy Law No. 105/2016/QH13 must undergo phase 4 clinical trials at the request of the Advisory Council to grant circulation registration when successful. The formula does

not meet the regulations in Clause 2, Article 7 of this Circular and no additional unwanted effects and adverse reactions of the drug are detected compared to the instructions for use of the drug that have been granted a certificate of circulation registration.

3. Traditional medicines specified in Article 8 of this Circular have not yet been subjected to phase 4 clinical trials in Vietnam.

**Article 10. Criteria to determine traditional drugs must be tested in all stages**

Traditional drugs that do not fall into the cases specified in Articles 7, 8 and 9 of this Circular must be subjected to full clinical trials in all stages in Vietnam.

**Article 11. Documents proving that traditional drugs meet the criteria for exemption from clinical trials or exemption from certain stages of clinical trials**

1. Ancient medicine specified in Point a, Clause 2, Article 7 of this Circular : Documents proving the origin of ancient medicine as prescribed in Clause 2, Article 3 of this Circular .

2. For traditional remedies specified in Point b, Clause 2, Article 7 or Point b, Clause 1, Article 8 of this Circular :

a) A copy of the certificate of traditional medicine, authenticated or stamped by the facility. In case of submitting a copy with the establishment's stamp, there must be an original or a certified copy for the receiving department to compare;

b) A certified copy of the acceptance document of the Science and Technology Council or the Traditional Medicine Ethics Council at the provincial level or equivalent or higher (if any).

3. For drugs used for treatment at medical examination and treatment facilities specified in Point c, Clause 2, Article 7 or Point c, Clause 1, Article 8 of this Circular :

a) Documents on drug formulas; how to prepare ingredients; dosage forms; how to use, route of administration; dosage; indications and contraindications;

b) Documents proving that it has been used to treat 200 (two hundred) patients or more for 10 (ten) years or more, with stable dosage, process, and dosage form;

c) A certified copy of the acceptance document assessing safety and effectiveness of the Science and Technology Council or the Provincial Ethics Council for Ancient and Traditional Medicine or equivalent or higher for the drugs specified at point c Clause 2 Article 7 ;

d) A certified copy of the acceptance document assessing safety and effectiveness of the Science and Technology Council or the Traditional Medicine Ethics Council at the grassroots level at the provincial traditional medicine hospital or equivalent. equivalent or more for drugs specified in Point c, Clause 1, Article 8 .

4. For traditional drugs that have been exempted from clinical trials and have changed dosage forms:

a) Documents on drug formulas; how to prepare ingredients; new dosage forms;

b) Instructions for use according to regulations on labeling of drugs and medicinal ingredients of the Ministry of Health, with the seal of the registration facility;

c) Manufacturing process after changing from the previous dosage form;

d) Certified copy of the acceptance document assessing safety and effectiveness in treating diseases and symptoms according to the original prescription of the Council of Science and Technology specialized in traditional medicine at the ministerial level or equivalent or higher.

5. For the reduction method specified in Point dd, Clause 2, Article 7 of this Circular :

a) Documents proving the origin of traditional medicine as prescribed in Clause 2, Article 3 of this Circular ;

b) Documents on drug formulas; Reasoning how to reduce; how to prepare ingredients; medicinal form; how to use, route of administration; dosage; indications and contraindications;

c) Documents and data proving the safety and clinical effectiveness of the drug after reduction.

**Article 12. Cases where traditional drugs must continue to be monitored for safety and effectiveness after being granted circulation registration**

1. Traditional drugs applying for circulation registration must continue to be monitored for safety and effectiveness, including:

a) Traditional medicines containing toxic medicinal herbs are on the list of toxic medicinal herbs of mineral origin in Appendix III and toxic medicinal herbs not marked with an asterisk (*) are on the list of toxic medicinal herbs of plant origin. , animals in Appendix I and

Appendix II issued together with Circular No. 42/2017/TT-BYT dated November 13, 2017 of the Minister of Health promulgating the List of toxic medicinal herbs;

b) Traditional drugs do not have sufficient clinical data to ensure safety and effectiveness, and the drugs are exempt from some clinical trial stages as prescribed in Article 8 of this Circular .

2. Traditional drugs that request to renew their marketing registration must continue to monitor safety and effectiveness when there is not enough clinical data to ensure safety and effectiveness according to regulations on clinical drug trials.

3. For traditional medicines specified in Clauses 1 and 2 of this Article, the time limit for issuance and extension of circulation registration is 03 years.

**Article 13. Requirements for reports on monitoring and evaluating safety and effectiveness during the circulation of traditional drugs**

Traditional medicines must continue to be monitored for safety and effectiveness as prescribed in Article 12 of this Circular every 6 months and when submitting registration dossiers for renewal according to the following regulations:

1. The registration facility is responsible for reporting the safety and effectiveness of the drug according to Form 8A Appendix I issued with this Circular, and storing records and documents related to the safety report. effectiveness of the drug.

2. Medical examination and treatment facilities that use drugs are responsible for reporting drug use according to Form 8B Appendix I issued with this Circular, and storing records and documents related to the report. Report the status of drug use to serve the inspection and evaluation of drug effectiveness and safety.

**Article 14. Requirements for clinical data to ensure safety and effectiveness of traditional drugs in marketing registration dossiers**

1. Clinical studies of the drug, data in clinical records, technical records to prove safety and effectiveness must be in accordance with the regulations of the Ministry of Health on good clinical drug testing practices. .

2. The available data in the clinical trial results of the drug can be used to analyze and explain the possible influence of epidemiological factors, pathology or living conditions in Vietnam. Nam to the safety and effectiveness of drugs.

**Chapter III**

**DOCUMENTS AND PROCEDURES FOR ISSUANCE, RENEWAL, CHANGE AND SUPPLEMENT OF TRADITIONAL MEDICINE REGISTRATION PAPER**

**SECTION I. APPLICATION DOCUMENT FOR ISSUANCE, RENEWAL, CHANGE AND SUPPLEMENT OF TRADITIONAL MEDICINE REGISTRATION PAPER**

**Article 15. Application dossier for issuance of certificate of registration for circulation of traditional drugs**

Dossier to request issuance of Certificate of registration for circulation of traditional drugs shall comply with the provisions of Clause 2, Article 56 of the Law on Pharmacy , including:

1. Administrative records are specifically specified in Article 16 of this Circular .

2. The technical dossier is specified in Article 17 of this Circular .

3. Actual label samples of traditional drugs circulated in the host country or reference country for imported traditional drugs.

**Article 16. Administrative records section**

The administrative records section includes the following papers and documents:

1. Application for issuance of registration certificate for circulation of traditional drugs according to Form No. 03A or Form No. 03B, Appendix I issued with this Circular.

2. Legal documents in case the facility registering traditional medicine is a manufacturing facility:

a) A copy of the Certificate of eligibility for pharmaceutical business with the scope of traditional drug production business for domestic traditional drug manufacturers;

b) CPP certificate of imported traditional medicine for foreign traditional medicine manufacturers, except traditional medicine. In case the CPP Certificate does not contain content confirming that the manufacturing facility meets GMP standards, the GMP Certificate of the foreign traditional medicine manufacturing facility must be submitted. In case there are many facilities participating in the drug production process, GMP certificates of all manufacturing facilities involved in the drug production process must be submitted.

3. Legal documents in case the facility registering traditional medicine is not a traditional medicine manufacturer:

a) Legal documents as prescribed in Points a and b, Clause 2 of this Article;

b) Legal documents of the establishment registering the circulation of traditional drugs:

- Copy of Certificate of eligibility for pharmaceutical business for domestic establishments with one of the following business scopes: production, wholesale, export, import of traditional drugs;

- License to establish a representative office in Vietnam and license to produce and trade drugs issued by a competent foreign state management agency according to regulations for traditional medicine manufacturers with representative offices. represented in Vietnam.

4. Power of attorney as prescribed in Clause 5, Article 4 of this Circular in case of authorization.

5. Product Summary according to Form No. 06A or Form No. 06B, Appendix I issued with this Circular;

6. Traditional medicine label sample: Label content complies with regulations of the Ministry of Health on labeling of drugs, medicinal ingredients and drug use instructions.

7. Instructions for use of traditional medicines according to regulations of the Ministry of Health on labeling of drugs, medicinal ingredients and drug use instructions.

8. Data security documents specified in Article 6 of this Circular (if any).

9. Other documents (if any).Additional

**Article 17. Technical documents section**

The technical dossier includes the following papers and documents:

1. Documents on the production process must meet the following requirements:

a) Documents on raw materials: Must describe fully and in detail the raw material production process (description of the production process is not required for excipients and materials in the pharmacopoeia, materials provided by the manufacturer). other production);

b) Documents on finished products must fully show the following information:

- Formula for the smallest packaging unit: ingredient name, including main ingredients, auxiliary ingredients and excipients; Applicable standards of raw materials; If produced from medicinal herbs that have not been standardized in terms of active ingredient content, the corresponding amount of medicinal ingredients must be clearly stated;

- Formula for a batch or production batch: ingredient name including main ingredients and excipients; mass or volume of each ingredient;

- Production process diagram including all stages in the production process;

- Description of the production process: full and detailed description of each stage in the production process;

- List of equipment and tools used in the production process: equipment name, parameters, purpose of use, status of use, registration or publication number (if any);

- Control during the production process: Full and detailed description of inspection and control criteria during the production process.

2. Documents on quality standards and drug testing methods must meet the following requirements:

a) For traditional medicinal ingredients included in the pharmacopoeia: specify the pharmacopoeia name and year of publication; For traditional medicinal ingredients not included in the pharmacopoeia: full and detailed description of criteria and testing methods;

b) Finished product standards: Full and detailed description of finished product criteria and testing methods;

c) Packaging standards: Full and detailed description of criteria and testing methods;

d) Drug testing certificate must meet the following requirements:

- Traditional medicine manufacturing facilities have a traditional medicine testing laboratory that meets Good Laboratory Practices (GLP) according to regulations of the Ministry of Health to self-assess standards and testing methods and submit government testing slips. manufacture factory;

- Traditional medicine manufacturing establishments that do not have a traditional medicine testing laboratory that meets Good Drug Testing Practices (GLP) according to regulations of the Ministry of Health must appraise standards and testing methods and submit the

testing certificate of the Ministry of Health. State-run drug testing facilities or drug testing service facilities that have been granted a Certificate of eligibility for pharmaceutical business.

d) Stability research requirements:

Traditional medicine manufacturing facilities must research and have documents proving stability, including:

- Stability research outline;

- Stability research data;

- Conclusion of stability study.

3. Documents proving that the drug meets safety and effectiveness requirements, including:

a) For traditional medicine:

- Clinical and pre-clinical research reports that have been accepted and approved by the competent authority, accompanied by a certified copy of the document approving the research results of the competent authority for each case. prescribed in Articles 7, 8, 9 and 10 of this Circular ;

- Toxicology reports for traditional medicines containing toxic medicinal herbs on the list of toxic medicinal herbs of mineral origin in Appendix III and toxic medicinal herbs not marked with an asterisk (*) on the list of medicinal herbs have toxicity of plant or animal origin in Appendix I and Appendix II issued together with Circular No. 42/2017/TT-BYT dated November 13, 2017 of the Minister of Health promulgating the List of medicinal herbs poison as medicine.

b) For traditional medicines: Report on toxicology for traditional medicines containing toxic medicinal herbs on the list of toxic medicinal herbs of mineral origin in Appendix III and unmarked toxic medicinal herbs star (*) belongs to the list of toxic medicinal materials of plant and animal origin in Appendix I and Appendix II issued with Circular No. 42/2017/TT-BYT dated November 13, 2017 of the Minister The Ministry of Health promulgates the List of toxic medicinal herbs, issued together with the results of toxicity analysis of traditional medicines performed by competent establishments.

4. Documents proving that traditional drugs meet the criteria for exemption from clinical trials or exemption from some stages of clinical trials specified in Article 11 of this Circular .

**Article 18. Dossier requesting extension of registration certificate for circulation of traditional drugs**

1. Application for renewal of registration according to Form No. 04A or Form No. 04B, Appendix I issued with this Circular.

2. Documents specified in Clause 2 and Clause 3 Article 16 of this Circular and documents specified in Clause 6 and Clause 7 Article 16 of this Circular for cases where traditional medicine has changes in administrative records at the time of registration renewal.

3. Report on circulation of traditional drugs according to Form No. 10, Appendix I issued with this Circular.

4. Report safety and effectiveness for drugs that require continued safety and effectiveness monitoring according to Form No. 08 Appendix I issued with this Circular.

5. Copy of drug circulation registration certificate issued in Vietnam.

**Article 19. Dossier requesting changes and additions to the certificate of registration for circulation of traditional drugs**

1. Application to change or supplement the registration certificate for circulation of traditional drugs according to Form No. 05A or Form No. 05B, Appendix I issued with this Circular.

2. Technical dossier for changed and supplemented content: Relevant documents as prescribed in Appendix II issued with this Circular.

3. A copy of the valid registration certificate for circulation of traditional drugs in Vietnam.

**SECTION II. PROCEDURES FOR ISSUING, EXTENDING, CHANGING AND ADDING TRADITIONAL MEDICINE REGISTRATION PAPER**

**Article 20. Procedures for granting registration certificates for circulation of traditional drugs**

1. The establishment requesting issuance of registration certificate for circulation of traditional drugs (registration facility) submits 01 set of application documents for issuance of registration certificate for circulation of traditional drugs (registration dossier) according to the provisions of Article 15. , 16, 17 This Circular is sent to the Traditional Medicine and Pharmacy Administration - Ministry of Health (receiving agency) in the form of direct submission, by post or online submission on the online public service system. of the Ministry of Health.

2. When receiving a complete registration dossier and meeting form requirements, the dossier-receiving agency shall issue to the registration facility a dossier receipt form according to Form No. 02 issued with this Circular. In case of insufficient documents according to regulations, the receiving agency shall issue a document or request (in case of direct submission) to the registration facility to supplement sufficient documents according to regulations.

3. For traditional drugs that are not subject to clinical trial, within 06 months from the date of receipt of complete dossiers, the dossier-receiving agency shall carry out the following procedures:

a) Organize appraisal of registration documents;

b) Submit to the Advisory Council to issue a certificate of registration for circulation of traditional drugs for registration dossiers that meet the requirements;

c) Issue registration certificates for circulation of traditional drugs at the request of the Advisory Council for issuance of circulation registration certificates for dossiers that meet the requirements.

4. For traditional drugs subject to clinical trial, within 12 months from the date of receipt of complete documents, the receiving agency shall carry out the procedures specified in Points a, b, c, Clause 3 of this Article.

5. In case the application does not meet the requirements as prescribed in Articles 15, 16, 17 of this Circular , within the time limit for reviewing the registration application, the receiving agency must promptly issue specific written instructions to the agency. The registration office amends and supplements the dossier until the dossier meets the requirements. The time for establishments to register amendments and supplements to documents is no more than 60 days from the date of receipt of the document from the receiving agency. The time the facility registers to amend or supplement the dossier is not included in the dossier review time limit. If the 60-day deadline is exceeded, the registration application is no longer valid and the establishment must re-implement the registration procedure.

6. In case of not granting a circulation registration certificate as prescribed in Clauses 3 and 4 of this Article, the agency receiving the application must respond in writing and clearly state the reason.

**Article 21. Procedures for extending the registration certificate for circulation of traditional drugs**

1. Before 03 months from the date of expiration of the registration certificate for circulation, the registration facility shall submit 01 set of documents to request the extension of the certificate of registration for circulation of traditional drugs (renewal documents) according to regulations. in Article 18 of this Circular to the Department of Traditional Medicine and Pharmacy Administration, Ministry of Health (receiving agency) in the form of direct submission, by post or online submission on the online public service system of the Ministry of Health. Ministry of Health. In case the above deadline has passed and the registration facility has not submitted an application for extension, the facility must carry out procedures for granting a circulation registration certificate as prescribed in Article 20 of this Circular .

2. When receiving an extension application with all components and meeting the format requirements, the application-receiving agency shall issue to the registering establishment an Application Receipt Form according to Form No. 02 issued with this Circular. In case of insufficient documents according to regulations, the receiving agency shall issue a document or request (in case of direct submission) to the registration facility to supplement sufficient documents according to regulations.

3. Within 01 month from the date of receipt of complete dossier, the dossier-receiving agency shall consider and approve the list of traditional drugs to extend the circulation registration certificate.

4. In case the dossier does not meet the requirements as prescribed in Article 18 of this Circular , within the time limit for reviewing the registration dossier, the receiving agency must promptly issue specific written instructions for the registrant to correct the application. Change and supplement documents until they meet the requirements. The time for establishments to register amendments and supplements to documents is no more than 30 days from the date of receipt of the document from the receiving agency. The time the facility registers to amend or supplement the dossier is not included in the dossier review time limit. If the 30-day deadline is exceeded, the extension application is no longer valid and the facility must re-implement the renewal procedure.

5. In case of non-renewal, the receiving agency must respond in writing and clearly state the reason.

**Article 22. Procedures for changing and supplementing traditional medicine circulation registration certificates**

1. The establishment requesting to change or supplement the registration certificate for circulation of traditional drugs (registration establishment) shall submit 01 set of dossier requesting change and supplementation of the registration certificate for circulation of traditional drugs (registration dossier). changes and supplements) according to the provisions of Article 19 of this Circular to the Department of Traditional Medicine and Pharmacy Administration, the Ministry of Health (receiving agency) in the form of direct submission, by post or online submission. on the online public service system of the Ministry of Health.

2. When receiving the application for registration of changes or additions with all components and meeting the format requirements, the agency receiving the application shall issue the application receipt to the registrant according to Form No. 02 issued with it. This circular. In case of insufficient documents according to regulations, the receiving agency shall issue a document or request (in case of direct submission) to the registration facility to supplement sufficient documents according to regulations.

3. For registration dossiers for circulation of traditional drugs with changes and additions specified in Appendix II.1 issued with this Circular, establishments are allowed to make changes and additions. immediately after the date the dossier-receiving agency issues a receipt to the registration facility.

4. For applications for registration of circulation of traditional drugs containing changes or additions specified in Appendix II.2 issued with this Circular, within 01 month from the date of receipt of complete application, The agency receiving the dossier shall have a written agreement with the contents of changes and additions to the traditional medicine circulation registration certificate for dossiers that meet the requirements.

5. In case the application does not meet the requirements as prescribed in Article 19 of this Circular, within the time limit for reviewing the application for registration of changes or additions, the receiving agency must promptly issue specific written instructions for the application. The registration facility amends and supplements the dossier until the dossier meets the requirements. The time for establishments to register amendments and supplements to documents is no more than 30 days from the date of receipt of the document from the receiving agency. The time the facility registers to amend or supplement the dossier is not included in the dossier review time limit. If the 30-day time limit exceeds, the application for registration of changes or additions is no longer valid and the establishment must re-implement the procedure for registration of changes and additions.

6. In case changes or additions to the circulation registration dossier are not allowed, the agency receiving the dossier must respond in writing and clearly state the reason.Additional

**Article 23. Priority cases to consider shortening the time for granting registration certificates for circulation of traditional drugs**

1. Traditional drugs are given priority to consider shortening the time for granting registration certificates for circulation of traditional drugs before the deadline specified in Article 20 of this Circular based on the request of the traditional drug registration facility stated in the Application. Registration is prescribed according to Form No. 03A or Form No. 03B, Appendix I issued with this Circular for the following cases:

a) Medicines that meet urgent needs for national defense, security, disease prevention and control, overcoming the consequences of natural disasters, disasters, and special treatment needs;

b) Domestic drugs produced on new lines meeting GMP standards within no more than 12 months from the date of issuance of the GMP certificate.

c) Traditional medicines are produced entirely from domestic medicinal materials meeting Good Practices in farming, harvesting and exploiting medicinal materials according to GACP standards.

2. Documents and procedures for traditional drugs in priority cases of shortening the period of circulation registration must comply with the provisions of Article 20 of this Circular .

**Chapter IV**

**DOCUMENTS AND PROCEDURES FOR ISSUANCE, RENEWAL, CHANGE AND SUPPLEMENT OF REGISTRATION PAPER FOR Circulation of PHARMACEUTICAL MATERIALS**

**SECTION I. APPLICATION DOCUMENTS FOR ISSUANCE, RENEWAL, CHANGE, AND SUPPLEMENT OF REGISTRATION DOCUMENTS FOR Circulating PHARMACEUTICAL MATERIALS**

**Article 24. Application dossier for issuance of registration certificate for circulation of medicinal materials**

Dossier to request issuance of registration certificate for circulation of medicinal materials shall comply with the provisions of Clause 2, Article 56 of the Law on Pharmacy , including:

1. Administrative records are specifically specified in Article 25 of this Circular .

2. The technical dossier is specified in Article 26 of this Circular .

3. Actual label samples of medicinal materials circulated in the host country or reference country for imported medicinal materials.

**Article 25. Administrative records section**

The administrative records section includes the following papers and documents:

1. Application for issuance of registration certificate for circulation of medicinal materials according to Form No. 03C Appendix I issued with this Circular.

2. Legal documents in case the facility registering for circulation of medicinal materials is a pharmaceutical manufacturing facility:

a) A copy of the Certificate of eligibility for pharmaceutical business with the scope of domestic production of medicinal materials and traditional medicines;

b) Copy of Business Registration Certificate for establishments cultivating, harvesting, and exploiting medicinal herbs in the country;

c) License to establish a Representative Office in Vietnam and License to produce and trade pharmaceuticals in the scope of producing medicinal materials, pre-processed and processed medicinal materials issued by a competent foreign state management agency for establishments producing medicinal materials, pre-processed and processed medicinal materials with representative offices in Vietnam.

3. Legal documents in case the facility registering for circulation of medicinal materials is not a pharmaceutical manufacturing facility:

a) Legal documents of the pharmaceutical manufacturing facility requesting registration specified in Clause 2 of this Article;

b) Legal documents of the facility registering for circulation of medicinal materials:

- Copy of Certificate of eligibility for pharmaceutical business for domestic establishments with one of the following business scopes: production, wholesale, export, import of medicinal materials or traditional medicines;

- License to establish a representative office in Vietnam and license to produce and trade pharmaceuticals in the scope of producing medicinal materials, pre-processed and processed medicinal materials, issued by foreign competent state management agencies. with the establishment registering for circulation with a representative office in Vietnam.

4. Power of attorney as prescribed in Clause 5, Article 4 of this Circular in case of authorization.

5. Product Summary according to Form No. 06C Appendix I issued with this Circular.

6. Pharmaceutical label sample: Label content complies with regulations of the Ministry of Health on labeling of drugs, medicinal ingredients and drug use instructions.

7. Instructions for use of medicinal materials comply with regulations of the Ministry of Health on labeling of drugs, medicinal ingredients and drug use instructions.

8. Other documents (if any).

**Article 26. Technical documents section**

The technical dossier includes the following papers and documents:

1. Documents on the medicinal herb processing process must meet the following requirements:

a) Formula for smallest packaging unit: ingredient name; Applicable standards of raw materials;

b) Formula for a batch or preliminary processing batch: name of ingredients; mass or volume of material;

c) Preliminary processing process diagram including all stages in the preliminary processing process;

d) Description of the preliminary processing process: full and detailed description of each stage in the production process;

d) List of equipment and tools used in the preliminary processing process: equipment name, parameters, purpose of use; registration or publication number (if any);

e) Documents on control during preliminary processing: Full and detailed description of inspection and control criteria during preliminary processing.

2. Documents on quality standards and testing methods must meet the following requirements:

a) Medicinal ingredients standards: Full and detailed description of criteria and testing methods of medicinal ingredients;

b) Packaging standards: Full and detailed description of criteria and testing methods;

c) The medicinal material testing certificate must meet the following requirements:

- A pharmaceutical manufacturing facility with a pharmaceutical testing laboratory that meets "Good Laboratory Practice" (GLP) for medicinal materials according to regulations of the Ministry of Health self-assess standards and testing methods and submits the form. testing by that production facility in the registration dossier;

- Pharmaceutical manufacturing facilities that do not have a pharmaceutical testing laboratory that meets "Good Laboratory Practice" (GLP) for medicinal materials according to regulations of the Ministry of Health must appraise standards and testing methods and submit Testing slips from state-owned drug testing facilities or drug testing service facilities that are granted a Certificate of eligibility for pharmaceutical business in the registration dossier.

**Article 27. Dossier requesting extension of registration certificate for circulation of medicinal materials**

1. Application for renewal of registration according to Form No. 04C, Appendix I issued with this Circular.

2. Documents specified in Clause 2, Clause 3, Article 25 of this Circular and documents specified in Clause 6, Clause 7, Article 25 of this Circular in case the medicinal material registration dossier has changes in the dossier. administrative documents at the time of renewal registration.

3. Report on circulation of medicinal materials according to Form No. 10, Appendix I issued with this Circular.

4. Safety and effectiveness report according to Form No. 08, Appendix I issued with this Circular for medicinal herbs on the list of toxic medicinal herbs issued by the Minister of Health.

5. Copy of the registration certificate for circulation of medicinal materials in Vietnam issued.

**Article 28. Dossier requesting changes and additions to the registration certificate for circulation of medicinal materials**

1. Application for change or supplementation of registration form Form No. 05C Appendix I issued with this Circular.

2. Relevant documents for each case of specific changes and additions are specified in Appendix II issued with this Circular.

3. A copy of the valid registration certificate for circulation of medicinal materials in Vietnam.

**SECTION II. PROCEDURES FOR ISSUANCE, RENEWAL, CHANGE AND ADDITION OF MEDICAL Circulation Registration Paper**

**Article 29. Procedures for granting registration certificates for circulation of medicinal materials**

1. The establishment requesting issuance of registration certificate for circulation of medicinal materials (registration facility) submits 01 set of application documents for issuance of registration certificate for circulation of medicinal materials (registration dossier) according to the provisions of Articles 24, 25, 26 This Circular is sent to the Department of Traditional Medicine and Pharmacy Administration - Ministry of Health (receiving agency) in the form of direct submission, by post or online submission on the online public service system of the Ministry of Health. international.

2. When receiving a complete registration dossier and meeting form requirements, the dossier-receiving agency shall issue to the registration facility a dossier receipt form according to Form No. 02 issued with this Circular. In case of insufficient documents according to regulations, the receiving agency shall issue a document or request (in case of direct submission) to the registration facility to supplement sufficient documents according to regulations.

3. Within 06 months from the date of receipt of complete documents, the receiving agency shall carry out the following procedures:

a) Organize appraisal of registration documents;

b) Submit to the Advisory Council for issuance of registration certificates for circulation of medicinal materials for registration dossiers that meet the requirements;

c) Issue registration certificates for circulation of medicinal materials at the request of the Advisory Council for issuance of circulation registration certificates for documents that meet the requirements.

4. In case the application does not meet the requirements as prescribed in Articles 24, 25, 26 of this Circular , within the time limit for reviewing the registration application, the receiving agency must promptly issue specific written instructions for the application. The registration facility amends and supplements the dossier until the dossier meets the requirements. The time for establishments to register amendments and supplements to documents is no more than 60 days from the date of receipt of the document from the receiving agency. The time the facility registers to amend or supplement the dossier is not included in the dossier review time limit. If the 60-day deadline is exceeded, the registration application is no longer valid and the establishment must re-implement the registration procedure.

5. In case of not granting a circulation registration certificate as prescribed in Clause 3, this Article, the receiving agency must respond in writing and clearly state the reason.

**Article 30. Procedures for extending the registration certificate for circulation of medicinal materials**

1. Before 03 months from the date of expiration of the registration certificate for circulation, the registration establishment shall submit 01 set of application for extension of registration for circulation of medicinal materials (extension application) according to the provisions of Article 27 of this Circular is sent to the Department of Traditional Medicine and Pharmacy Administration - Ministry of Health (receiving agency) in the form of direct submission or online submission on the online public service system. In case the above deadline has passed and the registration facility has not submitted an application for extension, the facility must carry out procedures for granting a circulation registration certificate as prescribed in Article 30 of this Circular .

2. When receiving an extension application with all components and meeting the format requirements, the application-receiving agency shall issue to the registering establishment an Application Receipt Form according to Form No. 02 issued with this Circular. In case of insufficient documents according to regulations, the receiving agency shall issue a document or request the registration facility to supplement sufficient documents according to regulations.

3. Within 03 months from the date of receipt of complete dossier, the dossier-receiving agency shall consider and approve the list of medicinal materials to extend the circulation registration certificate.

4. In case the dossier does not meet the requirements as prescribed in Article 27 of this Circular , within the time limit for reviewing the registration dossier, the receiving agency must promptly issue specific written instructions for the registrant to correct the application. Change and supplement documents until they meet the requirements. The time for establishments to register amendments and supplements to documents is no more than 60 days from the date of receipt of the document from the receiving agency. The time the facility registers to amend or supplement the dossier is not included in the dossier review time limit. If the 60-day deadline is exceeded, the extension application is no longer valid and the facility must re-implement the renewal procedure.

5. In case of non-renewal, the receiving agency must respond in writing and clearly state the reason.

**Article 31. Procedures for changing and supplementing the registration certificate for circulation of medicinal materials**

1. The establishment requesting to change or supplement the registration certificate for circulation of medicinal materials (registration establishment) submits 01 set of documents to request changes and supplements to the registration certificate for circulation of medicinal materials (registration dossier for change). , supplement) according to the provisions of Article 28 of this Circular to the Department of Traditional Medicine and Pharmacy Administration - Ministry of Health (receiving agency) in the form of direct submission, by post or online submission on the system. Online public service system of the Ministry of Health.

2. When receiving an extension application with all components and meeting the format requirements, the application-receiving agency shall issue to the registering establishment an Application Receipt Form according to Form No. 02 issued with this Circular. In case of insufficient documents according to regulations, the receiving agency shall issue a document or request the registration facility to supplement sufficient documents according to regulations.

3. For registration dossiers for circulation of medicinal materials containing changes and additions specified in Appendix II.1 issued with this Circular, the establishment may make the changes and additions immediately. after the date the dossier-receiving agency issues the receiving facility to the registration facility.

4. For registration dossiers for circulation of medicinal materials containing changes and additions specified in Appendix II.2 issued with this Circular, within 30 days from the date of receipt of complete dossiers, the The agency receiving the dossier shall have a written agreement with the contents of changes and additions to the registration certificate for circulation of medicinal materials for dossiers that meet the requirements.

5. In case the application does not meet the requirements as prescribed in Article 28 of this Circular , within the time limit for reviewing the application for registration of changes or additions, the receiving agency must promptly issue specific written instructions for the application. The registration facility amends and supplements the dossier until the dossier meets the requirements. The time for establishments to register amendments and supplements to documents is no more than 60 days from the date of receipt of the document from the receiving agency. The time the facility registers to amend or supplement the dossier is not included in the dossier review time limit. If the 60-day time limit exceeds, the application for registration of changes or additions is no longer valid and the establishment must re-implement the procedure for registration of changes and additions.

6. In case changes or additions to the circulation registration dossier are not allowed, the agency receiving the dossier must respond in writing and clearly state the reason.Additional

**Article 32. Priority cases to consider shortening the time for granting registration certificates for circulation of medicinal materials**

1. Medicinal ingredients are given priority for consideration and issuance of a certificate of registration for circulation of medicinal ingredients before the deadline specified in Article 29 of this Circular based on the request of the medicinal ingredient registration facility stated in the Registration Application prescribed in the Form No. 03C Appendix I issued with this Circular for the following cases:

a) Medicinal materials are grown and exploited domestically according to standards of Good Practices for cultivating, harvesting and exploiting medicinal materials according to GACP principles and standards;

b) New medicinal materials are imported to Vietnam for cultivation based on scientific and technological research proving productivity and quality within no more than 12 months from the date of acceptance of the scientific research results.

2. Documents and procedures for medicinal materials in the priority case of shortening the period of circulation registration must comply with the provisions of Article 29 of this Circular .

**Chapter V**

**REVOKING THE REGISTRATION OF CIRCULATION OF TRADITIONAL MEDICINES AND PHARMACEUTICAL MEDICINES**

**Article 33. Dossier for revocation of registration certificate for circulation of traditional drugs and medicinal materials**

1. Copy of the Decision to recall traditional drugs and medicinal materials for cases where traditional drugs and medicinal materials are recalled according to the provisions of Points a and b, Clause 1, Article 58 of the Pharmacy Law .

2. Copy of the Decision to revoke the certificate of pharmaceutical products revoked by a competent foreign agency in cases where traditional drugs and medicinal materials are revoked according to the provisions of Point c, Clause 1, Article 58 of the Law medicine .

3. Certified copy of the Minutes of administrative violations on traditional drugs and medicinal materials for cases where traditional drugs and medicinal materials are recalled according to the provisions of Points d and dd, Clause 1, Article 58 of the Law on Pharmacy .

4. Original documents proving that medicinal materials or traditional drugs contain medicinal materials recommended by the World Health Organization, a competent Vietnamese management agency or the country of origin of the medicinal materials or traditional drugs. safe and ineffective for users in cases where traditional drugs and medicinal materials are recalled according to the provisions of Point e, Clause 1, Article 58 of the Pharmacy Law .

5. Application for revocation of registration certificate for circulation of traditional drugs and medicinal materials of the manufacturing facility or establishment registering traditional drugs and medicinal materials according to Form No. 11 Appendix I issued with this Circular for In cases where traditional drugs or medicinal materials are recalled according to the provisions of Point g, Clause 1, Article 58 of the Pharmacy Law .

**Article 34. Procedures for revocation of registration papers for circulation of traditional drugs and medicinal materials**

1. Within 30 days from the date the Traditional Medicine and Pharmacy Administration receives the documents as prescribed in Clauses 1, 2, 3, 4, Article 33 of this Circular from the competent agencies, led by the Administration. issued by the Traditional Medicine and Pharmacy Administration, the product registration establishment or product manufacturing facility, the Director of the Traditional Medicine and Pharmacy Administration shall issue a decision to revoke the circulation registration certificate of traditional medicine and pharmacy. Whether.

2. Within 30 days from the date the manufacturer or establishment registering traditional drugs and medicinal materials submits a request to revoke the certificate of circulation registration of traditional drugs and medicinal materials according to the provisions of Clause 5, Article 33. This Circular to the Department of Traditional Medicine and Pharmacy Administration, the Director of the Traditional Medicine and Pharmacy Administration, issues a decision to revoke the registration certificate for circulation of traditional drugs and medicinal materials.

**Article 35. Regulations on stopping receiving applications for issuance and extension of registration certificates for circulation of traditional drugs and medicinal materials**

1. Stop receiving dossiers for issuance and extension of registration certificates for circulation of traditional drugs and medicinal herbs shall comply with the provisions of Clauses 2, 3 and 4, Article 100 of Decree No. 54/2017/ND-CP dated January 8. 5 of 2017 of the Government detailing a number of articles and measures to implement the Pharmacy Law .

2. The Minister of Health authorizes the Director of the Department of Traditional Medicine and Pharmacy to issue a decision to stop receiving applications for issuance and extension of circulation registration certificates for traditional drugs and medicinal materials.

**Chapter VI**

**CONSULTATION COUNCIL AND EXPERTS FOR APPRAISAL OF GRANT OF REGISTRATION FOR CIRCULATION OF TRADITIONAL MEDICINES AND PHARMACEUTICAL MEDICINES**

**Article 36. Organization and activities of the Advisory Council for granting registration certificates for circulation of traditional drugs and medicinal materials**

1. The Advisory Council for issuance of drug circulation registration certificates in the field of traditional medicines and medicinal materials (hereinafter referred to as the Advisory Council) is established by the Minister of Health.

2. The Advisory Council is responsible for advising the Minister of Health in granting, extending, changing, and supplementing registration certificates for traditional drugs and medicinal materials circulating in Vietnam. Traditional drugs must be continued. Continue to monitor safety and effectiveness when circulating; Recognizing traditional drugs as exempt from clinical trials or certain stages of clinical trials; policies on harmonizing regulations on registration of drugs and medicinal ingredients with countries in the region and around the world; policies on production, import and circulation of traditional medicines and medicinal materials in Vietnam; the use of traditional drugs and medicinal herbs on Vietnamese people to evaluate the safety and effectiveness of drugs when necessary.

3. The Advisory Council for granting circulation registration includes members who are experts in the fields of quality, preparation, pharmacology, clinical, law, and management of medicinal materials and traditional drugs. The secretary is a representative of the Department of Traditional Medicine and Pharmacy Administration.

4. The Advisory Council operates according to the principle: the advisory opinions of the Advisory Council must ensure legal and scientific basis and must be expressed in the Minutes of the Advisory Council's meeting. The Advisory Council is responsible before the Minister of Health and before the law for those opinions and advice.

5. The Minister of Health promulgates regulations on the organization and operation of the Advisory Council for granting drug registration numbers in the field of traditional drugs and medicinal materials, and the coordination mechanism between the Advisory Council and expert groups appraisal during the process of granting registration numbers for circulation of traditional drugs and medicinal materials at the request of the Director of the Department of Traditional Medicine and Pharmacy Administration.

**Article 37. Organization and activities of experts participating in the appraisal of traditional drug and herbal medicine registration dossiers**

1. The Director of the Department of Traditional Medicine and Pharmacy Administration shall establish groups of experts to evaluate traditional drug and herbal medicine registration dossiers (hereinafter referred to as expert evaluation groups).

2. The group of appraisal experts is responsible for advising the Department of Traditional Medicine and Pharmacy Administration in evaluating the registration dossier and recommending the issuance of a registration certificate or supplementation or non-issuance of a registration certificate.

3. The appraisal expert group operates according to the principle: The appraisal experts' comments or suggestions must ensure a legal and scientific basis and must be expressed in the record of appraisal of the dossier. drug registration. The appraisal expert is responsible before the Director of the Department of Traditional Medicine and Pharmacy Administration and before the law for the contents, advice and suggestions related to the appraisal of registration dossiers.

4. The Traditional Medicine and Pharmacy Administration develops and promulgates regulations on selection criteria, organization and operations of expert groups evaluating registration dossiers; Sign an annual contract with an appraisal expert; pay for experts; Organize appraisal and synthesize appraisal results to submit to the Advisory Council; organize training courses for appraisal experts; Conduct assessment of professional capacity and compliance with regulations to make appropriate adjustments and additions of appraisal experts.Additional

**Chapter VII**

**TERMS ENFORCEMENT**

**Article 38. Effectiveness of implementation**

1. This Circular takes effect from October 28, 2018.

2. Abolish the regulations on registration of oriental medicine prescribed in Circular No. 44/2014/TT-BYT dated November 25, 2014 of the Minister of Health regulating drug registration from the date this Circular takes effect. effect.

3. Abolish the provisions in Clause 3, Article 5, Clause 3, Article 6 and Clause 3, Article 7 of Circular No. 03/2012/TT-BYT dated February 2, 2012 of the Minister of Health guiding on drug testing above clinical.

**Article 39. Transitional provisions**

1. Oriental medicine registration dossiers submitted before the effective date of this Circular are evaluated and granted registration numbers according to the provisions of Circular No. 44/2014/TT-BYT dated November 25, 2014 of The Minister of Health regulates drug registration.

2. For oriental medicines and medicinal herbs that have been granted circulation registration before the effective date of this Circular, 03 months before the expiration of the issued circulation registration, the establishment Register and send the extension dossier to the Traditional Medicine and Pharmacy Administration to act as a focal point and coordinate with the Drug Administration to determine whether the drug is a herbal medicine or a traditional medicine to carry out procedures to extend the circulation registration certificate according to regulations.

**Article 40. Terms of reference**

In case legal documents and regulations cited in this Circular are changed, supplemented or replaced, the new legal documents shall apply.

**Article 41. Implementation organization**

1. The Department of Traditional Medicine and Pharmacy Administration is responsible for:

a) Guidance on implementing the provisions of this Circular;

b) Update the list of traditional drugs and medicinal materials for which circulation registration is granted by the Ministry of Health in batches and other traditional drug and medicinal material registration information on the Department's website (website). Manage Traditional Medicine and Pharmacy within 15 days from the date of issuance of the Decision on issuance of the Certificate of Circulation Registration.

2. Departments of Health of provinces and centrally run cities are responsible for examining and inspecting the implementation of this Circular for pharmaceutical production and business units within their management.

3. The establishment requesting registration for circulation of traditional drugs and medicinal materials is responsible for the legality and accuracy of the registration dossier and the origin and quality of the registered traditional drugs and medicinal materials.

**Article 42. Responsibility for implementation**

Director of the Traditional Medicine and Pharmacy Administration, Chief of the Ministry Office, Chief Inspector of the Ministry, Directors of Departments, Directors, Heads of units under and under the Ministry of Health, Departments of Health of provinces and cities directly under the Ministry of Health. Centrally run, pharmaceutical business establishments and other relevant agencies, organizations and individuals are responsible for implementing this Circular.

During the implementation process, if there are any difficulties or problems, agencies, organizations and individuals should promptly report them to the Traditional Medicine and Pharmacy Administration, Ministry of Health for consideration and resolution./.

**KT. MINISTER**
**DEPUTY MINISTER**

**Nguyen Viet Tien**

***Recipient:***
- Social Affairs Committee of the National Assembly (for reporting);
- Government Office (Official Gazette; Government Portal);
- Minister (to report);
- Deputy Ministers of Health (for information);
- Ministries, ministerial-level agencies, agencies under the Government;
- Ministry of Justice (Department of Inspection of Legal Documents);
- People's Councils, People's Committees of provinces and centrally run cities;
- Department of Health of provinces and centrally run cities;
- Health of Ministries and Sectors;
- Vietnam Pharmaceutical Corporation;
- Vietnam Association of Pharmaceutical Enterprises;
- Vietnam Pharmaceutical Association;
- Association of medicinal herbs;
- Domestic and foreign drug production and trading enterprises;
- MOH electronic information portal;
- Saved: VT, PC, YDCT(03).

## APPENDIX I

REGISTRATION FORMS FOR CIRCULATION
*(Issued together with Circular No. 21/2018/TT-BYT dated September 12, 2018 of the Minister of Health)*

**FORM 01: COVER PAGE**

**TRADITIONAL/MEDICAL MEDICINE REGISTRATION DOCUMENTS**

1. Name and address of the facility registering traditional drugs/herbal ingredients

a) Facility name:

b) Facility address:

2. Name and address of the traditional medicine/herbal medicine manufacturing facility

a) Facility name:

b) Facility address:

3. Name of traditional medicine/herbal medicine:

4. Type of registration: Specify one of the following types: Grant/Extension/Change, supplement.

**FORM NO. 02: RECEPTION FORM**

MINISTRY OF **HEALTH**
**DEPARTMENT OF TRADITIONAL MEDICINE AND PHARMACEUTICAL MANAGEMENT -------**

**SOCIALIST REPUBLIC OF VIETNAM**
**Independence - Freedom - Happiness**
**----------**

**RECEIVING FORM OF DRUGS/MEDICAL REGISTRATION DOCUMENTS**

**Registered company name:**

**The Traditional Medicine and Pharmacy Administration has received the Company's drug registration application(s) as follows:**

| No | Name of medicine/medicinal ingredient | Profile Code | Note |
|---|---|---|---|

| | | | |
|---|---|---|---|
| first | | | |
| 2 | | | |

**Submitted documents include:**

| | Content | Note |
|---|---|---|
| **I.** | **01 set of original documents, including:** | |
| **first.** | **Administrative records and product information** | |
| **2** | **Technical documents** | |
| **3** | **Actual label samples of traditional drugs/medicinal materials circulated in the host country or reference country for imported traditional drugs/medicinal materials** | |
| **4** | **Dossier requesting recognition of traditional drugs exempted from clinical trials or exempted from certain stages of clinical trials (if any)** | |

**Hanoi Day Month Year**

**Person receiving documents**

***Note: The application is considered valid for appraisal after the enterprise has paid the fee and received the fee receipt at the Financial Planning Department - Traditional Medicine and Pharmacy Administration (Phone: )***

**FORM NO. 03: APPLICATION FOR ISSUANCE OF REGISTRATION CERTIFICATE**

**FORM NO. 03A: APPLICATION FOR ISSUANCE OF TRADITIONAL MEDICINE REGISTRATION CERTIFICATE (EXCLUDING TRADITIONAL MEDICINES)**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |
| | |

**II. Product details**

**1. Product name, dosage form:**

1.1. Tradenames:

1.2. Dosage forms:

1.3. Route of use:

1.4. Registration certificate No.[3] : date of issue: date of expiration:

**2. Product description:**

2.1. Description of dosage form:

2.2. Description of packaging:

2.3. Quality standards:

2.4. Due date:

2.5. Storage conditions:

**3. Formula (including content of medicinal ingredients and excipients) for the smallest dosage unit or for the smallest packaging unit**

| TT | Ingredient | Content | Identify medicinal ingredients/excipients | Manufacturer (name, address) | Standard[1] |
|---|---|---|---|---|---|
| first | | | | | |
| 2 | | | | | |

**III. Attached documents include:**

1. Administrative records

2. Technical records

3. Intellectual property documents (if any)

**IV. Recommend data security for registered drugs**

The drug registration facility requests the Traditional Medicine and Pharmacy Administration to consider implementing confidentiality for the following data submitted with the drug registration dossier:

□ Toxicity test data (Document No....)

□ Clinical drug trial data (Document No....)

The drug registration facility hereby commits that the above data fully meets the data security conditions as prescribed by law and the drug registration facility will fulfill the burden of proof when approved by the competent authority. request.

**V. Commitment of the registration facility**

The drug registration facility hereby commits to:

1. Checked, signed and stamped the relevant parts of all documents submitted in this drug registration application and confirmed that these are legal documents and the content is true. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

2. Ensure that the drug is manufactured in accordance with the submitted application for drug registration.

3. Notify and request permission from the competent authority according to regulations when there are any changes to the drug registration dossier when the drug has been granted a circulation registration number.

4. Take full responsibility for intellectual property related to the drug applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[3] *Only fill in in case of applying for a marketing registration certificate according to the provisions of Point c, Clause 2, Article 55 of the Pharmaceutical Law .*

[1] *If it is a Pharmacopoeia standard, please clearly state which version*

**FORM NO. 03B: APPLICATION FOR Issuance of TRADITIONAL MEDICINE REGISTRATION CERTIFICATE**

**1. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |
| | |

**II. Product details**

**1. Product name, processing method:**

1.1. Tradenames:

1.2. Processing method:

1.3. Registration certificate No.[3]: date of issue: date of expiration:

**2. Product description:**

2.1. Description of packaging:

2.2. Quality standards:

2.3. Due date:

2.4. Storage conditions:

**3. Formula (including content of medicinal ingredients and auxiliary ingredients) for the smallest dosage unit or for the smallest packaging unit**

| TT | Ingredient | Content | Identify medicinal ingredients/auxiliary ingredients | Manufacturer (name, address) | Standard [1] |
|---|---|---|---|---|---|
| first | | | | | |
| 2 | | | | | |

**III. Attached documents include:**

1. Administrative records

2. Technical records

3. Intellectual property documents (if any)

**IV. Commitment of the registration facility**

The drug registration facility hereby commits to:

1. Checked, signed and stamped the relevant parts of all documents submitted in this traditional medicine registration application and confirmed that these are legal documents and the content is true. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

2. Ensure that traditional medicines are produced in accordance with the documents submitted for registration of traditional medicines.

3. Notify and request permission from the competent authority according to regulations when there are any changes to the traditional medicine registration dossier when the traditional medicine has been granted a circulation registration number.

4. Take full responsibility for intellectual property related to the traditional medicine applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[3] *Only fill in in case of applying for a marketing registration certificate according to the provisions of Point c, Clause 2, Article 55 of the Pharmaceutical Law .*

[1] *If it is a Pharmacopoeia standard, please clearly state which version*

**FORM 03C: APPLICATION FOR PHARMACEUTICAL INGREDIENT REGISTRATION CERTIFICATE**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |

**II. Product details**

**1. Product name:**

**2. Product description:**

2.1. Description of packaging:

2.2. Quality standards:

2.3. Due date:

2.4. Storage conditions:

2.5. Registration certificate No.[3] : date of issue: date of expiration:

**III. Attached documents include:**

1. Administrative records

2. Technical records

3. Intellectual property documents (if any)

**IV. Commitment of the registration facility**

The drug registration facility hereby commits to:

1. Checked, signed and stamped the relevant parts of all documents submitted in this medicinal herb registration application and confirmed that these are legal documents and the content is true. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

2. Ensure that medicinal materials are produced in accordance with the documents submitted for registration of medicinal materials.

3. Notify and request permission from the competent authority according to regulations when there are any changes to the medicinal material registration dossier when the medicinal material has been granted a circulation registration number.

4. Take full responsibility for intellectual property related to the medicinal materials applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[3] *Only fill in in case of applying for a marketing registration certificate according to the provisions of Point c, Clause 2, Article 55 of the Pharmaceutical Law .*

**FORM NO. 04: APPLICATION FOR RENEWAL OF TRADITIONAL MEDICINE REGISTRATION CERTIFICATE**

**FORM NO. 04A: APPLICATION FOR RENEWAL OF TRADITIONAL MEDICINE REGISTRATION CERTIFICATE (EXCLUDING TRADITIONAL MEDICINES)**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered facility

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |
| | |

**II. Product details**

**1. Product name, dosage form:**

1.1. Tradenames:

1.2. Dosage forms:

1.3. Route of use:

1.4. Registration number: date of issue: date of expiration:

**2. Product description:**

2.1. Description of dosage form:

2.2. Description of packaging:

2.3. Quality standards:

2.4. Due date:

2.5. Storage conditions:

**3. Formula (including content of medicinal ingredients and excipients) for the smallest dosage unit or for the smallest packaging unit**

| TT | Ingredient | Content | Identify medicinal ingredients/excipients | Manufacturer (name, address) | Standard [1] |
|---|---|---|---|---|---|
| first | | | | | |
| 2 | | | | | |

**III. Documents accompanying the provisions of this Circular include:...**

**IV. Commitment of the registration facility**

The drug registration facility hereby commits to:

1. The drug is actually circulating on the market.

2. During the process of circulation, the drug does not violate regulations on drug registration, circulation and other provisions of law.

3. Checked and confirmed that the above content is true. The attached documents are identical to those submitted to the Department of Traditional Medicine and Pharmacy Administration. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

4. Take full responsibility for intellectual property related to the drug applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[1] *If it is a Pharmacopoeia standard, please clearly state which version*

**FORM NO. 04B: APPLICATION FOR RENEWAL OF TRADITIONAL MEDICINE REGISTRATION PAPER**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility** [1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role [2] |
|---|---|
| | |
| | |

**II. Product details**

**1. Product name, processing method:**

1.1. Name of traditional medicine:

1.2. Processing method:

1.3. Registration number: date of issue: date of expiration:

**2. Product description:**

2.1. Description of processing method:

2.2. Description of packaging:

2.3. Quality standards:

2.4. Due date:

2.5. Storage conditions:

**3. Formula (including content of medicinal ingredients and auxiliary ingredients) for the smallest dosage unit or for the smallest packaging unit**

| TT | Ingredient | Content | Identify medicinal ingredients/auxiliary ingredients | Manufacturer (name, address) | Standard [1] |
|---|---|---|---|---|---|
| first | | | | | |
| 2 | | | | | |

**III. Documents accompanying the provisions of this Circular include:...**

**IV. Commitment of the registration facility**

The traditional medicine registration facility hereby commits to:

1. The traditional medicine is actually circulating on the market.

2. During the process of circulation, the traditional medicine does not violate regulations on registration, circulation of drugs and other provisions of law.

3. Checked and confirmed that the above content is true. The attached documents are identical to those submitted to the Department of Traditional Medicine and Pharmacy Administration. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

4. Take full responsibility for intellectual property related to the traditional medicine applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[1] *If it is a Pharmacopoeia standard, please clearly state which version*

**FORM NO. 04C: APPLICATION FOR RENEWAL OF PHARMACY REGISTRATION CERTIFICATE**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |

**II. Product details**

**1. Product name:**

**2. Registration number:** date of issue: date of expiration:

**3. Product description:**

3.1. Description of packaging:

3.2. Quality standards:

3.3. Due date:

3.4. Storage conditions:

**4. Report the number of batches of medicinal materials imported or produced**

**III. Documents accompanying the provisions of this Circular include:...**

**IV. Commitment of the registration facility**

The traditional medicine registration facility hereby commits to:

1. Actual medicinal materials circulated on the market.

2. During the process of circulation, medicinal materials do not violate regulations on registration, circulation of drugs and other provisions of law.

3. Checked and confirmed that the above content is true. The attached documents are identical to those submitted to the Department of Traditional Medicine and Pharmacy Administration. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

4. Take full responsibility for intellectual property related to the medicinal materials applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

**FORM NO. 05: APPLICATION FOR CHANGES AND ADDITIONS TO TRADITIONAL MEDICINE REGISTRATION DOCUMENTS**

**FORM NO. 05A: APPLICATION FOR CHANGES AND ADDITIONS TO TRADITIONAL MEDICINE REGISTRATION DOCUMENTS (EXCLUDING TRADITIONAL MEDICINES)**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered facility

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |

**II. Product details**

**1. Product name, dosage form:**

1.1. Tradenames:

1.2. Dosage forms:

1.3. Route of use:

1.4. Registration number: date of issue: date of expiration:

**2. Product description:**

2.1. Description of dosage form:

2.2. Description of packaging:

2.3. Quality standards:

2.4. Due date:

2.5. Storage conditions:

**3. Formula (including content of medicinal ingredients and excipients) for the smallest dosage unit or for the smallest packaging unit**

| TT | Ingredient | Content | Identify medicinal ingredients/excipients | Manufacturer (name, address) | Standard [1] |
|---|---|---|---|---|---|
| first | | | | | |
| 2 | | | | | |

**III. Content and reason for change**

1. Changed content:

2. Reason for change:

**IV. Attached technical documents [2]:**

first.

2.

**V. Commitment of the registration facility**

The registration facility hereby commits to have checked, signed and stamped the relevant parts of all documents submitted in this application and confirms that these are legal documents and the content is true. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

Date... month... year
**Director of drug registration facility**
*(Sign directly, write full name, stamp)*

---

1 *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

2 *Clearly state the preparation stage, "research organization contract", franchising,...*

1 *If it is a Pharmacopoeia standard, please clearly state which version*

*2* *Technical documents corresponding to each changed content as prescribed in the Appendix to this Circular.*

**FORM NO. 05B: APPLICATION FOR CHANGES AND ADDITIONS TO TRADITIONAL MEDICINE REGISTRATION DOCUMENTS**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |
| | |

**II. Product details**

**1. Product name, processing method:**

1.1. Name of traditional medicine:

1.2. Processing method:

1.3. Registration number: date of issue: date of expiration:

**2. Product description:**

2.1. Description of processing method:

2.2. Description of packaging:

2.3. Quality standards:

2.4. Due date:

2.5. Storage conditions:

**3. Formula (including content of medicinal ingredients and auxiliary ingredients) for the smallest dosage unit or for the smallest packaging unit**

| TT | Ingredient | Content | Identify medicinal ingredients/auxiliary ingredients | Manufacturer (name, address) | Standard[1] |
|---|---|---|---|---|---|
| first | | | | | |
| 2 | | | | | |

**III. Content and reason for change**

1. Changed content:

2. Reason for change:

**IV. Attached technical documents [2] :**

first.

2.

**V. Commitment of the registration facility**

The registration facility hereby commits to have checked, signed and stamped the relevant parts of all documents submitted in this application and confirms that these are legal documents and the content is true. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

Date... month... year
**Director of drug registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[1] *If it is a Pharmacopoeia standard, please clearly state which version*

[2] *Technical documents corresponding to each changed content as prescribed in the Appendix to this Circular.*

**FORM NO. 05C: APPLICATION FOR CHANGES AND ADDITIONS TO PHARMACY REGISTRATION DOCUMENTS**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility [1]**

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role [2] |
|---|---|
| | |
| | |

**II. Product details**

**1. Product name:**

**2. Registration number:** date of issue: date of expiration:

**3. Product description:**

3.1. Description of packaging:

3.2. Quality standards:

3.3. Due date:

3.4. Storage conditions:

**III. Content and reason for change**

1. Changed content:

2. Reason for change:

**IV. Technical documents attached [1] :**

first.

2.

**V. Commitment of the registration facility**

The registration facility hereby commits to have checked, signed and stamped the relevant parts of all documents submitted in this application and confirms that these are legal documents and the content is true. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

Date... month... year
**Director of drug registration facility**
*(Sign directly, write full name, stamp)*

---

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

[3] *Technical documents corresponding to each change content as prescribed in the Appendix to this Circular.*

**FORM NO. 06: SUMMARY OF PRODUCTS REQUIRED FOR CIRCULATION REGISTRATION CERTIFICATE**

**FORM NO. 06A: Summary of products requesting circulation registration certificate for traditional drugs**

**(not including traditional medicine)**

**PRODUCT SUMMARY**

| | |
|---|---|
| **Drug name:** | |
| **Dosage forms:** | |
| **Registered company name:**<br>Address:<br>Phone:<br>Fax: | **Name of manufacturing facility (name of franchisor and franchisee** *for franchised drugs).*<br>Address:<br>Phone:<br>Fax: |
| **Name of representative office in Vietnam (for foreign drugs) or headquarters of the company registering the drug in the** | **Name of packaging facility (if any):** |

| | |
|---|---|
| **country** *(if different from the registered company address)*<br>Address:<br>Phone:<br>Fax | Address:<br>Phone:<br>Fax: |
| **Storage conditions:** | **Due date:** |
| **Route of use:** | **Standard** [1] |

**Dosage formula** *(for one dose unit or smallest packaging unit)*

*Ingredient:*

| Name of medicinal material, parts used | Mass | Manufacturer (name, detailed address) | Standard [21] |
|---|---|---|---|
| | | | |

| Excipients | Content | Manufacturer (name, detailed address) | Standard [21] |
|---|---|---|---|
| | | | |

**Packaging process:**

_____

[1] If it is a Pharmacopoeia standard, please clearly state the version

**FORM NO. 06B: Summary of products requesting circulation registration certificate for traditional medicine**

**PRODUCT SUMMARY**

| | |
|---|---|
| **Name of traditional medicine:** | |
| **Processing method:** | |
| **Registered company name:**<br>Address:<br>Phone:<br>Fax: | **Name of manufacturing facility (name of franchisor and franchisee** *for franchised drugs):*<br>Address:<br>Phone:<br>Fax: |
| **Name of representative office in Vietnam (for foreign drugs) or headquarters of the company registering the drug in the country** *(if different from the registered company address)*<br>Address:<br>Phone:<br>Fax | **Name of packaging facility (if any):**<br>Address:<br>Phone:<br>Fax: |
| **Storage conditions:** | **Due date:** |
| **Standard** [1] **:** | |

**Processing formula** *(for one dose unit or smallest packaging unit)*

*Ingredient:*

| Name of medicinal material, parts used | Mass | Manufacturer (name, detailed address) | Standard [22] |
|---|---|---|---|
| | | | |

| Accessories | Content | Manufacturer (name, detailed address) | Standard [22] |
|---|---|---|---|
| | | | |

**Packaging process:**

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1 If it is a Pharmacopoeia standard, please clearly state the version

**FORM NO. 06C: Summary of products requested for circulation registration certificate for medicinal herbs**

**PRODUCT SUMMARY**

| | |
|---|---|
| **Name of medicinal material:** | **Parts used:** |
| **Science name:** | |
| **Registered company name:**<br>Address:<br>Phone:<br>Fax: | **Name of manufacturing facility (name of franchisor and franchisee** *for franchised drugs):*<br>Address:<br>Phone:<br>Fax: |
| **Name of representative office in Vietnam (for foreign drugs) or headquarters of the company registering the drug in the country** *(if different from the registered company address)*<br>Address:<br>Phone:<br>Fax | **Name of packaging facility (if any):**<br>Address:<br>Phone:<br>Fax: |
| **Storage conditions:** | **Due date:** |
| **Standard [1]:** | |
| **Packaging process:** | |

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1 If it is a Pharmacopoeia standard, please clearly state the version

**FORM NO. 07: SUMMARY OF PRODUCTS RECOMMENDED FOR RENEWAL OF CIRCULATION REGISTRATION PAPER**

**FORM NO. 07A: Summary of products requesting extension of circulation registration certificate for traditional drugs (not including traditional drugs)**

**PRODUCT SUMMARY**

| | |
|---|---|
| **Drug name:** | |
| **Dosage forms:** | |
| **Registered company name:**<br>Address:<br>Phone:<br>Fax: | **Name of manufacturing facility (name of franchising facility and franchisee** *for franchised drugs)* .<br>Address:<br>Phone:<br>Fax: |
| **Name of representative office in Vietnam (for foreign drugs) or headquarters of the company registering the drug in the country** *(if different from the registered company address)*<br>Address:<br>Phone: | **Name of packaging facility (if any):**<br>Address:<br>Phone:<br>Fax: |

| | |
|---|---|
| Fax | |
| **Storage conditions:** | **Due date:** |
| **Route of use:** | **Standard** [1] |
| **Circulation registration certificate:**<br>**Date of issuance of circulation registration certificate:**<br>**1st extension:**<br>**Second extension:** | **Registration expiration date:**<br>**Expiry date of 1st renewal:**<br>**Expiry date of second extension:** |

**Dosage formula** *(for one dose unit or smallest packaging unit)*

*Ingredient:*

| Name of medicinal material, parts used | Mass | Manufacturer (name, detailed address) | Standard [1] |
|---|---|---|---|
| | | | |

| Excipients | Content | Manufacturer (name, detailed address) | Standard [24] |
|---|---|---|---|
| | | | |

**Packaging process:**

_____

[1] If it is a Pharmacopoeia standard, please clearly state the version

**FORM NO. 07B: Summary of products requesting extension of circulation registration certificate for traditional medicine**

**PRODUCT SUMMARY**

| | |
|---|---|
| **Name of traditional medicine:** | |
| **Processing method:** | |
| **Registered company name:**<br>Address:<br>Phone:<br>Fax: | **Name of manufacturing facility (name of franchising facility and franchisee** *for franchised drugs)* .<br>Address:<br>Phone:<br>Fax: |
| **Name of representative office in Vietnam (for foreign drugs) or headquarters of the company registering the drug in the country** *(if different from the registered company address)*<br>Address:<br>Phone:<br>Fax | **Name of packaging facility (if any):**<br>Address:<br>Phone:<br>Fax: |
| **Storage conditions:** | **Due date:** |
| **Standard** [1] **:** | |
| **Circulation registration certificate:**<br>Date of issuance of circulation registration certificate:<br>1st extension:<br>Second extension: | <br>Registration expiration date:<br>Expiry date of 1st renewal:<br>Expiry date of second extension: |

**Processing formula** *(for one dose unit or smallest packaging unit)*

*Ingredient:*

| Name of medicinal material, parts used | Mass | Manufacturer (name, detailed address) | Standard [1] |
|---|---|---|---|
| | | | |

| Accessories | Content | Manufacturer (name, detailed address) | Standard [1] |
|---|---|---|---|
| | | | |

**Packaging process:**

_____

[1] If it is a Pharmacopoeia standard, please clearly state the version

**FORM NO. 07C: Summary of products requesting extension of circulation registration certificate for medicinal herbs**

**PRODUCT SUMMARY**

| **Name of medicinal material:** | |
|---|---|
| **Registered company name:**<br>Address:<br>Phone:<br>Fax: | **Name of manufacturing facility (name of franchising facility and franchisee** *for franchised drugs)* .<br>Address:<br>Phone :<br>Fax: |
| **Name of representative office in Vietnam (for foreign drugs) or headquarters of the company registering the drug in the country** *(if different from the registered company address)*<br>Address:<br>Phone:<br>Fax | **Name of packaging facility (if any):**<br>Address:<br>Phone:<br>Fax: |
| **Storage conditions:** | **Due date:** |
| **Standard [1] :** | |
| **Circulation registration certificate:**<br>Date of issuance of circulation registration certificate:<br>1st extension:<br>Second extension: | <br>Registration expiration date:<br>Expiry date of 1st renewal:<br>Expiry date of second extension: |

**Packaging process:**

_____

[1] If it is a Pharmacopoeia standard, please clearly state the version

**FORM NO. 08: REPORT ON SAFETY AND EFFECTIVENESS OF TRADITIONAL MEDICINES/TOXIC PHARMACEUTICAL MEDICINES**

**FORM 08A: Report on safety and effectiveness of traditional drugs/toxic medicinal herbs of the registration facility**

**REPORT ON SAFETY AND EFFECTIVENESS OF TRADITIONAL MEDICINES/TOXIC PHARMACEUTICAL MEDICINES**

**Name of registered facility**

**SOCIALIST REPUBLIC OF VIETNAM**
**Independence - Freedom - Happiness**
**----------**

Number: ……. *……., date …. year …….*

To: Ministry of Health (Department of Traditional Medicine and Pharmacy Administration)

Implement regulations on reporting the safety and effectiveness of traditional drugs/toxic medicinal materials during circulation and when registering for renewal of traditional drugs that require reporting on safety, effectiveness or pharmacology. toxic materials, establishments.... report on the situation of using traditional drugs/toxic medicinal materials as follows:

1. Name of registered facility (address):

2. Name of manufacturing facility (address):

3. Name of medicine/medicinal ingredient:

4. Dosage form[1]:

5. Formula, ingredients[1]:

6. Indication[1]:

7. Route[1]:

8. Registration certificate number: Date of issuance of registration certificate: Date of expiration of registration certificate:

9. Summary table of reports of adverse reactions of toxic drugs/medicinal materials sent to ADR Centers and national drug information related to unwanted effects of the drug after the drug was put into circulation on the market Vietnam market *(attached with copies of reports according to the Form of the National Center for Drug Information and Adverse Drug Reaction Monitoring)*

10. Summary table of the use of toxic drugs/medicinal herbs at medical examination and treatment facilities nationwide *(attached with a certified report of each medical examination and treatment facility according to form 08B)* includes:

- Information about medical examination and treatment facilities that use toxic drugs/herbal ingredients *(specify name and address of each facility):*

- Total amount of toxic drugs/herbal ingredients used:

- Total number of patients who have used toxic drugs/medicinal herbs:

- Used Time:

11. Summary table of information updates on the safety and effectiveness of drugs/medicinal materials that have been made during the circulation process (updates approved by the Traditional Medicine and Pharmacy Administration; updates with notification; updates according to official guidance of the Department of Traditional Medicine and Pharmacy (if any).

12. Summary table of results of clinical studies conducted in Vietnam (if any). The registration facility commits: the reported content is true. If it is not correct, the facility will take full responsibility./.

Date... month... year
**Director of registration facility** *or*
**Chief representative in Vietnam**
*(Sign directly, write full name, stamp)*

---

[1] If it is a toxic medicinal material, this content does not need to be reported.

**FORM 08B: Report on the use of traditional medicines/toxic medicinal herbs**

**REPORT ON THE USE OF TRADITIONAL MEDICINES/TOXIC MEDICINES**

**Name of medical examination and treatment facility**

**SOCIALIST REPUBLIC OF VIETNAM**
**Independence - Freedom - Happiness**
**----------**

Number:…… *……., day month Year ……*

To: Ministry of Health (Department of Traditional Medicine and Pharmacy Administration)

Implement regulations on reporting the safety and effectiveness of toxic drugs/medicinal ingredients when re-registering for drugs that require reporting of safety, effectiveness or toxic medicinal ingredients, basis.... reporting The situation of using toxic drugs/medicinal materials is as follows:

1. Drug name/herbal ingredient name:

2. Registration number:

3. Dosage form [1]:

4. Medicinal ingredients, concentration/content [1]:

5. Quantity of drugs/herbal ingredients used:

6. Number of patients who have used drugs/medicinal herbs:

7. Usage time:

8. Evaluate the safety and effectiveness of used drugs/herbal ingredients *(with attached data).*

9. Adverse drug/medicinal reactions (ADR): ADR manifestations, number of cases, results of ADR handling *(attached data).*

10. Recommendations and suggestions (specify whether to continue using drugs/herbal ingredients at the treatment facility or not?).

(Treatment facility) commits and takes responsibility for the above report contents./.

**Director/Deputy Director of**
**medical examination and treatment facility**
*(Sign directly, write full name, stamp)*

***Destination***
as above;
- Company registration;
- Save:….

_____

[1] If it is a toxic medicinal material, this content does not need to be reported.

**FORM NO. 09: AUTHORIZATION LETTER**

**Form 09A -** Authorization to be in the name of the registration facility;

**Form 09B -** Authorization to sign the drug/medicinal registration application;

**Form 09C -** Authorization to use trademarked drug/medicinal ingredients.

**Form 09A**

**AUTHORIZATION IN THE NAME OF THE REGISTRATION FACILITY**

Title of the company (name, address of the authorized facility)

**AUTHORIZATION LETTER**

We, ……

(Name and address of product owner)

This document appoints…….

(Name and address of registered facility)

On our behalf, the establishment registers the following products:

Product's name:

Dosage form/processing method, content:

Number of issued Registration Certificate (for drugs/medicinal ingredients registered for renewal, registration of changes or supplements):

at the Ministry of Health (Department of Traditional Medicine and Pharmacy Administration)

The company (_____) - the authorized facility - will be the owner of the circulation registration number and responsible to the Ministry of Health (Traditional Medicine and Pharmacy Administration) for all issues related to This product is in Vietnam.

| **Director or legal representative of the authorized facility** | **Director or legal representative of the authorized establishment** |
|---|---|
| Signed (signed directly), stamped: | Signed (signed directly), stamped: |
| *Day month Year* | *Day month Year* |

**Form 09B**

**AUTHORIZATION TO SIGN ON DRUGS/MEDICAL REGISTRATION DOCUMENTS**

Title of the company (name, address of the authorized facility)

**AUTHORIZATION LETTER**

We, ……

(Name and address of product owner/drug registration facility)

This document authorizes Mr./Ms. …….

Chief representative of the company's representative office in ……, Vietnam signs and stamps the representative office's seal on our behalf on the product documents:

Product's name:

Dosage form/processing method, content:

Number of issued Registration Certificate (for drugs/medicinal ingredients registered for renewal, registration of changes or supplements):

Registered at the Ministry of Health (Department of Traditional Medicine and Pharmacy Administration)

Validity period of authorization letter:

The person authorized to sign the application will be responsible to the Ministry of Health (Traditional Medicine and Pharmacy Administration) for all issues related to this product in Vietnam.

| **Director or legal representative of the authorized facility** | **Head of authorized representative office** |
|---|---|
| Signed (signed directly), stamped: | Signed (signed directly), stamped: |
| *Day month Year* | *Day month Year* |

**Form 09C**

**AUTHORIZATION TO USE REGISTERED TRADEMARK NAME OF MEDICINE/MEDICAL MEDICINE**

(When the trademark owner is not the drug/medicinal registration facility)

Title of the company (name, address of the firm)

**AUTHORIZATION LETTER**

We, ……

(Name and address of registered trademark owner - authorization basis)

I hereby agree to: …….

(Name and address of authorized facility)

Copyright:

Validity period of authorization: this authorization is valid from .... to……

We commit that allowing the company (_____) to use the above registered trademark does not violate the legal intellectual property rights of any third party and commit to take full responsibility in case there was a dispute.

| **Director or legal representative of the authorized facility** | **Director or legal representative of the authorized establishment** |
|---|---|
| Signed and sealed_____ | Signed and sealed_____ |
| *Day month Year* | *Day month Year* |

**FORM NO. 10: REPORT ON THE PROCESS OF CIRCULATION OF TRADITIONAL MEDICINES/PHARMACEUTICAL MEDICINES**

**REPORT ON THE CIRCULATION PROCESS OF TRADITIONAL/MEDICAL MEDICINES**

*(From the time the Registration Certificate is issued until the Registration Certificate is renewed)*

1. Name of registered facility (address):

2. Name of manufacturing facility (address):

3. Name of drug/medicinal ingredient that has been granted Registration Certificate:

4. Dosage form/Processing method:

5. Preparation formula:

6. Registration certificate: date of issue:

7. Circulation on the market:

Yes □ No □

8. Quality violations:

Yes □ No □

*If so, please clearly state the violating content:*

- Number of violations: - Type of violation:

9. Violation of regulations and regulations related to registration of drugs/medicinal materials and circulation of drugs/medicinal materials:

Yes □ No □

*If there is a violation, clearly state the violation content:*

- Number of violations: - Violation content:

10. Changes during the validity period of the Registration Certificate compared to the application for which the Registration Certificate was issued:

Yes □ No □

*If there are any changes, please attach a copy of the official letter of approval.*

11. Changes when renewing the Registration Certificate (expired Registration Certificate) compared to the application for issuance of the Registration Certificate:

Yes □ No □

*If there is any change, the content of the change must be clearly stated compared to the approved application for issuance of the Registration Certificate.*

The registration company commits that: other than the contents requested to be changed in section 8 of the report on circulation of traditional drugs/herbal herbs, there will be no changes compared to the approved application for issuance of the Registration Certificate.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

**FORM NO. 11: APPLICATION FOR REVOKING REGISTRATION PAPER**

**I. Information about the registration facility and manufacturing facility**

**1. Registration facility (the facility that owns the circulation registration certificate)**

1.1. Name of registered establishment:

1.2. Address: Website *(if any)*

1.3. Phone number: Fax number:

email:

1.4. Name and address of representative office or contact person in Vietnam (if any):

Name:

Landline phone: Mobile phone:

Contact address:

**2. Production facility**[1]

2.1. Name of manufacturing facility

2.2. Address: Website *(if any)*

2.3. Phone number: Fax number:

email:

2.4. Other production facilities:

| Name and address | Role[2] |
|---|---|
| | |

**II. Product details**

**1. Product name:**

**2. Registration number:** date of issue: date of expiration:

**3. Product description:**

3.1. Description of packaging:

3.2. Quality standards:

3.3. Due date:

3.4. Storage conditions:

**4. Report the batch number of traditional drugs/medicinal materials imported or produced**

**III. Reason for recall:**

**IV. Commitment of the registration facility**

The registration facility hereby commits to:

1. Traditional medicines/medicinal herbs are actually circulating on the market.

2. After the registration of circulation of traditional drugs/medicinal herbs is revoked, the company will recall the products circulating on the market.

3. Checked and confirmed that the above content is true. The attached documents are identical to those submitted to the Department of Traditional Medicine and Pharmacy Administration. If there is any falsification or untruth, the registration facility will take full responsibility and will be punished according to the provisions of law.

4. Take full responsibility for intellectual property related to traditional drugs/medicinal materials applying for registration.

Date... month... year
**Director of registration facility**
*(Sign directly, write full name, stamp)*

_____

[1] *The final manufacturer is responsible for releasing the product batch. In case the production facility is a registered facility, there is no need to fill in the information.*

[2] *Clearly state the preparation stage, "research organization contract", franchising,...*

**APPENDIX II.1**

CASES OF CHANGE AND ADDITION TO THE CIRCULATION REGISTRATION DOCUMENT ARE IMPLEMENTED IMMEDIATELY AFTER THE DATE THE RECEIVING AGENCY ISSUES THE DOCUMENT RECEIVING FORM
*(Issued together with Circular No. 21/2018/TT-BYT dated September 12, 2018). 2018 by the Minister of Health)*

| Status | Content changes/additions | Condition | Request records |
|---|---|---|---|
| first | Add or remove content on the label, including instructions for use | Content unrelated to the professional aspects of traditional medicines and medicinal herbs *(logos, additional distribution companies...)* | 1. Official dispatch reporting changes and additions;<br>2. Approved old label + new label (clearly state the changes on the label); |
| 2 | Change material characterization | | 1. Official dispatch reporting changes and additions;<br>2. The change section involves changing the material's characterization |
| 3 | Change standards to test materials | Applicable to cases of change or supplementation of registration papers for circulation of traditional drugs (excluding traditional drugs and medicinal herbs); | 1. Official dispatch reporting changes and additions;<br>2. Changes related to changes in quality standards and testing methods. |
| 4 | Change the stability/shelf life of ingredients | Does not affect the quality of traditional medicines (excluding traditional medicines and medicinal herbs); | 1. Official dispatch reporting changes and additions;<br>2. Related changes and guidance on stability studies. |
| 5 | Change storage conditions of raw materials | Applicable to cases of change or supplementation of registration papers for circulation of traditional drugs (excluding traditional drugs and medicinal herbs); | 1. Official dispatch reporting changes and additions;<br>2. Related changes and guidance on stability studies. |
| 6 | Changing the production process of raw materials: Diagram, steps, batches, batches, process appraisal... *(not including traditional medicines and medicinal herbs).* | - In the direction of improving the old process.<br>- Does not change the quality and stability of ingredients. | 1. Official dispatch reporting changes and additions;<br>2. Changes related to the production process. |
| 7 | Change packaging supplier *(replace, add or remove)* | - Does not change the quality and stability of the drug | 1. Official dispatch reporting changes and additions. |
| 8 | Changing standards and/or testing methods of raw materials *(only applicable to changes and additions to the circulation registration certificate of traditional drugs* | - Does not change or affect the standards and quality of finished drugs. | 1. Official dispatch reporting changes and additions. |

| | | | |
|---|---|---|---|
| | *(excluding traditional drugs and medicinal herbs);* | - Or make the quality standards of finished products stricter or better. | 2. Changes related to quality standards and testing methods. |
| 9 | Alternate medication measuring devices *(e.g., from spoon to cup)* | | 1. Official dispatch reporting changes and additions. |
| ten | Other changes at the request of the establishment registering traditional drugs and medicinal materials in the cases specified in Appendix II.2 | - Does not change or affect the quality and effectiveness of the drug. | Papers and documents corresponding to changes |

**APPENDIX II.2.**

CASES OF CHANGE AND ADDITION TO THE CIRCULATION REGISTRATION DOCUMENT MUST HAVE WRITTEN ACCEPTANCE OF THE DOCUMENT RECEIVING AGENCY

*(Issued together with Circular No. 21/2018/TT-BYT dated September 12, 2018 of Health Minister)*

| **Status** | **Content changes/additions** | **Condition** | **Documentation requirements need to be submitted** |
|---|---|---|---|
| first | Change the name and/or address of the registered facility | The registry basis remains unchanged | Confirmation from the competent authority allowing change of name and/or address of the registered establishment. |
| 2 | Change of registration facility (from one facility to another) | Other parts remain unchanged | Legal entity licenses of the new registered establishment. |
| 3 | Change the name and/or address of the manufacturing facility/packaging facility | - Production location remains unchanged<br>- Other parts remain unchanged<br>- Or that production facility is owned by another legal entity (in accordance with the provisions of law). | - Certificate of eligibility for pharmaceutical business in the scope of traditional medicine production<br>- Confirmations from competent authorities allowing changes. |
| 4 | Change production location/packaging facility | - Manufacturer does not change<br>- New production location in the same country as the old location. | 1. License (CPP or GMP certificate).<br>2. Certificate of eligibility for production<br>3. Technical records: Production process; quality standards and testing methods |
| 5 | Changing or adding excipient ingredients (including changing the excipient ratio). | - Does not change or affect the standards and quality of finished drugs. | Technical records: Production process; quality standards and testing methods |
| 6 | Change batch release basis | | Technical profile: corresponding change section |
| 7 | Change drug name | | - Drug circulation permit (CPP) with new name in the country where the drug production facility is located (for imported drugs). |
| 8 | Change the characterization of the finished product | | Technical file: related changes section |
| 9 | Change the standard to test the finished product | | Technical file: related changes section |
| ten | Change the closing system of direct and indirect packaging | - Better quality<br>- more stable | Technical file: Related changes section |
| 11 | Change in stability/expiry date of traditional/herbal medicines | | |
| 11.1 | Increase shelf life | | Technical file: Related changes and guidance on stability studies |
| 11.2 | Reduced expiration date | | 1. Technical records: Related changes and instructions on stability studies<br>2. Report the number of traditional medicines/medicinal herbs circulating on the market |

| | | | |
|---|---|---|---|
| | | | 3. Commit to recalling traditional medicines/medicinal herbs with a shelf life longer than the new one. |
| twelfth | Change storage conditions of traditional medicines/medicinal herbs | | Technical file: Related changes and guidance on stability studies |
| 13 | Change storage conditions of raw materials | | Technical file: Related changes and guidance on stability studies |
| 14 | Changing the production process of drugs/medicinal ingredients: Diagram, steps, batches, batches, process validation... | In the direction of improving the old process | Technical records: Related documents. |
| 15 | Change standards and/or testing methods of finished products *(including validation of analytical methods)*. | In a stricter direction | Technical records: Related documents. |
| 16 | Change/addition of packaging specifications | | 1. Approved old label + new label<br><br>2. Technical records: Including (1) Packaging standards (if there are changes in packaging, packaging quality) (2) Records monitoring the stability of the new packaging (if there are changes in packaging). primary envelope). |
| 17 | Change the form/design of packaging and labels | In a better direction and the label content remains unchanged | 1. Approved old label + new label<br><br>2. Technical records: Related documents.. |