MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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CIRCULARS

REGULATIONS ON REGISTRATION OF CIRCULATION OF DRUGS AND MEDICINAL INGREDIENTS

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;

Pursuant to Decree No. 155/2018/ND-CP dated November 12, 2018 of the Government amending and supplementing a number of regulations related to business investment conditions under the state management of the Ministry of Health economic;

At the request of the Director of the Drug Administration of Vietnam.

The Minister of Health promulgates a Circular regulating the registration for circulation of drugs and medicinal ingredients.

Chapter I

GENERAL RULES

Article 1. Scope

1. This Circular details:

a) Documents and procedures for issuance, extension, change, supplementation, and revocation of registration papers for circulation of pharmaceutical chemicals, vaccines, biological products, herbal drugs, and medicinal ingredients (pharmaceutical ingredients, semi-finished products) medicinal ingredients, excipients, capsule shells) for human use in Vietnam;

b) Requirements for clinical data to ensure safety and effectiveness in drug registration dossiers;

c) Criteria to determine cases of exemption from testing, exemption from some stages of clinical drug testing in Vietnam, the drug must require phase 4 clinical trial;

d) Principles of organization and operation of experts appraising dossiers requesting issuance, extension, change, and supplementation of registration papers for circulation of drugs and medicinal ingredients;

d) Principles of organization and operation of experts appraising dossiers requesting licenses to import drugs without circulation registration for the cases specified in Point a, Clause 43, Article 5 of Decree No. 155/2018 /ND-CP dated November 12, 2018 of the Government amending and supplementing a number of regulations related to business investment conditions under the state management of the Ministry of Health (hereinafter referred to as Decree No. 155/2018/ND-CP);

e) Principles of organization and operation of the Advisory Council for issuance of circulation registration certificates for drugs and medicinal ingredients (hereinafter referred to as the Council);

g) Procedures for appraisal of dossiers requesting issuance, extension, change or supplementation of registration papers for circulation of drugs and medicinal ingredients; Procedure for appraisal of dossiers for importing drugs without circulation registration certificate.

2. This Circular is not required to apply to the cases specified in Points a and b, Clause 2, Article 54 of the Law on Pharmacy and semi-finished pharmaceutical products produced by the facility itself to produce finished drugs specified in Point e Clause 1 Article 93 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 (hereinafter referred to as Decree No. 54/ 2017/ND-CP), except in cases where the registration facility voluntarily applies.

Article 2. Explanation of terms

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

1. *ASEAN Common Technical File (ACTD)* is a set of documents guiding drug registration dossiers that meet the common technical requirements of the Association of Southeast Asian Nations (ASEAN) specified in Appendix I issued attached to this Circular.

2. *ICH-CTD general technical dossier* is the common dossier form of the International Conference on harmonization of registration procedures for pharmaceuticals for human use.

3. *Major changes* are changes that have a clear, direct impact on the quality, safety and effectiveness of the drug, specified in Appendix II issued with this Circular.

4. *Minor changes* are changes that do not affect or have very little effect on the effectiveness, quality and safety of the drug, specified in Appendix II issued with this Circular.

5. *The facility that registers drugs and medicinal ingredients* is the facility that submits an application for granting, extending, changing or supplementing the registration certificate for circulation of drugs and medicinal ingredients.

6. *Drug manufacturing facility* is a facility that carries out one, several stages or the entire production process or releases a batch of drugs.

7. *A facility that produces medicinal ingredients* is a facility that produces raw materials to produce finished drugs or a facility that releases batches of medicinal ingredients.

8. *Certificate of Pharmaceutical Products (CPP)* is a certificate issued according to the Quality Certification System for pharmaceutical products circulated in international trade of the World Health Organization (WHO).

9. *The European Medicines Agency (EMA)* and *the Stringent Regulatory Authorities (SRA)* are agencies including:

a) European Medicines Agency (EMA);

b) Stringent Regulatory Authorities (SRA): are pharmaceutical management agencies classified by the World Health Organization (WHO) as part of the SRA list, including:

- ICH members before October 23, 2015, including: US Food and Drug Administration (US-FDA), European Union Drug Administration , European Union UK Medicines and Medical Products Administration (MHRA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA);

- ICH observer members before October 23, 2015 include: Drug Administration of the European Free Trade Association (EFTA) with representatives of the Swiss Medicines Agency (Swissmedic) and Health Canada (Health Canada);

- Members with association and mutual recognition agreements with ICH members before October 23, 2015 include: Australia, Iceland, Liechtenstein and Norway.

10. *Product license holder/Marketing authorization holder* is the facility that owns the drug circulation license recorded on the Certificate of Pharmaceutical Product (CPP) according to the form issued by WHO.

11. *Semi-finished pharmaceutical products* are raw materials for the production of drugs of medicinal origin in the form of extracts, granules, powders, extracts, essential oils, resins, gums, and jelly.

Article 3. Responsibilities of establishments registering drugs and medicinal ingredients

1. Take full responsibility before the law for the accuracy, legality, and truthfulness of all documents in the registration dossier. Coordinate with production facilities and competent domestic and foreign agencies in responding to documents from the Drug Administration requesting to check the authenticity of relevant legal documents in the registration dossier. Sign medicine.

2. Carry out registration of changes and additions as prescribed in Clause 4, Article 27, Clause 3, Article 30, Clause 3, Article 32 and Article 38 of this Circular while the registration for circulation of drugs and medicinal ingredients is still valid. effect.

3. Responsible for changing and supplementing label content and instructions for drug use in accordance with the content in the Drug Administration's updated request document while the drug circulation registration is still valid. No application for registration of changes or additions is required.

4. Ensure the quality, safety and effectiveness of drugs and medicinal ingredients in accordance with the registration dossier.

5. Notify in writing the Drug Administration of Vietnam within 30 days from the date of the decision to revoke the circulation registration certificate in any country in the world for drugs and medicinal ingredients that have been licensed. Registration for circulation in Vietnam is still valid and clearly states the reason for revocation.

6. Closely coordinate with drug manufacturers to conduct research or provide additional information related to registered drugs when there is information or evidence related to the safety and effectiveness of the drug during the process. submitted for circulation at the request of the competent management agency.

7. Coordinate with drug manufacturing, importing and distributing establishments to monitor, supervise, collect, synthesize, evaluate and send reports to the National Center for Drug Information and Feedback Monitoring. Adverse drug reactions (National Center for DI & ADR) information on cases of post-vaccination reactions, adverse drug reactions according to the provisions of Clause 5, Article 77 of the Pharmacy Law , national guidelines on vigilance issued by the Ministry of Health and related regulations.

8. Ensure maintenance of pharmaceutical business conditions of the registration facility within the validity period of the registration certificate for circulation of drugs and medicinal ingredients. In case it no longer meets the operating conditions, the registration facility must be responsible for making changes to the registration facility according to the provisions of Clause 4, Article 27, Clause 3, Article 30, Clause 3, Article 32 and Article 3. 38 of this Circular within 30 days from the date the registered establishment is no longer eligible to operate.

9. Responsible for issues related to intellectual property rights for drugs and medicinal ingredients registered for circulation in Vietnam.

10. Coordinate with production facilities to update quality standards of drugs and medicinal ingredients according to the provisions of Circular No. 1 / 2018/TT-BYT dated May 4, 2018 of the Minister of Health regulating quality of drugs and medicinal ingredients (hereinafter abbreviated as Circular No. 11/2018/TT-BYT) and Circular No. 38/2021/TT-BYT dated December 31, 2021 of the Minister of Health regulating on the quality of medicinal materials, traditional medicinal herbs, and traditional medicines (hereinafter referred to as Circular No. 38/2021/TT-BYT).

11. Implement the approved risk management plan in the application for issuance or extension of circulation registration for vaccines.

12. Take responsibility according to the provisions of Clause 2, Article 57 of the Pharmacy Law and the provisions of this Article for drugs and medicinal ingredients registered by the establishment from the date the Drug Administration of Vietnam signs an official dispatch permitting change of establishment. registration facility, including drugs and medicinal ingredients that have been put into circulation before the Drug Administration of Vietnam has issued an official dispatch permitting the conversion of the registration facility.

13. Coordinate with the production facility to provide one of the papers and documents specified in Clause 11, Article 22 of this Circular to the competent management agency upon request .

14. Take responsibility according to the provisions of this Circular and other relevant laws.

Article 4. Responsibilities of establishments producing drugs and medicinal ingredients

1. Must produce drugs and medicinal ingredients at the right facility with a production license/certificate of eligibility for pharmaceutical business with the scope of manufacturing drugs and medicinal ingredients issued by a competent management agency. .

2. Take full responsibility before the law for the accuracy, legality, and truthfulness of all documents related to drugs and medicinal ingredients provided by the drug and medicinal ingredient manufacturing facility to the agency. Drug registration office to register for circulation in Vietnam.

3. Coordinate with establishments registering drugs and medicinal ingredients:

a) Implement the provisions in Clauses 2, 3 and 4, Article 3 of this Circular ;

b) Implement requirements for inspection and assessment of production facilities when requested by competent management agencies.

4. Request to revoke the registration certificate for circulation of drugs and medicinal ingredients produced by the manufacturer in case the drugs or medicinal ingredients have problems with quality, safety and effectiveness that affect the health of people. Use according to Form 1/TT issued with this Circular.

5. Ensure the operating conditions of the production facility within the validity period of the registration certificate for circulation of drugs and medicinal ingredients.

6. In case the facility registering drugs or medicinal ingredients does not meet the conditions for operation according to the notification of the competent management agency, the manufacturing facility may change the registration facility of the drug or raw material. medicinal materials within 30 days from the date of written notification.

7. Update drug quality standards and medicinal ingredients according to regulations in Circular No. 11/2018/TT-BYT and Circular No. 38/2021/TT-BYT .

8. Responsible for evaluating and ensuring that the facility producing medicinal ingredients meets good practices in manufacturing medicinal ingredients, storing and providing one of the papers and documents specified in Clause 11, Article 22. This Circular is available to competent management agencies upon request.

Article 5. Regulations on safety and effectiveness monitoring and evaluation reports

1. Pharmaceutical business establishments and medical examination and treatment establishments must monitor, supervise, collect, synthesize, evaluate and report to competent authorities on cases of post-vaccination reactions. strains, adverse drug reactions according to the provisions of Article 77, Article 78 of the Pharmacy Law , national guidelines on pharmacovigilance issued by the Ministry of Health and relevant regulations.

2. Drug registration establishments must report on monitoring and evaluating the safety and effectiveness of drugs specified in Clause 2, Article 8 of this Circular according to Form 2A/TT (for drugs) or Form 2B/TT (for drugs). Vaccine):

a) Every 6 months during the period of validity of the circulation registration certificate, send it to the National DI & ADR Center;

b) When submitting an application for extension of registration for circulation at the Drug Administration of Vietnam.

3. Medical examination and treatment facilities that use drugs shall report drug use according to Form 2C/TT issued with this Circular every 6 months during the period of valid circulation registration for with drugs specified in Clause 2, Article 8 of this Circular and send it to the National DI & ADR Center.

4. Every 6 months, the National DI & ADR Center is responsible for synthesizing, evaluating and sending reports to the Drug Administration of Vietnam.

Article 6. Language, form of records, number of records and documents.

1. Language used in registration documents

Drug and medicinal ingredient registration dossiers must be written in Vietnamese or English. Particularly, the drug instructions for use and summary of product characteristics must be written in Vietnamese.

2. Drug and medicinal ingredient registration dossiers must be prepared on A4 paper size, securely bound. The application must have a cover page (Form 3/TT) arranged in the correct order of the table of contents (Form 4/TT), with separation between sections. The separated parts must be numbered sequentially and have the confirmation stamp of the registration facility or the drug or medicinal ingredient manufacturer on the first page of each part in the entire dossier (the office's stamp is acceptable). representative for foreign drugs). This regulation does not apply to online submissions.

The following documents must be bound into separate sections and accompanied by 1 application:

a) Bioequivalence research documents;

b) Preclinical and clinical documents;

c) Documents assessing compliance with GMP as prescribed in Articles 95, 98 of Decree No. 54/2017/ND-CP and Clause 53, Article 4, Clause 51, Article 5 of Decree 155/2018/ND-CP for establishments Foreign manufacturers of drugs and medicinal ingredients when registering for circulation in Vietnam.

3. Drugs can be registered in the same dossier when they have the following elements in common: drug name; dosage forms; route of administration; drug quality standards; manufacturer's name and address; same dosage formula, in which: has the same pharmaceutical content calculated in divided dose units for solid drugs with divided doses; have the same concentration or pharmaceutical content for undivided solid, liquid or semi-solid drugs; have the same concentration or content of pharmaceutical ingredients and packaging materials in direct contact with the drug for injectable and infusion drugs.

4. Number of documents that must be submitted in the application dossier for issuance or extension of circulation registration certificate, specifically as follows:

a) 01 (one) set with complete documents as prescribed in Clauses 1, 2, 3, 5, Article 27 of this Circular for pharmaceutical drugs, vaccines, biological products and documents specified in Clause 1, 2 Article 30, Clause 1, 2 Article 32 of this Circular for medicinal herbs and medicinal ingredients;

b) 01 (one) copy of complete documents for vaccines; 02 (two) copies of documents including registration form , quality standards and testing methods for drugs and medicinal ingredients for the remaining cases;

c) 02 (two) sets of drug label samples , drug ingredients and instructions for use of the drug expected to be circulated with confirmation stamp of the registration facility (representative office's seal is accepted for with foreign drugs) or production facilities. Labels of drugs and medicinal ingredients are mounted and designed on appropriate paper size but not smaller than A4 size. In case of online application, the facility only submits 01 set of drug label samples, medicinal ingredients and drug use instructions.

5. Number of documents to be submitted in the application for registration of changes or additions to the circulation registration certificate:

a) 01 (one) full set of documents as prescribed in Clause 4, Article 27 of this Circular for pharmaceutical drugs, vaccines, biological products and Clause 3, Article 30, Clause 3, Article 32 of this Circular for medicinal herbs, medicinal ingredients;

b) 02 (two) sets of drug label samples, medicinal ingredients and drug use instructions requested to be changed in case of changing the label or instructions for use, with confirmation stamp of the registration facility (accepted). receive the seal of the representative office for foreign drugs) or the manufacturing facility. Labels of drugs and medicinal ingredients are mounted and designed on appropriate paper size but not smaller than A4 size. In case of online application, the facility only submits 01 set of drug label samples, medicinal ingredients and drug use instructions.

6. Regulations on application of online records:

a) Quantity and composition of documents: 01 (one) complete set of documents as prescribed in this Circular (except cover page); For documents requiring data security, the facility must submit them directly to the Drug Administration of Vietnam according to the provisions of Circular No. 05/2010/TT-BYT dated March 1, 2010 of the Minister of Health guiding security of testing data in drug registration (hereinafter referred to as Circular No. 05/2010/TT-BYT);

b) The online application submission route follows the announcement of the Ministry of Health. From the date of application of all online application submission, registration establishments submit online applications in accordance with the provisions in Point a of this Clause. In case there is a request to provide a paper copy of the registration dossier for review and comparison, the Drug Administration of Vietnam will issue a written notification.

Article 7. Fees for registration of drugs and medicinal ingredients

Establishments registering drugs and medicinal ingredients must pay fees related to registration of drugs and medicinal ingredients according to current law provisions on fees and charges.

Article 8. Validity and symbols of registration papers for circulation of drugs and medicinal ingredients and deadline for submitting registration applications for extension; Number of circulation registration papers for drugs with the same pharmaceutical substance or medicinal ingredient, dosage form, route of administration, content or concentration in a dosage unit

1. The validity period of the registration certificate for circulation of drugs and medicinal ingredients is 05 (five) years from the date of issue or extension, except for the cases specified in Clause 2 of this Article.

2. The validity period of the circulation registration certificate is 03 (three) years from the date of issue for the following drugs:

a) New drugs, vaccines issued with circulation registration for the first time, reference biological products, similar biological products issued with circulation registration for the first time in Vietnam;

b) The drug has the same pharmaceutical ingredients, concentration, content, dosage form as the new drug but the new drug has not been granted a circulation registration certificate for a period of 05 (five) years;

c) Cases of continued safe and effective monitoring according to the advice of the Council;

d) Drugs fall into the cases specified in Points a, b and c of this Clause, but at the time of submitting the application for renewal of the marketing registration certificate, there is no safety and effectiveness report due to the reason that it is not yet in circulation or there is a report. Reported safety and effectiveness, but the number of drugs used, number of patients, and duration of use are limited according to the opinion of the Council or recommendations from medical examination and treatment facilities on the need for continued safety monitoring. , effective.

3. Each drug or medicinal ingredient that is granted a circulation registration certificate will have a registration number according to the structure specified in Appendix VI issued with this Circular.

4. Deadline for submitting registration application for renewal: Within 12 months before the registration certificate expires, the registration facility must submit an application to renew the registration certificate.

5. In case there are changes in administrative records in the renewal application, after 12 months from the date of issuance of the Decision to extend the marketing registration certificate, the establishment must implement the changes approved in the application. extension file.

6. Number of circulation registration certificates for drugs from the same manufacturing facility with the same pharmaceutical substance or medicinal ingredient; dosage forms; route of administration; content or concentration in a dosage unit: 01 circulation registration certificate with the trade name

and 01 circulation registration certificate with the international generic name. This regulation does not apply to drugs produced for processing and drugs produced for the sole purpose of export.

Article 9. Classification criteria and cases of announcement of original brand-name drugs and reference biological products

1. Criteria for classifying generic drugs and reference biological products

a) Drugs granted registration for circulation in Vietnam are classified as generic drugs or reference biological products when they simultaneously meet the following criteria:

- Has complete clinical data on safety and effectiveness as prescribed in Article 13 of this Circular ;

As for reference biological products, there must be complete records and data on quality, pre-clinical, and clinical in the direction of developing a biological product from scratch, not developing in the direction of biosimilars;

- Licensed for circulation by one of the management agencies specified in Clause 9, Article 2 of this Circular , except for new drugs manufactured in Vietnam.

b) For drugs that have been declared original brand names or reference biological products by the Ministry of Health, then order processing or transfer of production technology for one, some or all stages at drug manufacturing facilities in Vietnam. Vietnam must ensure that drugs with announced brand names, reference biological products, and drugs processed or transferred technology manufactured in Vietnam meet the following criteria:

- Same preparation formula;

- Same production process;

- Same raw material quality standards;

- Same quality standards for finished drugs;

In case there is a change in one of the criteria at this point or other changes related to the quality of the drug, these changes must be approved by the pharmaceutical management agency of the manufacturing country or the regulatory management agency. Clause 9, Article 2 of this Circular has issued a marketing authorization for that drug or the registration facility must provide data proving that the drug manufactured in Vietnam is equivalent in quality to the original brand name drug or reference biological product before approval. processing or technology transfer.

c) If a drug has been announced as an original brand name drug or a reference biological product, if the manufacturing facility has changed, the drug with a new circulation registration certificate from the changed manufacturer will also be classified as an original brand name drug or biological product. reference product on the basis of a written request from the registration facility if it simultaneously meets the following criteria:

- The drug is licensed for circulation by one of the management agencies specified in Clause 9, Article 2 of this Circular ;

- The drug simultaneously meets the criteria specified in Point b, Clause 1 of this Article.

In case there is a change in one of the criteria in Point b, Clause 1 of this Article or other changes related to the quality of the drug, these changes must be approved by the pharmaceutical management agency of the manufacturing country or the drug management agency. The management specified in Clause 9, Article 2 of this Circular has issued a license to circulate the drug or the registration facility must provide data proving that the drug produced at the new facility is equivalent in quality to the original brand name drug or biological product. reference product before changing production facilities.

2. Cases where drugs are classified as generic drugs or reference biological products:

a) Drugs that have been declared by the Ministry of Health to be generic drugs and reference biological products that are entirely produced in a country with a management agency specified in Clause 9, Article 2 of this Circular will continue to be classified as generic drugs. , reference biological product if it falls into one of the following cases:

- Drugs whose circulation registration is still valid or has been extended or changed or supplemented is not specified in Point b, Clause 2, Article 55 of the Pharmacy Law . The registration facility is not required to submit an application for classification of original brand-name drugs or reference biological products;

- The drug is granted a new circulation registration certificate in the form of re-registration specified in Circular No. 44/2014/TT-BYT dated November 25, 2014 of the Minister of Health regulating drug registration (hereinafter referred to as Circular No. 44/2014/TT-BYT) that have the same preparation formula, production process, raw material quality standards, and finished drug quality standards compared to the original brand name drug or reference biological product. The reference has been published or changes related to the above content have been approved by the Drug Administration of Vietnam or the host country. The registration facility submits an application to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular;

- The drug changes its production facility and is granted a new circulation registration certificate that meets the provisions of Point c, Clause 1 of this Article. The registration facility submits an application to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular.

b) Drugs manufactured abroad that have been declared by the Ministry of Health to be original brand-name drugs and reference biological products are not entirely produced in a country with a management agency specified in Clause 9, Article 2 of this Circular but are licensed Permitted for circulation in countries with management agencies on the list specified in Clause 9, Article 2 of this Circular will continue to be classified as original brand name drugs or reference biological products if they fall into one of the following cases:

- Drugs whose circulation registration is still valid or has been extended or changed or supplemented other than those specified in Point b, Clause 2, Article 55 of the Pharmacy Law ;

- Drugs that are granted new circulation registration certificates in the form of re-registration specified in Circular No. 44/2014/TT-BYT that have the same preparation formula, production process, and criteria . Raw material quality standards, finished drug quality standards compared to original brand name drugs, reference biological products have been announced or changes related to the above content have been approved by Vietnamese or host country management agencies. Browser;

- The drug changes its production facility and is granted a new circulation registration certificate that meets the provisions of Point c, Clause 1 of this Article;

The registration facility submits an application to update the classification of original brand-name drugs and reference biological products for the above 3 cases according to the provisions in Appendix II issued with this Circular.

c) The drug has been declared by the Ministry of Health to be an original brand name drug, a reference biological product produced in all stages in Vietnam or produced in one or several stages in Vietnam and the remaining production stages are approved. made entirely in a country with a management agency specified in Clause 9, Article 2 of this Circular will continue to be classified as a generic drug or reference biological product if it falls into one of the following cases:

- Drugs whose circulation registration is still valid or has been extended or changed or supplemented is not specified in Point b, Clause 2, Article 55 of the Pharmacy Law . The registration facility is not required to submit an application for classification of original brand-name drugs or reference biological products;

- The drug is granted a new circulation registration certificate in the form of re-registration specified in Circular No. 44/2014/TT-BYT with the same preparation formula, production process, raw material quality standards, and standards. Finished drug quality standards compared to the original brand name drug or reference biological product have been announced or changes related to the above content have been approved by the Vietnamese management agency or the host country. The registration facility submits an application to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular;

- The drug changes its production facility and is granted a new circulation registration certificate that meets the regulations at Point c, Clause 1 of this Article. The registration facility submits an application to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular.

d) The drug has been declared by the Ministry of Health to be an original brand name drug, the reference biological product is produced in one or several stages in Vietnam and the remaining production stages are not entirely carried out in a country with a regulatory agency. prescribed in Clause 9, Article 2 of this Circular but licensed for circulation in a country with a management agency specified in Clause 9, Article 2 of this Circular, will continue to be classified as original brand name drugs or reference biological products if they belong to one of the following cases:

- Drugs whose circulation registration is still valid or has been extended or changed or supplemented other than the cases specified in Point b, Clause 2, Article 55 of the Pharmacy Law ;

- The drug is granted a new circulation registration certificate in the form of re-registration specified in Circular No. 44/2014/TT-BYT with the same preparation formula, production process, raw material quality standards, and standards. Finished drug quality standards compared to the original brand name drug or reference biological product have been announced or changes related to the above content have been approved by the Vietnamese management agency or the host country;

- The drug changes its production facility and is granted a new circulation registration certificate that meets the provisions of Point c, Clause 1 of this Article;

The registration facility submits an application to update the classification of original brand-name drugs and reference biological products for the above 3 cases according to the provisions in Appendix II issued with this Circular.

d) Drugs that have been declared by the Ministry of Health to be original brand-name drugs or reference biological products that are entirely produced in a country with a management agency specified in Clause 9, Article 2 of this Circular , and are processed or transferred with production technology. produced in Vietnam, only if the drug is processed or has technology transferred to produce one, some, or all of the production stages in Vietnam and is granted a marketing registration certificate will it continue to be classified as a generic, biological brand name drug. reference product if it meets the provisions in Point b, Clause 1 of this Article. Establishments registering drugs for processing or transferring production technology in Vietnam shall submit dossiers to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular;

e) Drugs that have been declared by the Ministry of Health to be original brand-name drugs or reference biological products are not entirely produced in a country with a management agency specified in Clause 9, Article 2 of this Circular but are licensed for circulation in that country. If there is a management agency specified in Clause 9, Article 2 of this Circular , processing or transfer of production technology in Vietnam will be processed or transfer of production technology for one, some or all of the drugs. Production stages in Vietnam and issuance of new circulation registration certificates will continue to be classified as original brand-name drugs or reference biological products if they meet the regulations in Point b, Clause 1 of this Article. Establishments registering processed drugs or transferring production technology in Vietnam shall submit dossiers to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular;

g) Drugs that have not been announced by the Ministry of Health as original brand name or reference biological product, if they meet the provisions in Point a, Clause 1 of this Article, will be classified as original brand name drug or reference biological product. The registration facility submits an application to update the classification of original brand-name drugs and reference biological products according to the provisions in Appendix II issued with this Circular.

Article 10. Criteria for classifying drugs with proven bioequivalence

Drugs granted registration for circulation in Vietnam are classified as drugs with proven bioequivalence when there is a bioequivalence report that meets the regulations of the Ministry of Health on drugs subject to bioequivalence testing and Requirements for dossiers reporting bioequivalence research data in drug circulation registration in Vietnam.

Article 11. Data security requirements for drug registration dossiers

Drug registration establishments that need data security for drug registration dossiers must comply with the provisions of Circular 05/2010/TT-BYT and must clearly state the request in the registration application according to Form 5/TT ban. attached to this Circular.

Article 12. Regulations on verifying the authenticity of legal documents

1. Before granting a marketing registration certificate, the Drug Administration of Vietnam verifies the legal documents submitted in the drug registration dossier in the following specific cases:

a) For CPP:

- CPP shows signs of erasing or modifying information;

- CPP in drug registration dossiers of manufacturing establishments and registration establishments that have been administratively sanctioned by competent Vietnamese agencies for providing information related to technical dossiers that are not Based on research or actual production by manufacturing facilities on the list published on the website of the Drug Administration of Vietnam. The application period for CPP authentication is 02 years from the end of the period of temporary suspension of receiving applications for issuance and extension of circulation registration certificates;

- CPP of drugs manufactured by a facility that has a drug registered for circulation in Vietnam for the first time, except in cases where the drug has many facilities participating in the production of which at least one facility has a drug that has been granted a circulation registration certificate. in Viet Nam;

- CPP is an electronic version provided by self-search from the website or English database of the issuing agency or competent authority of the country that cannot be searched online via the link. The electronic information page that the facility provides in its application;

- CPP does not have a confirmation stamp from the competent authority of the issuing country;

- Cases where authentication is required by the Council.

b) For legal documents related to registration establishments and production establishments: Verification of authenticity is applied to legal documents of registration establishments and first-time production establishments. drugs registered in Vietnam.

2. For drugs that have been granted circulation registration, the Drug Administration of Vietnam verifies the authenticity of legal documents when receiving information in the form of documents, official emails, and information. Through the mass media, reports related to the status of licensing and circulation of drugs in the host country need verification, clarification or information about failure to meet the operating conditions of the drug manufacturing facility or establishment. foreign registration office.

3. Verification of the authenticity of the CPP and legal documents submitted in the drug registration application is done in the form of official documents or emails in the following manner:

a) Verifying the authenticity of legal documents related to consular legalization : The Drug Administration of Vietnam coordinates with the Consular Department - Ministry of Foreign Affairs or diplomatic agencies with consular legalization functions of Vietnam abroad to verify authority and information related to consular legalization of foreign legal documents for use in Vietnam for the cases specified in sections 2, 3, points a and Point b Clause 1 of this Article;

b) Verify the authenticity of the content of legal documents: The Drug Administration of Vietnam coordinates with the agency issuing/issuing legal documents to verify the information stated in the above documents for the following documents: cases specified in items 1, 4, 5, 6, point a, clause 1 of this Article.

4. Verification of the authenticity of legal documents specified in Clause 1 of this Article is carried out simultaneously with the procedure for appraising the drug registration dossier and within the time limit specified in Clause 5, Article 56 of the Pharmacy Law . Drugs will only be considered for circulation registration if there are verification results that meet the requirements of the competent authorities mentioned in Clause 3 of this Article.

The written request for authentication of legal documents is sent at the same time to the drug registration facility. Within 06 months from the date the Drug Administration of Vietnam carries out verification and does not receive authentication results from the competent authority, the Drug Administration of Vietnam shall report to the Council on the status of legal document authentication and recommendations. Export registration has not yet been issued.

chapter II

CLINICAL DATA REQUIREMENTS TO ENSURE SAFETY, EFFECTIVENESS AND CRITERIA FOR DETERMINING CASES OF TRIAL EXEMPTIONS, EXEMPTIONS FROM CERTAIN CLINICAL DRUG TRIAL PHASES, DRUGS SUBJECT TO PHASE 4 CLINICAL TRIAL IN VIETNAM

Article 13. Regulations on clinical data in circulation registration dossiers for pharmaceutical drugs, vaccines, and biological products

1. Requirements for clinical data to ensure the safety and effectiveness of new pharmaceutical drugs, vaccines, and biological products in the circulation registration dossier.

a) Clinical studies of the drug and data in clinical records must be consistent with the guidelines of ICH, the Ministry of Health of Vietnam or the guidelines of other organizations recognized by Vietnam (including: guidelines instructions of international organizations of which Vietnam is a member, instructions of management agencies specified in Clause 9, Article 2 of this Circular) , except for the cases specified in Clause 3 of this Article;

b) Clinical data (except for biological products similar to reference biological products that have been granted registration for circulation in Vietnam) must have enough information to analyze and explain the influence of human race factors. Asia related to the safety and effectiveness of the drug in order to extrapolate clinical data to the Asian race according to the instructions specified in Point a of this Clause or there must be bridging research data according to ICH guidelines. -E5 is intended to extrapolate clinical data to Asian populations;

c) Vaccines that have been licensed for circulation meet the provisions of Point d, Clause 4, Article 22 of this Circular and have complete clinical data on safety and effectiveness as prescribed in Points a and b of this Clause, but has not been produced at all stages on the production lines of member countries specified in Clause 9, Article 2 of this Circular , there must be clinical data related to the assessment of safety and immunogenicity in human populations. target entity in Vietnam before being granted a marketing authorization;

d) Vaccines that have sufficient clinical data to evaluate safety and effectiveness as prescribed in Points a and b of this Clause but do not meet the provisions in Point d, Clause 4, Article 22 of this Circular must have clinical data. clinical assessment related to safety and immunogenicity assessment in target populations in Vietnam before marketing authorization.

2. Pharmaceutical drugs with content or concentration, route of administration, method of administration, dosage, indications, patient population or dosage form that affect the biopharmaceuticals of the drug are different from the original licensed brand name drug. marketed in Vietnam or different from a drug licensed for circulation by one of the management agencies specified in Clause 9, Article 2 of this Circular , but the original brand name drug has not been licensed for circulation in Vietnam, must have clinical data. according to the provisions of Points a and b, Clause 1 and Clause 3 of this Article before being granted a marketing license.

3. In case the research was conducted before the date of regulations and guidelines on drug research and development specified in Point a, Clause 1 of this Article, the research data will be considered accepted for appraisal.

Article 14. Requirements for clinical data to ensure safety and effectiveness in marketing registration dossiers for drugs with new combinations of similar pharmaceutical substances and biological products

1. Drugs with new combinations of pharmaceutical substances must have complete clinical data according to the guidance of the US FDA, EMA or WHO on clinical development of fixed-dose combination drugs as prescribed in Appendix IV. promulgated together with this Circular.

2. Similar biological products must have complete clinical data according to the guidance on developing similar biological products issued by the Ministry of Health of Vietnam or guidance from WHO. Acceptance of US FDA, EMA guidelines and guidelines developed on the basis of these guidelines. Instructions of WHO, US FDA, EMA according to Appendix IV issued with this Circular.

Article 15. Requirements for clinical data to ensure safety and effectiveness in marketing registration dossiers for new pharmaceutical drugs that are not original brand-name drugs

1. For drugs licensed for circulation in the host country that are prescription drugs (except for drugs manufactured in Vietnam) and there is at least one similar drug (same pharmaceutical substance, concentration, content, form). preparation, route of administration) licensed for circulation by one of the management agencies specified in Clause 9, Article 2 of this Circular must have clinical data that meets one of the following cases:

a) There is clinical data of the same drug that is authorized for use by the owner. Clinical data of similar drugs must meet the regulations in Article 13 of this Circular ;

b) There is clinical data gathered from research projects published in medical literature and data on bioequivalence research (except in cases where the drug does not require bioequivalence testing according to regulations of the agency). host country management agency).

2. For non-prescription drugs according to the regulations of the host country (except for drugs manufactured in Vietnam and the cases specified in Clause 3 of this Article) and there is at least one similar drug (same pharmaceutical ingredient, concentration, content, dosage form, route of administration) licensed for marketing by at least one country in the world must have clinical data that meets one of the following cases:

a) There is clinical data of the same drug that is authorized for use by the owner. Clinical data of similar drugs must meet the regulations in Article 13 of this Circular ;

b) There is clinical data gathered from research projects published in medical literature and data on bioequivalence research (except in cases where the drug does not require bioequivalence testing according to regulations of the agency). host country management agency).

3. For drugs licensed for circulation and classified as non-prescription drugs by at least one of the management agencies specified in Clause 9, Article 2 of this Circular , there must be explanatory documents and evidence to prove it. The use of pharmaceutical substances in the composition of the drug (indications, dosage, route of administration, intended users) has been clearly stated in the Vietnam National Pharmacopoeia, Vietnam Pharmacopoeia, Pharmacopoeia or other documents. accepted by one of the management agencies specified in Clause 9, Article 2 of this Circular .

Article 16. Requirements for clinical data for drugs that have been granted registration for circulation in Vietnam but have changes and additions related to clinical data compared to the approved drug registration dossier

Pharmaceutical drugs, vaccines, biological products, and medicinal herbs that have been granted a certificate of registration for circulation in Vietnam have changes and additions related to clinical data compared to the drug registration dossier . approved, the registration facility must supplement clinical data as prescribed in Appendix II issued with this Circular.

Article 17. Criteria for determining exemption from one or several stages of testing new pharmaceutical drugs, vaccines, and clinical biological products before granting marketing authorization

Medicines that do not meet the regulations in Article 13 of this Circular will be considered and decided by the Minister of Health to exempt one or several stages of clinical drug testing (including exemption and reduction of clinical data) on the basis of private opinions. consultation of the Council when falling into one of the following cases:

1. Drugs that meet urgent needs for national defense, security, disease prevention and control, and overcoming the consequences of natural disasters and disasters for which there are no other drugs available on the market that can replace them.

2. The drug has been licensed for circulation by at least one of the management agencies specified in Clause 9, Article 2 of this Circular based on clinical records of exemptions and exemptions according to the regulations of these agencies.

3. Drugs used to treat rare diseases; fatal disease.

4. Vaccines and biological products are produced in Vietnam in the form of technology transfer of one, several or all stages of the finished product production process for which vaccines and biological products have data before the technology transfer. Clinical data meet the regulations in Clause 1, Article 13, Article 14 of this Circular .

Article 18. Requirements for clinical data in circulation registration dossiers for herbal drugs

1. Requirements for clinical data to ensure safety and effectiveness in circulation registration dossiers for new herbal drugs

a) Clinical studies of drugs and data in clinical records must be consistent with the Guidelines for pre-clinical and clinical research of herbal drugs of the Ministry of Health or other organizations recognized by Vietnam. including: Research guidelines for evaluating the safety and effectiveness of herbal medicines by (Research guidelines for evaluating the safety and efficacy of herbal medicines) or management agencies specified in Clause 9, Article 2 of this Circular . In case the research was conducted before the above regulations and guidelines on drug research and development were issued, the research data will be considered accepted for appraisal;

b) Medicinal drugs with data cited from the following documents are accepted as clinical data to consider the safety and effectiveness of the drug:

- Treatises related to the safety and effectiveness of drugs mentioned in pharmacopoeias and pharmacopoeia of Vietnam or other countries in the world;

- Articles evaluating the safety and effectiveness of drugs are published in journals on the SCI (Science Citation Index) list - Scientific citation index and clinical data gathered from journals. Research published in other medical literature;

- Report assessing the safety and effectiveness of national, ministerial or provincial science and technology projects that have been accepted .

2. Medicinal herbs are not required to submit clinical data as prescribed in Clause 1 of this Article if one of the following conditions is met:

a) A herbal drug that has the same ingredients, amount of medicinal materials, indications, route of administration, and dosage form as another herbal drug that has been granted a circulation registration certificate (including cases where the circulation registration certificate has been issued). expired) except for drugs that have been identified as traditional drugs and do not have indications for diseases on the List of diseases issued by the Minister of Health according to the provisions of Point b, Clause 1, Article 89 of the Pharmacy Law ;

b) In case the herbal medicine has the same ingredients, amount of medicinal ingredients, indications, route of administration, and dosage form as a new herbal medicine licensed for circulation in Vietnam on the basis of complete clinical data. according to the provisions of Clause 1 of this Article and there are no additional indications for diseases on the List of diseases issued by the Minister of Health according to the provisions of Point b, Clause 1, Article 89 of the Pharmacy Law , they will be considered for marketing authorization. When that other medicinal drug has been licensed for circulation, the validity of the circulation registration certificate is extended for 05 years.

Article 19. Criteria for determining cases of exemption from one or several stages of clinical testing of herbal drugs before granting marketing authorization

Medicinal drugs that do not meet the regulations in Article 18 of this Circular shall be considered and decided by the Minister of Health to exempt one or several stages of clinical drug testing (including exemption and reduction of clinical data) on the basis of Based on the Council's advisory opinion in one of the following cases:

1. Drugs that meet urgent needs for national defense, security, disease prevention and control, and overcoming the consequences of natural disasters and disasters for which there are no other drugs available on the market that can replace them.

2. The drug has been licensed for circulation by at least one of the reference management agencies specified in Clause 9, Article 2 of this Circular based on clinical records of exemptions and exemptions according to the regulations of these agencies.

3. The drug has indications for diseases on the List of diseases issued by the Minister of Health according to the provisions of Point b, Clause 1, Article 89 of the Pharmacy Law but is not exempt from clinical trials specified in Clause 3, Article 20 This Circular .

4. The drug has a new combination of medicinal herbs that have been used as medicine in Vietnam and has no indication for diseases on the List of diseases promulgated by the Minister of Health as prescribed in Point b, Clause 1. Article 89 of the Pharmacy Law .

Article 20. Criteria for determining cases exempt from clinical trials in Vietnam before granting marketing authorization

1. Generic drugs have the same pharmaceutical ingredients, content, concentration, route of administration, method of administration, dosage, indications, patient population, and dosage form as another drug that has been granted a circulation registration certificate.

2. New drugs (except vaccines) have been licensed for circulation in at least one country in the world and have complete clinical data on safety and effectiveness as prescribed in Articles 13 and 18 of this Circular .

3. Medicinal drugs that have been granted circulation registration before the effective date of the 2016 Pharmacy Law and do not have indications for diseases on the List of diseases issued by the Minister of Health.

4. The vaccine meets the regulations in Point d, Clause 4, Article 22 of this Circular , is produced in all stages in a country with a management agency specified in Clause 9, Article 2 of this Circular and has complete data. Clinical safety and effectiveness as prescribed in Article 13 of this Circular .

Article 21. Criteria to determine cases requiring phase IV clinical trials in Vietnam

The drug has been granted a circulation registration certificate but needs further assessment of safety and effectiveness based on the Council's advisory opinions.

Chapter III

DOSSIER FOR REGISTRATION OF DRUGS AND MEDICINAL INGREDIENTS

Section 1. GENERAL PROVISIONS ON APPLICATIONS FOR ISSUANCE, EXTENSION, CHANGE, AND SUPPLEMENT OF CIRCULATION REGISTRATION PAPER FOR DRUGS AND MEDICINAL INGREDIENTS

Article 22. Regulations on documents in application dossiers for granting, extending, changing and supplementing circulation registration certificates for drugs and medicinal ingredients

1. Documents issued by foreign competent authorities must be consularly legalized according to the provisions of law on consular legalization, except for cases exempted according to the provisions of law.

2. Licenses, certificates, confirmations, registration papers (collectively referred to as legal documents) in the dossier must be valid at the time of receipt recorded on the Receipt Form for legal documents containing validity period. In case the CPP does not state the validity period, the validity period is calculated as 24 months from the date of issue.

3. Legal documents:

a) The original copy must have full signature , signer's name and confirmation stamp of the competent authority of the issuing country or the certified copy must be issued by a competent agency or organization of Vietnam. authenticated according to the provisions of Vietnamese law on authenticating copies from originals. In case of necessity, the original must be presented for comparison;

b) In case the issued legal document is an electronic copy (accepting a copy that does not have enough signature, signer's name or confirmation stamp of the competent authority of the country issuing the legal document), The registration facility must submit one of the following documents:

- Original or certified copy of legal documents certified by a foreign competent authority and consularly legalized according to regulations;

- Results of self-searching legal documents from the website or English database of legal document-issuing agencies or competent agencies of other countries with the facility's confirmation stamp attached with the document. The document provides information on the search link to the Drug Administration of Vietnam. The registration facility must take full responsibility before the law for the legality and accuracy of these documents and information and the results of its own search.

4. Regulations for CPP:

a) CPP must be issued by a competent authority and have sufficient content according to the WHO form published on the WHO website (https://www.who.int).

b) The CPP must have the signature, name of the signer, date of issue and seal of the CPP-issuing agency. In case the CPP does not have a confirmation stamp from the competent authority of the issuing country, the registration facility will provide documents proving that the CPP does not require a seal according to regulations in the host country.

c) For generic drugs, herbal drugs, probiotics, drugs that extend, change or supplement the circulation registration certificate:

There must be 01 CPP issued by the competent authority of the manufacturing country certifying that the drug is licensed and actually circulated in that country.

In case CPP confirms that the drug is not licensed for circulation in the manufacturing country or licensed but not actually circulated in the manufacturing country, the registration facility must provide 01 additional legal document issued by the management agency. The provisions in Clause 9, Article 2 of this Circular confirm that the drug is licensed and actually circulated in that country with the following minimum contents: drug name, active ingredients, concentration or content of active ingredients, dosage form, name and address of the manufacturing facility.

d) For new pharmaceutical drugs , vaccines, and imported biological products, except probiotics:

There must be 01 CPP issued by the competent authority of the manufacturing country, certifying that the drug is licensed and actually circulated in that country.

In case the competent authority of the manufacturing country issues a CPP on the list specified in Clause 9, Article 2 of this Circular , only 01 CPP must be submitted.

In case the competent authority of the manufacturing country to issue CPP is not on the list specified in Clause 9, Article 2 of this Circular , there must be additional legal documents issued by the management authority specified in Clause 9, Article 2 of the Circular. This confirms that the drug is licensed and actually circulated in that country with the following minimum contents : drug name, active ingredients, concentration or content of active ingredients, dosage form, name and address of the manufacturing facility. or documents proving that the drug belongs to the WHO pre-evaluation drug list.

d) For drugs requesting to be classified as generic drugs or reference biological products:

There must be 01 CPP issued by the competent authority of the manufacturing country, certifying that the drug is licensed and actually circulated in that country.

In case the competent authority of the manufacturing country issues a CPP on the list specified in Clause 9, Article 2 of this Circular , only 01 CPP must be submitted.

In case the competent authority of the manufacturing country to issue CPP is not on the list specified in Clause 9, Article 2 of this Circular , there must be additional legal documents issued by the management authority specified in Clause 9, Article 2 of the Circular. This confirms that the drug is licensed and actually circulated in that country with the following minimum contents: drug name, pharmaceutical ingredients, concentration or content of pharmaceutical ingredients, dosage form, name and address of the manufacturing facility.

e) For imported drugs, vaccines, and biological products that cannot provide CPP that meets the provisions of Points c and d of this Clause, the Minister of Health shall consider and decide on the basis of the Council's advisory opinion when The drug is licensed for circulation by at least one competent authority in the world and falls into one of the following cases:

- Medicines, vaccines, biological products to meet the needs of national defense and security; preventing and fighting epidemics and diseases, overcoming the consequences of natural disasters and catastrophes, medicine serving the state's health program;

- Vaccines used for the national expanded vaccination program for which there are no other vaccines available on the market that can replace them in terms of quantity, quality, safety, effectiveness or cost of vaccine use;

- In other special cases, there are written agreements and mutual recognition between competent agencies on conditions for production and circulation of drugs, vaccines, and biological products.

g) The information shown on the CPP must be consistent with the relevant information in the drug registration dossier. In case the information shown on the CPP is not consistent with the administrative documents in the drug registration dossier, the registration facility must provide a written explanation accompanied by supporting documents.

5. The registration application and other records and documents in the relevant administrative records section must be signed and stamped, do not use a stamped signature. Registration and production establishments can use digital signatures to sign related documents of the registration and production establishment. The registration and use of digital signatures is carried out in accordance with the provisions of Decree No. 130/2018/ND-CP dated September 27, 2018 of the Government detailing the implementation of the electronic transaction law on digital signatures. and digital signature authentication service. The above documents must be signed by one of the following titles:

a) Chairman of the Board of members and board of directors; general manager; managing director; director of registration and production facilities;

b) The assigned person according to the provisions of the company charter, work assignment document or other documents proving the signing authority of the signer;

c) The person authorized to directly sign by the people specified in point a or b of this clause.

6. Regulations for letters of authorization:

a) Authorization in the name of the registration facility must contain the following contents:

- Name and address of the marketing authorization holder or authorized manufacturing facility;

- Name and address of the authorized registration facility;

- Drug name; concentration of drug content; dosage forms;

- Copyright.

In case of authorization of multiple drugs, the authorization letter must have a list of drugs with all the above contents.

The letter of authorization in the name of the registration facility for foreign drugs must be consularly legalized according to regulations. The authorization letter must be an original or a certified copy.

b) Authorization to sign on the registration dossier must contain the following contents:

- Name and address of the registered facility;

- Name and title of the authorizer and authorized person;

- Drug name; concentration and content of pharmaceutical ingredients; dosage forms;

- Copyright;

- Validity of authorization letter.

In case of authorization of multiple drugs, the authorization letter must have a list of drugs with all the above contents.

In case the person authorized to sign on the file is not the head of the representative office, the authorization letter must have the seal and signature of the head of the representative office in Vietnam for confirmation.

The letter of authorization must be an original or a copy with the confirmation stamp of the representative office (in case of a foreign registration establishment) or the confirmation stamp of the domestic registration establishment.

c) Number of authorization letters in the file:

- In case the registration facility is different from the production facility, each application must be submitted with a letter of authorization in the name of the registration facility;

- In case the title of the person signing on the application is not one of the titles specified in Points a and b, Clause 5 of this Article, each application must be accompanied by a letter of authorization to sign on the registration application.

7. Certificate of eligibility for pharmaceutical business with one of the following business forms: production, wholesale, export, import of drugs and medicinal ingredients (for Vietnamese registered establishments).

8. License to establish representative office in Vietnam.

In case the name and address of the registered establishment on the License to establish a Representative Office in Vietnam is different from the name and address on the legal documents of the registered establishment issued by a foreign competent management agency. supporting documents must be provided.

9. Legal documents issued by a competent foreign management agency allowing the implementation of at least one of the following business forms: production, wholesale, export, import of drugs and medicinal ingredients (for foreign registration establishments).

In case the drug registration facility is also the drug manufacturing facility listed on the CPP, it is not required to submit legal documents as prescribed in this Clause.

In cases where countries do not issue licenses to manufacture, wholesale, export or import drugs and medicinal ingredients, an establishment license or business registration with the scope of business in at least one of the following forms is required. following: manufacturing, wholesaling, exporting, importing drugs and medicinal ingredients accompanied by a certificate from a competent authority certifying that the facility meets the conditions and is operating in pharmacy or one of the following certificates: Recognize good drug manufacturing practices, good drug distribution practices, good drug supply practices, and good drug storage practices.

For establishments registering medicinal ingredients, in case the host country does not issue pharmaceutical business licenses to establishments trading in medicinal ingredients, licenses will be accepted according to the regulations of the host country, including the following contents: The content determines the business scope of the establishment as one of the following forms: production, wholesale, export, import of medicinal materials.

10. In case the registration facility is already on the list of establishments registering drugs and medicinal ingredients published on the website of the Drug Administration of Vietnam, the documents specified in Clause 7 are not required. , 8, 9 This.

11. Documents proving that the facility producing pharmaceutical ingredients, excipients, capsule shells, semi-finished pharmaceutical products and medicinal materials (for the production of medicinal materials) meets good manufacturing practices for medicinal materials (GMP) Can be one of the following documents:

a) GMP certificate ;

b) Production license with confirmation that the production facility meets GMP;

c) CPP for pharmaceutical substances that meet GMP;

d) Certificate of conformity with European Pharmacopoeia monograph (CEP);

d) For excipients in the application for registration of finished drugs and semi-finished medicinal ingredients:

In case the documents specified in one of Points a, b, d of this Clause cannot be provided, the facility manufacturing finished and semi-finished drugs shall conduct a self-assessment of the facility's compliance with good manufacturing practices. production of excipients according to the provisions of Point dd, Clause 1, Article 3, Point b, Clause 3, Article 3 and Point dd, Clause 5, Article 20, Circular No. 35/2018/TT-BYT dated November 22, 2018 of the Minister of Health regulations on good manufacturing practices for drugs and medicinal ingredients (amended and supplemented at Points a, b and dd, Clause 6, Article 1 of Circular No. 29/2020/TT-BYT dated December 31, 2020 of the Ministry Health amends, supplements and abolishes a number of legal documents promulgated by the Minister of Health, issued jointly by the Minister of Health) and self-announces in the drug registration dossier the principles and practical standards good production practices that the excipient manufacturer meets and commits to be responsible before the law for this declaration according to Form 10/TT issued with this Circular;

e) For medicinal materials in the drug registration dossier:

In case the documents specified in Points a and b of this Clause cannot be provided, the facility will provide a certificate of compliance with good farming and collecting medicinal practices (GACP);

g) Other legal documents issued by competent authorities with minimum contents including: name and address of the manufacturer, confirmation that the production facility meets GMP and the name of the pharmaceutical substance / excipient pharmaceuticals/capsules/semi-finished pharmaceutical products/medicinal materials.

12. Samples of drug labels, medicinal ingredients and drug use instructions actually circulated in the manufacturing country or CPP granting country with the confirmation stamp of the representative office or registration facility or manufacturing facility (accepted). Receive color prints according to the label model currently circulating in the host country). In case the actual drug use instructions in the host country are not in English, a translation into English or Vietnamese with the confirmation stamp of the representative office, registration facility or manufacturing facility is required. .

13. Samples of drug labels, medicinal ingredients and instructions for use of drugs expected to be circulated in Vietnam shall comply with regulations of the Minister of Health regulating labeling of drugs, medicinal ingredients and other requirements. specifically as follows:

a) Sample labels and instructions for use intended for circulation must be certified by the representative office, registration facility or manufacturing facility;

b) The outer packaging label of drugs and medicinal ingredients must be printed with bar code (Bar code) or QR code (Quick response) or DataMatrix Code (DMC) according to the roadmap specified in Point l, Clause 1, Article 48 of the Circular. This .

14. In case the facility manufacturing drugs and medicinal ingredients is listed in the list of manufacturing facilities published on the website of the Drug Administration of Vietnam and has been assessed to meet GMP, there is no requirement. must submit a dossier assessing compliance with good manufacturing practices in the registration dossier for drugs and medicinal ingredients.

15. Quality standards, testing methods, test reports and stability research records (applicable to both pharmaceutical substance and finished drug dossiers) must be originals with the facility's seal of approval. production, in case there are many production facilities participating in the production of finished products, accept the seal of the facility responsible for drug quality inspection or batch release; In case of submitting a copy, there must be a confirmation stamp of the registration facility (representative office stamp is accepted for foreign drugs).

In case the pharmaceutical substance dossier does not have the confirmation stamp of the pharmaceutical substance manufacturing facility, the finished drug manufacturing facility must stamp the confirmation and be responsible before the law for accuracy, legality, and honesty. of this document.

The testing certificate must include the following information: administrative information (name, address of the manufacturing facility, number of testing certificate, name and signature of the person assigned responsibility, date of issuance of the testing certificate) and information. information about drug samples and medicinal ingredients (product name, batch number, expiry date, applicable quality standards, quality indicators, quality requirements, testing results, conclusions about product batch quality).

16. Regulations on testing certificates, quality standard appraisal results, and experimental testing methods in Vietnam:

Testing slips, quality standard appraisal results, experimental testing methods for manufacturing facilities that do not meet GMP according to the roadmap of the Ministry of Health or cases notified by the Drug Administration according to regulations. specified in Appendix III issued with this Circular with certification from a state-owned drug testing facility that meets GLP standards or a drug and drug raw material testing service business that has been granted a certificate of eligibility. Business documents appropriate to the scope of operations must be originals or certified copies .

17. Certificate of medicinal ingredients permitted for production or circulation in the manufacturing country, including the following mandatory information: name of ingredients; name and address of the manufacturing facility; country of manufacture; signature, stamp and full name of the person signing the confirmation .

Article 23. General regulations on administrative documents in dossiers requesting issuance, extension, change, and supplementation of circulation registration certificates for drugs and medicinal ingredients

1. Administrative documents of the application dossier for issuance of registration certificate for circulation of new pharmaceutical drugs, vaccines, and biological products include:

a) Registration application according to Form 5/TT issued with this Circular;

b) Power of attorney in the name of the registration facility (if any);

c) Authorization letter to sign on the registration dossier (if any);

d) Samples of drug labels, medicinal ingredients and instructions for use of drugs expected to be circulated;

d) Certificate of eligibility for pharmaceutical business for Vietnamese registered establishments;

e) Legal documents, license to establish representative offices in Vietnam for foreign registered establishments;

g) Summary of product characteristics for new pharmaceutical drugs, vaccines, and biological products according to Form 6/TT issued with this Circular;

h) Legal documents of the facility manufacturing pharmaceutical ingredients, excipients, capsule shells, semi-finished pharmaceutical products, and medicinal materials;

i) Certificate of the testing facility for the cases specified in Clause 16, Article 22 of this Circular ;

k) Risk management plan (for vaccines) according to Form 7/TT issued with this Circular;

l) Samples of drug labels and instructions for use of drugs actually circulated in the manufacturing country or CPP granting country for foreign drug registration dossiers;

m) CPP certificate for foreign drug registration dossiers;

n) Documents assessing compliance with GMP for the cases specified in Article 95 of Decree No. 54/2017/ND-CP for foreign manufacturers of drugs and medicinal ingredients when registering for storage. in Vietnam for foreign drug registration applications (except in cases where the facility has published information to meet GMP on the website of the Drug Administration of Vietnam or the facility has submitted a request to the Department of Drug Administration of Vietnam). Pharmacology assesses compliance with GMP).

2. Administrative documents and application dossiers for issuance of registration certificates for circulation of generic drugs, herbal drugs, and medicinal ingredients as prescribed in Points a, b, c, d, dd, e, h, i, l , m, n Clause 1 of this Article and the certificate of medicinal ingredients permitted to be produced or circulated in the manufacturing country for registration dossiers of medicinal ingredients produced abroad.

3. Administrative documents and dossiers requesting extension of registration for circulation of pharmaceutical drugs, vaccines, biological products, herbal drugs, and medicinal ingredients as prescribed in Points a, c, d, e, m, n Clause 1 of this Article and the following documents:

a) Power of attorney in the name of the registration facility in case of changing the registration facility at the time of submitting the extension application;

b) Report on circulation of drugs and medicinal ingredients according to Form 8/TT issued with this Circular;

c) Copy of registration certificate for circulation of drugs and medicinal ingredients in Vietnam;

d) Report on monitoring and evaluating safety and effectiveness; Drug use status according to Form 2/TT issued with this Circular for dossiers for renewal of pharmaceutical drugs, vaccines, biological products, and herbal drugs that require monitoring and safety assessment reports. effective as prescribed in Clause 2, Article 5 of this Circular ;

d) Certificate of medicinal ingredients allowed to be produced or circulated in the manufacturing country for applications for renewal of medicinal ingredients produced abroad.

4. Administrative documents and dossiers requesting change or supplementation of registration papers for circulation of pharmaceutical chemicals, vaccines, biological products, herbal drugs, and medicinal ingredients as prescribed in Points a and c, Clause 1 of this Article .

5. Administrative documents of application for drug circulation registration certificate according to the shortened appraisal process as prescribed in Points a, b, c, d, dd, e, h, i, l , m Clause 1 This.

Section 2. DOCUMENTARY APPLICATION FOR ISSUANCE, EXTENTATION, CHANGE, SUPPLEMENT OF CIRCULATION REGISTRATION PAPER FOR PHARMACEUTICAL DRUGS, VACCINES, AND BIOGRAPHICAL PRODUCTS

Article 24. Quality documents in dossiers requesting issuance, change, and supplementation of registration papers for circulation of pharmaceutical drugs, vaccines, and biological products

Quality documents comply with the instructions in Part II - ACTD or Part 3-ICH-CTD and the following regulations:

1. For vaccines, serum containing antibodies, derivatives of human blood and plasma:

a) Batch release certificate issued by the competent authority of the CPP-issuing country according to regulations or one of the management agencies specified in Clause 9, Article 2 of this Circular ;

b) Testing documents , quality standards and testing methods are certified by the National Institute for Testing Vaccines and Medical Biologicals.

2. For rare drugs, drugs to meet the needs of national defense and security; Preventing and fighting epidemics and diseases, overcoming consequences of natural disasters and disasters, and drugs for special treatment needs:

a) Rare drugs to treat rare diseases: available stability study data according to ASEAN or ICH guidelines;

b) Medicines to meet the needs of national defense and security; Preventing and fighting epidemics and diseases, overcoming consequences of natural disasters and catastrophes:

Accept the stability study data available at the time of application for registration to consider the shelf life of the drug based on the opinion of the Council in case the time period of the drug stability study data is has not met the minimum research time requirements according to ASEAN guidelines.

After being granted a marketing registration certificate, the facility must continue to submit finished product stability study documents until the actual minimum stability study period meets the ASEAN guidelines on the Department of Food and Drug Administration. Pharmacy in the form of changes and supplements specified in Appendix II of this Circular to review and update the expiration date according to regulations.

In case the drug does not meet the results of the stability study according to the outline in the registration dossier, the establishment must immediately report to the Drug Administration of Vietnam to submit to the Council for consideration the drug's shelf life.

Based on the advice of the Council, the Drug Administration of Vietnam shall consider and decide on the expiry date of the drug, including the manufactured drug batches, based on actual stability research data.

c) Drugs for special treatment needs: available stability study data according to ASEAN or ICH guidelines are decided by the Minister of Health based on the opinion of the Council in the case of a registered facility. Sign proving that the drug cannot be stored in climatic conditions of zone IVb according to ASEAN guidelines.

3. In case the production facility uses medicinal ingredients that have been granted registration for circulation in Vietnam:

a) It is not required to submit quality documents related to raw materials and documents specified in Point h, Clause 1, Article 23 of this Circular in the finished drug registration dossier;

b) The registration facility must submit:

- 01 drug raw material testing certificate tested by the finished drug manufacturing facility must have all quality criteria with a quality level equivalent to or stricter than the quality level in the raw material manufacturing facility's standards. Whether. In case the finished drug manufacturing facility is not capable of testing all quality criteria, the facility must provide an analysis sheet of the missing criteria issued by the State Testing Agency or the service business establishment . Testing stations for drugs and medicinal ingredients that have been granted a certificate of eligibility for pharmaceutical business;

- 01 test report of raw materials for making drugs tested by the facility producing the raw materials.

4. For drugs, please follow the shortened appraisal process

a) Pharmaceutical substance profile:

- Drug substance name (recorded according to international generic name);

- Name and address of the facility manufacturing the pharmaceutical substance and semi-finished product containing the pharmaceutical substance;

- Quality standards and testing methods for pharmaceutical substances and semi-finished products containing pharmaceutical substances. In case the drug is registered according to Vietnam Pharmacopoeia standards or reference pharmacopoeia standards according to regulations of the Ministry of Health, only write the pharmacopoeia name, applicable pharmacopoeia version or write the current pharmacopoeia;

- 01 Testing slip of pharmaceutical ingredients and semi-finished products from a facility that produces pharmaceutical ingredients and semi-finished products and 01 Testing slip of pharmaceutical ingredients and semi-finished products from a facility that produces finished drugs;

- For pharmaceutical ingredients in the form of semi-finished products, there must be additional dosage formulas and production processes for semi-finished products containing pharmaceutical ingredients of the semi-finished product manufacturing facility.

b) Finished product documents:

- Description and ingredients according to instructions in Part P .1- ACTD;

- Quality standards and testing methods for finished drugs. In case of registration according to Vietnam Pharmacopoeia standards or reference pharmacopoeia standards according to regulations of the Ministry of Health, write the pharmacopoeia name, pharmacopoeia version or write the current pharmacopoeia;

- Production of finished products, including: production batch formula; manufacturing processes and process control; control of critical steps and intermediate products.

- Finished product testing certificate;

- Primary packaging: Describe the form, materials and quality standards of primary packaging;

- Report on stability research of finished drugs .

c) The remaining documents of the quality dossier shall be carried out according to the instructions in Part II - ACTD or Part 3-ICH-CTD kept at the registration facility and production facility.

5. Documents specified in this Article must comply with the following regulations:

a) Apply according to the regulations in Appendix I issued with this Circular, including:

- ASEAN Common Technical File (ACTD);

- Instructions for stability research;

- Guidance on production process appraisal;

- Guidance on evaluating analytical methods;

- Guidance on bioavailability and bioequivalence research;

b) For drug dossiers prepared according to the ICH-CTD form and corresponding ICH technical instructions, dossier conversion is not required as prescribed in Point a of this Clause;

c) In case the raw material has a certificate of compliance with the European Pharmacopoeia (CEP): The drug substance profile at Points a and b of this Clause can be replaced by submitting the following set of documents:

- Certificate of compliance with the European Pharmacopoeia (CEP) for the medicinal substance accompanied by all annexes issued by the European Council for the Quality of Medicines (EDQM);

- Analytical data of batches of pharmaceutical ingredients;

- If the deadline for retesting the quality of the drug substance is not stated in the CEP, submit data on the stability study of the drug substance.

Article 25. Pre-clinical documents in dossiers requesting issuance, change or supplementation of registration papers for circulation of pharmaceutical drugs, vaccines and biological products

Preclinical documents follow the instructions in Part III-ACTD or Component 4-ICH-CTD.

For probiotics with the same origin, bacterial strain, concentration, content, indication, and dosage as those licensed by one of the management agencies specified in Clause 9, Article 2 of this Circular , Preclinical documents are not required to be submitted.

Article 26. Clinical documents in dossiers requesting issuance, change, or supplementation of registration papers for circulation of pharmaceutical drugs, vaccines, and biological products

Clinical documentation follows the instructions in Part IV-ACTD or Component 5-ICH-CTD.

For probiotics with the same origin, bacterial strain, concentration, content, indication, and dosage as those licensed by one of the management agencies specified in Clause 9, Article 2 of this Circular , No clinical documentation required.

Article 27. Dossier to request issuance, extension, change or supplementation of registration certificate for circulation of pharmaceutical drugs, vaccines and biological products

1. Dossier to request a certificate of registration for circulation of new pharmaceutical drugs, vaccines, and biological products includes:

a) Administrative documents as prescribed in Clause 1, Article 23 of this Circular .

b) Quality documents specified in Article 24 of this Circular ;

c) Pre-clinical documents specified in Article 25 of this Circular ;

d) Clinical documents specified in Article 26 of this Circular ;

d) In case the registration facility requests classification of original brand name drugs or reference biological products when submitting an application for issuance of a drug circulation registration certificate, it shall comply with the provisions of Points a, b, c, d, Clause 1 of this Article. 1 This Article and item 2, point a, clause 1, Article 9 of this Circular .

2. Application dossier for issuance of registration certificate for circulation of generic drugs, including:

a) Administrative documents as prescribed in Clause 2, Article 23 of this Circular ;

b) Quality documents specified in Article 24 of this Circular .

3. Dossier to request extension of drug circulation registration certificate:

a) Administrative documents as prescribed in Clause 3, Article 23 of this Circular ;

b) Relevant documents as prescribed in Appendix II issued with this Circular for cases where drugs have changes in administrative records (excluding changes to drug label samples and drug use instructions).).

In case the registration facility has submitted changes to the administrative dossier before the time of submitting the extension application but has not yet been approved, this part of the dossier is not required to be resubmitted in the dossier to renew the circulation registration certificate.

4. Dossier requesting changes or additions to the drug circulation registration certificate includes:

a) Administrative documents as prescribed in Clause 4, Article 23 of this Circular ;

b) Documents corresponding to major changes and minor changes specified in Appendix II issued with this Circular. For vaccines from the same manufacturing facility or the holder of the drug marketing authorization accepts to change the location of the manufacturing facility in the same country or outside the country where the marketing authorization was granted.

5. Application dossier for issuance of drug circulation registration certificate according to the shortened appraisal process, including:

a) Administrative documents as prescribed in Clause 5, Article 23 of this Circular ;

b) Quality documents comply with the provisions of Points a and b, Clause 4, Article 24 of this Circular .

Section 3. DOCUMENTARY APPLICATION FOR ISSUANCE, RENEWAL, CHANGE, AND SUPPLEMENT OF Circulation Registration Paper for PHARMACEUTICAL DRUGS

Article 28. Quality documents in the dossier requesting issuance, change or supplementation of registration certificate for circulation of herbal drugs

1. Raw materials

a) Production process (only applicable to medicinal raw materials): Full and detailed description of the preliminary processing and processing of medicinal raw materials. If the raw materials are semi-finished pharmaceutical products or herbal extracts, a detailed description of the process for producing semi-finished medicinal herbs and medicinal extracts from medicinal raw materials must be described (except in the case of semi-finished medicinal herbs or medicinal extracts that have been processed). issued with a circulation registration certificate);

b) Quality standards and testing methods

- For medicinal materials other than semi-finished medicinal products: comply with the provisions of Circular No. 38/2021/TT-BYT ;

- For semi-finished pharmaceutical products, the same regulations on quality standards and testing methods for medicinal materials other than semi-finished pharmaceutical products shall apply as prescribed in Circular No. 38/2021/TT-BYT .

c) Raw material testing certificate

- 01 Pharmaceutical testing certificate from the finished drug manufacturing facility. In case the finished drug manufacturing facility does not have enough capacity to check all quality criteria, the facility must provide an analysis sheet of the missing criteria issued by the State Testing Agency or the service business establishment. testing of drugs and medicinal ingredients that have been granted a certificate of eligibility for pharmaceutical business; testing carried out;

- 01 Certificate of testing for semi-finished pharmaceutical products and herbal extracts from a facility that produces semi-finished pharmaceutical products and herbal extracts and 01 Certificate of testing for semi-finished pharmaceutical products and herbal extracts from a facility that produces finished drugs. .

2. Finished product

a) Production process

- Formula for the smallest packaging unit: name, content, concentration, volume, applicable standards of each ingredient in the formula for the smallest packaging unit. In case of production from semi-finished pharmaceutical products, medicinal herbs, it is necessary to clearly state the volume of medicinal materials corresponding to the semi-finished pharmaceutical products, medicinal herbs or the high ratio of medicinal herbs, semi-finished medicinal products compared to the original medicinal materials. first or accompanied by the content (%) of the pharmaceutical substance or group of compounds quantified according to each medicinal ingredient;

- Formula for a batch of finished drug production: clearly state the name, weight, and volume of each ingredient in the batch formula;

- Drug production process diagram : fully shows all stages in the drug production process, including the path of raw materials and is consistent with the description of the production process ;

- Description of the drug manufacturing process: a complete and detailed description of the steps taken in each stage of the production process, including full technical specifications of each stage;

- Equipment list: equipment name, parameters , purpose of use;

- Control during the production process: Full and detailed description of inspection and control criteria for each stage including name of criteria, acceptance standards, control method, control frequency, number amount of sample taken for control;

b) Quality standards and testing methods

- Formula for the smallest packaging unit: name, content, concentration, volume, applicable standards of each ingredient in the formula for the smallest packaging unit. In case of production from semi-finished pharmaceutical products, medicinal herbs, it is necessary to clearly state the volume of medicinal materials corresponding to the semi-finished pharmaceutical products, medicinal herbs or the high ratio of medicinal herbs,

semi-finished medicinal products compared to the original medicinal materials. first or accompanied by the content (%) of the pharmaceutical substance or group of compounds quantified according to each medicinal ingredient;

- Finished product standards: comply with regulations in Circular No. 11/2018/TT-BYT ;

c) Finished product testing certificate;

d) Packaging standards: Full and detailed description of packaging materials, quality criteria, quality levels and testing methods;

d) Stability study report according to the stability study instructions specified in Appendix I issued with this Circular.

Article 29. Safe and effective documents in application dossiers for granting, extending, changing or supplementing circulation registration certificates for herbal drugs

1. Safety and effectiveness documents for herbal drugs comply with the provisions of Appendix V issued with this Circular or according to the regulations of ASEAN (ACTD), ICH-CTD

2. Documents specified in Point b, Clause 1, Article 18 of this Circular (if any).

Article 30. Dossier to request issuance, extension, change or supplementation of registration certificate for circulation of medicinal drugs

1. Application dossier for issuance of registration certificate for circulation of medicinal drugs, including:

a) Administrative documents as prescribed in Clause 2, Article 23 of this Circular ;

b) Quality documents specified in Article 28 of this Circular ;

c) Safety and effectiveness documents specified in Article 29 of this Circular ;

2. Dossier requesting extension of registration certificate for circulation of medicinal herbs:

a) Administrative documents as prescribed in Clause 3, Article 23 of this Circular ;

b) Relevant documents as prescribed in Section D, Appendix II issued with this Circular for cases where the drug has changes in administrative records at the time of renewal of the marketing registration certificate (excluding change the drug label and instruction sheet).

In case the registration facility has submitted changes to the administrative dossier before the time of submitting the extension application but has not yet been approved, this part of the dossier is not required to be resubmitted in the dossier to renew the circulation registration certificate.

3. Dossier requesting change or supplementation of registration certificate for circulation of medicinal drugs, including:

a) Administrative documents as prescribed in Clause 4, Article 23 of this Circular ;

b) Documents corresponding to major changes and minor changes specified in Section D, Appendix II issued with this Circular.

Section 4. DOSSIER FOR REGISTRATION OF MEDICINAL INGREDIENTS

Article 31. Quality documents in the dossier requesting issuance, change or supplementation of registration certificate for circulation of medicinal ingredients

1. For pharmaceutical ingredients: Follow the ACTD dossier for pharmaceutical ingredients. In case the drug substance is registered for quality according to the manufacturer's standards, it must be submitted with the overall drug substance dossier (Drug Master File).

2. For raw materials in the form of semi-finished products containing pharmaceutical substances: Follow the ACTD dossier like registering finished drugs, in which the dossier on finished products is replaced by the dossier on registered semi-finished products; Formulas for one dose unit or smallest packaging unit are replaced by production batch formulas.

3. For semi-finished pharmaceutical ingredients, excipients, and capsule shells:

a) Preparation formula for semi-finished pharmaceutical products, excipients in pre-mixed form, capsule shell: ingredients, weight, volume, quality standards of each ingredient in the formula. In case of using materials of animal origin, information on incidental substances (virus safety data) must be provided;

b) Production process

- Production process diagram: shows all stages in the production process including the path of materials and is consistent with the description of the production process;

- Description of the production process: a complete and detailed description of the steps taken in each stage of the production process, including full technical specifications of each stage ;

- Equipment list: equipment name, parameters, purpose of use;

- Control during the production process: Full and detailed description of inspection and control criteria for each stage including name of criteria, acceptance standards, control method, control frequency, number amount of sample taken for control.

c) Quality standards and testing methods

- For semi-finished pharmaceutical products, the same regulations on quality standards and testing methods for medicinal materials other than semi-finished pharmaceutical products shall apply as prescribed in Circular No. 38/2021/TT- BYT ;

- For excipients and capsule shells: comply with regulations in Circular No. 11/2018/TT-BYT .

d) Test certificate;

d) Packaging standards: Full and detailed description of packaging materials, quality criteria, quality levels and testing methods;

e) Stability study report, including stability study outline; stability study data; results and discussion.

Article 32. Dossier to request issuance, extension, change or supplementation of registration certificate for circulation of medicinal ingredients

1. Application dossier for issuance of registration certificate for circulation of medicinal ingredients, including:

a) Administrative documents as prescribed in Clause 2, Article 23 of this Circular ;

b) Quality documents specified in Article 31 of this Circular .

2. Dossier to request extension of registration certificate for circulation of medicinal ingredients:

a) Administrative documents as prescribed in Clause 3, Article 23 of this Circular ;

b) Relevant documents as prescribed in Section B, Appendix II issued with this Circular for cases where medicinal ingredients have changes in administrative records at the time of renewal of marketing registration (does not include changing the label of medicinal ingredients).

In case the registration facility has submitted changes to the administrative dossier before the time of submitting the extension application but has not yet been approved, this part of the dossier is not required to be resubmitted in the dossier to renew the circulation registration certificate.

3. Dossier requesting change or supplementation of registration certificate for circulation of medicinal ingredients, including:

a) Administrative documents as prescribed in Clause 4, Article 23 of this Circular ;

b) Documents corresponding to major and minor changes as prescribed in Part B, Appendix II issued with this Circular.

Chapter IV

PROCEDURES FOR ISSUING, EXTENDING, CHANGING AND SUPPLEMENTING REGISTRATION PAPER FOR CIRCULATION OF DRUGS AND MEDICINAL INGREDIENTS; PROCEDURES FOR APPRAISAL DOCUMENTS FOR IMPORTING MEDICINES WITHOUT CIRCULATION REGISTRATION CERTIFICATE

Article 33. Cases are carried out according to the expedited and shortened appraisal process

1. Cases are carried out according to the expedited appraisal process

The property registration dossier is appraised according to the expedited appraisal process when one of the following conditions is met:

a) Drugs on the List of rare drugs issued by the Minister of Health;

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

c) Domestic drugs are produced on new lines meeting GMP standards or on upgraded lines meeting GMP-EU, GMP-PIC/S standards and equivalent within no more than 18 months from the date of issuance of the license. GMP certification;

d) Vaccines that have been pre-assessed by WHO and are used in the national expanded vaccination program;

d) Specialized drugs, drugs with special dosage forms with no more than 02 (two) similar drugs (same pharmaceutical ingredients, same dosage form, same content, concentration) with drug circulation registration certificate in Vietnam that is still valid at the time of application submission, including:

- Cancer treatment drugs;

- New generation antiviral treatment drugs;

- New generation antibiotics;

- Drugs used in the treatment of dengue fever, tuberculosis, and malaria;

- Immunosuppressive drugs used in organ transplantation.

e) Domestically produced drugs, including:

- Drugs manufactured or transferred in manufacturing technology in Vietnam for cancer treatment drugs, vaccines, biological products, new generation antiviral drugs, new generation antibiotics, Immunosuppressants used in organ transplantation;

- Medicinal drugs with scientific and technological topics at the national, ministerial or provincial level that have been accepted and met the requirements, the drugs are produced entirely from domestic pharmaceutical sources that meet GACP;

- New domestically produced drugs have completed clinical trials in Vietnam;

g) New drugs (cancer treatment, new generation antivirals, new generation antibiotics), reference biological products;

h) Original brand name drugs are manufactured or transferred with manufacturing technology in Vietnam ;

i) The drug's production facility is changed, resulting in a new circulation registration certificate being issued as prescribed in Point b, Clause 2, Article 55 of the Pharmacy Law .

2 . Cases are assessed according to an abbreviated process

Drug registration dossiers are evaluated according to the shortened appraisal process when the following conditions are simultaneously met:

a) Drugs are manufactured at facilities that are periodically assessed by the Drug Administration of Vietnam to meet good drug manufacturing practices;

b) Drugs on the List of non-prescription drugs;

c) The drug is not a modified release dosage form;

d) Do not use the medicine directly on the eyes.

Article 34. Authority to issue, extend, change and supplement circulation registration certificates for drugs and medicinal ingredients

1. The Drug Administration of Vietnam and units decided by the Minister of Health (hereinafter referred to as appraisal units) organize the appraisal of dossiers for granting, extending, changing and supplementing drug circulation registration certificates. , medicinal ingredients, except for the cases specified in Point b, Clause 2 of this Article.

2. Drug Administration:

a) Issuing, extending, approving changes, supplementing drug circulation registration certificates, announcing original brand name drugs, reference biological products, drugs with bioequivalence research reports on the basis of consulting opinions of The Council for each specific case or the Council's general policy applicable to each type of change or addition, except for the cases specified in Point b of this Clause;

b) Announce on the website of the Drug Administration of Vietnam the content of changes and additions to the registration certificate for circulation of drugs and medicinal ingredients for minor changes that only require notification.

Article 35. General regulations on procedures for granting, extending, changing and supplementing circulation registration certificates for drugs and medicinal ingredients

1. Applications are submitted online, in person or by post to the Drug Administration of Vietnam.

2. After receiving the complete dossier, the Drug Administration of Vietnam shall return to the registration facility the dossier receipt form according to Form 9/TT issued with this Circular.

The Drug Administration of Vietnam receives applications without being required to submit CPP for the cases specified in Point e, Clause 4, Article 22 of this Circular and documents specified in Point b, Clause 1, Article 24 of this Circular at the time of submission. file.

3. For dossiers to import drugs that do not have a certificate of circulation, the receipt of dossiers shall comply with the provisions of Point b, Clause 1, Article 77 of Decree No. 54/2017/ND-CP .

4. Organize appraisal of dossiers requesting issuance, extension, change , supplementation of circulation registration certificates for drugs, medicinal ingredients and dossiers for import of drugs without circulation registration certificates:

a) The Drug Administration of Vietnam transfers the dossier to experts or units assigned by the Ministry of Health to organize the appraisal on the basis of the list of experts established by the Drug Administration or the appraisal units. approve;

b) Based on the synthesis of appraisal opinions of experts or appraisal units and review of relevant information, the Drug Administration of Vietnam is responsible for proposing the issuance, extension, or replacement of change, supplement or not yet issue, extend, change, supplement or not issue, extend, change or supplement the registration certificate for circulation of drugs and medicinal ingredients; issued, not yet issued, or not granted a license to import drugs that do not have a circulation registration certificate. The Drug Administration's proposed opinions are shown in the appraisal minutes;

c) The Drug Administration of Vietnam submits to the Council for consideration and advice on the proposals of the Drug Administration of Vietnam specified in Point b of this Clause for the following cases:

- Granted, not granted; extended, not extended; Approve or disapprove changes or supplements to circulation registration papers for drugs and medicinal ingredients, except for the cases specified in Clause 5 of this Article;

- Announce or not announce original brand name drugs and reference biological products, except in cases where the drug registration facility is not required to submit a request for classification of original brand name drugs or reference biological products as prescribed in Article 9 of this Circular ;

- Issuing or not granting licenses to import drugs without circulation registration;

- Other cases proposed by the Drug Administration of Vietnam to meet urgent needs in disease prevention and treatment.

5. For dossiers requesting issuance, extension, change, or supplementation of registration papers for circulation of drugs and medicinal ingredients, establishments are only allowed to amend and supplement no more than 03 times. If the number of amendments and supplements mentioned above is exceeded and the application for amendments and supplements is not satisfactory, the Drug Administration of Vietnam shall issue an official dispatch notifying it of its disapproval of granting or extending the circulation registration certificate . Approve documents for changes and additions. Submitted documents are no longer valid.

Article 36. Procedures for granting drug circulation registration certificates, procedures for appraisal of dossiers for importing drugs without circulation registration certificates

1. Within a maximum period of 12 months from the date of receipt of complete documents for the application for drug circulation registration (except for the cases specified in Article 39 of this Circular), the Drug Administration of Vietnam shall issue the registration certificate. Registration of drug circulation. In case of non-issue or not yet issued , the Drug Administration of Vietnam will respond in writing and clearly state the reason. The time to resolve the steps is specified, specifically as follows:

a) Within 02 months from the date of receiving the dossier, the Drug Administration of Vietnam will review, classify and send the dossier to appraisal experts or appraisal units. Within 06 months from the date of receiving the dossier from the Drug Administration of Vietnam, the appraisal experts or appraisal units must complete the appraisal record and send it to the Drug Administration of Vietnam to synthesize and propose the above opinions. appraisal record as prescribed in Clause 4, Article 35 of this Circular ;

b) Within 02 months from the date of receipt of the appraisal record, the Drug Administration of Vietnam shall issue a written response to the unsatisfactory appraisal dossier and clearly state the reason. For dossiers proposed to be issued by the Drug Administration of Vietnam, not granted or proposed to require review and advice from the Council, the Drug Administration of Vietnam will transfer the Council Office to hold a Council meeting;

c) Within 01 month from the date of receiving documents from the Drug Administration of Vietnam, the Council Office shall organize a Council meeting and send the minutes of the Council meeting to the Drug Administration of Vietnam;

d) Within 01 month from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall issue a decision to grant a marketing registration certificate for dossiers that meet the requirements; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

2. Within 36 months for cases requiring additional pre-clinical and clinical documents, bioequivalence documents, stability research documents or within 12 months for other cases To supplement other documents, from the date the Drug Administration of Vietnam issues a written notification, the registration facility must submit additional documents as requested. After this deadline, if the registration facility does not submit additional documents, the submitted documents are no longer valid.

The registration facility is allowed to notify the Drug Administration of Vietnam in writing about the registration dossier submitted and under appraisal in cases of updating information related to the safety and effectiveness of the drug. drugs or legal documents of the registration facility, drug manufacturing facility, drug raw materials compared to the submitted dossier.

The time from the date of written notification from the Drug Administration of Vietnam to the time the registration facility submits additional documents is not counted in the time limit specified in Clause 5, Article 56 of the Pharmacy Law .

3. Within 06 months from the date of receipt of complete additional documents, the Drug Administration of Vietnam shall issue a decision to grant a marketing registration certificate for satisfactory dossiers or issue a written response to the appraisal dossier. fail according to the Council's conclusion or provide a written response to the unsatisfactory appraisal dossier and clearly state the reason. The time to resolve the steps is specified, specifically as follows:

a) Within 01 month from the date of receiving the dossier, the Drug Administration of Vietnam will review, classify and send the dossier to appraisal experts or appraisal units. Within 02 months from the date of receiving the dossier from the Drug Administration of Vietnam, the appraisal experts or appraisal units must complete the appraisal record and send it to the Drug Administration of Vietnam to summarize and propose the above opinions. appraisal record as prescribed in Clause 4, Article 35 of this Circular ;

b) Within 01 month from the date of receiving the appraisal record, the Drug Administration of Vietnam shall issue a written response to the unsatisfactory appraisal dossier and clearly state the reason. For dossiers proposed to be issued by the Drug Administration of Vietnam, not granted or proposed to require review and advice from the Council, the Drug Administration of Vietnam will transfer the Council Office to a meeting to organize the Council;

c) Within 01 month from the date of receiving documents from the Drug Administration of Vietnam, the Council Office shall organize a Council meeting and send the minutes of the Council meeting to the Drug Administration of Vietnam;

d) Within 01 month from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall issue a decision to grant a marketing registration certificate for dossiers that meet the requirements; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

4. Procedures for appraising dossiers for importing drugs without circulation registration:

a) Within 05 working days from the date of receipt of complete dossier, the Drug Administration of Vietnam shall transfer the dossier to appraisal experts or appraisal units.

The appraisal time is no more than 30 days for dossiers that do not require clinical data or documents proving similarity to the reference biological product, or no more than 60 days for dossiers that require data. Clinical data or documents proving similarity to the reference biological product from the date the Drug Administration of Vietnam transfers the dossier to the appraisal expert or appraisal unit;

b) Within 20 days from the date of receipt of the appraisal record:

- The Drug Administration of Vietnam synthesizes the appraisal opinions of appraisal experts or appraisal units and reviews relevant information to propose whether or not to issue a license to import unlicensed drugs. circulation registration.

- For documents that need to be submitted to the Council according to the provisions of Point c, Clause 4, Article 35 of this Circular , the Drug Administration of Vietnam shall submit them to the Council at the nearest meeting;

- For unsatisfactory appraisal dossiers, the Drug Administration of Vietnam shall issue a written response clearly stating the reason.

c) Within 05 working days from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall issue an import license for satisfactory documents; or have a written response according to the Council's conclusion to the appraisal dossier that has not passed or does not meet the requirements and clearly states the reason;

d) After receiving the import facility's amended and supplemented dossier, the Drug Administration of Vietnam shall comply with the provisions of Points a, b and c of this Clause.

For dossiers that the Council requires to be amended or supplemented and do not require re-submission to the Council next time, the Drug Administration of Vietnam shall notify the establishment of amendments and supplements; In case the revised or supplemented dossier meets the requirements, the Drug Administration of Vietnam shall grant the license without having to submit it again to the Council.

Article 37. Procedures for extending registration papers for circulation of drugs and medicinal ingredients

1. Within 03 months from the date of receipt of complete documents, the Drug Administration of Vietnam shall extend the registration certificate for circulation of drugs and medicinal ingredients. In case of non-renewal or non-renewal, the Drug Administration of Vietnam will respond in writing and clearly state the reason. The time for each step is specified, specifically as follows:

a) Within 08 working days from the date of receiving the dossier, the Drug Administration of Vietnam will review, classify and send the dossier to appraisal experts or appraisal units. Within 01 month from the date of receiving the dossier from the Drug Administration, the appraisal experts or appraisal units must complete the appraisal record and send it to the Drug Administration to summarize and conclude the appraisal record. determined according to the provisions of Clause 4, Article 35 of this Circular ;

b) Within 12 working days from the date of receiving the appraisal record, the Drug Administration of Vietnam shall issue a written response to the unsatisfactory appraisal dossier and clearly state the reason. For dossiers proposed to be extended, not extended by the Drug Administration of Vietnam, or requiring the approval and advice of the Council, the Drug Administration of Vietnam will transfer the Council Office to hold a Council meeting;

c) Within 06 working days from the date of receiving documents from the Drug Administration of Vietnam, the Council Office organizes a Council meeting and sends the minutes of the Council meeting to the Drug Administration of Vietnam;

d) Within 18 working days from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall issue a decision to extend the marketing registration certificate for satisfactory dossiers; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

2. Within 12 months for cases of additional documents, from the date of the Drug Administration's written notification, the registration facility must submit additional documents as requested. After this deadline, if the registration facility does not submit additional documents, the submitted documents are no longer valid.

The registration facility is allowed to notify in writing updates to the Drug Administration of the dossier submitted and under appraisal in cases of updating information related to the safety and effectiveness of the drug or Legal papers of the registration facility, drug and drug raw material manufacturing facility compared to the submitted dossier.

The time from the date of written notification from the Drug Administration of Vietnam to the time the registration facility submits additional documents is not counted in the time limit specified in Clause 5, Article 56 of the Pharmacy Law .

3. Within 03 months from the date of receipt of complete additional documents, the Drug Administration of Vietnam shall issue a decision to extend the marketing registration certificate for satisfactory dossiers; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

The order and time for reviewing additional documents shall comply with the provisions in Clause 1 of this Article.

Article 38. Procedures for changing and supplementing the circulation registration certificate of drugs and medicinal ingredients while the circulation registration certificate of drugs and medicinal ingredients is still valid

1. Change or supplement the registration certificate for circulation of drugs and medicinal ingredients, except for the cases specified in Clause 2 of this Article

Within 03 months from the date of receipt of complete dossier, the Drug Administration of Vietnam approves the changes and additions. In case of disapproval or not yet approved, the Drug Administration of Vietnam will respond in writing and clearly state the reason. The time for each step is specified, specifically as follows:

a) Within 08 working days from the date of receiving complete dossiers, the Drug Administration of Vietnam will review, classify and send dossiers to experts or appraisal units. Within 01 month from the date of receiving documents from the Drug Administration of Vietnam, experts and appraisal units must complete the appraisal record and send it to the Drug Administration of Vietnam to synthesize and conclude the appraisal record according to regulations. specified in Clause 4, Article 35 of this Circular ;

b) Within 12 working days from the date of receiving the appraisal record from the appraisal experts or appraisal units, the Drug Administration of Vietnam shall issue a written response to the appraisal dossier that has not passed or failed. achieve and clearly state the reasons. For satisfactory appraisal dossiers or other cases requiring appraisal opinions and advice from the Council, the Drug Administration of Vietnam will transfer the Council Office to hold a Council meeting;

c) Within 06 working days from the date of receiving documents from the Drug Administration of Vietnam, the Council Office organizes a Council meeting and sends the Council meeting minutes to the Drug Administration of Vietnam;

d) Within 18 working days from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall announce generic drugs, reference biological products, drugs with bioequivalence research reports, and approve the content. Change, supplement or provide a written response according to the Council's conclusion to the appraisal dossier that has not passed or fails, clearly stating the reason.

2. Changes and supplements to the circulation registration certificate of drugs and medicinal ingredients for minor changes that only require notification:

Within 15 working days from the date of receiving complete dossiers, the Drug Administration of Vietnam will classify and announce minor changes that only require notification on the Administration's website. Pharmacy. In case the content of changes or additions does not conform to the classification of minor changes that only require notification, the Drug Administration of Vietnam shall issue a written notification.

The facility shall make and take full responsibility for the content of changes and additions from the date of receipt recorded on the application receipt. Drug registration establishments and manufacturing establishments are responsible before the law for the accuracy and truthfulness of additional change information and are only required to notify and store records and documents for competent authorities. right to post-market inspection.

3. Within 36 months for cases requiring additional pre-clinical and clinical documents, bioequivalence documents, stability research documents or within 12 months for other cases To supplement other documents, from the date the Drug Administration of Vietnam issues a written notification, the registration facility must submit additional documents as requested. After this deadline, if the registration facility does not submit additional documents, the submitted documents are no longer valid.

The registration facility is allowed to notify the Drug Administration of Vietnam in writing about the registration dossier submitted and under appraisal in cases of updating information related to the safety and effectiveness of the drug. drugs or legal documents of the registration facility, drug manufacturing facility, drug raw materials compared to the submitted dossier.

The time from the date of written notification from the Drug Administration of Vietnam to the time the registration facility submits additional documents is not counted in the time limit specified in Clause 5, Article 56 of the Pharmacy Law .

4. Within 02 months from the date of receipt of complete supporting documents for the dossier specified in Clause 1 of this Article, the Drug Administration of Vietnam approves changes and supplements to the marketing registration certificate for satisfactory dossiers. bridge; Have a written response to the unsatisfactory or unsatisfactory appraisal dossier and clearly state the reason. The time for each step is specified, specifically as follows:

a) Within 05 working days from the date of receiving complete dossiers, the Drug Administration of Vietnam will review, classify and send dossiers to appraisal experts or appraisal units. Within 08 working days from the date of receiving the dossier from the Drug Administration of Vietnam, the appraisal experts or appraisal units must complete the appraisal record and send it to the Drug Administration of Vietnam to summarize and conclude the minutes. appraisal copy as prescribed in Clause 4, Article 35 of this Circular ;

b) Within 07 working days from the date of receiving the appraisal record from the appraisal experts or appraisal units, the Drug Administration of Vietnam shall issue a written response to the appraisal dossier that has not passed or failed. achieve and clearly state the reasons. For satisfactory appraisal dossiers or other cases requiring appraisal and advice from the Council, the Drug Administration of Vietnam will transfer the Council Office to hold a Council meeting;

c) Within 06 working days from the date of receiving documents from the Drug Administration of Vietnam, the Council Office organizes a Council meeting and sends the minutes of the Council meeting to the Drug Administration of Vietnam;

d) Within 18 working days from the date of receipt of the Council meeting minutes , the Drug Administration of Vietnam shall announce original brand-name drugs, reference biological products, and drugs with bioequivalence research reports; Approve the content of changes and additions of drugs for satisfactory dossiers. The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

5. Time limit for implementation of changes and additions to the registration certificate for circulation of drugs and medicinal ingredients: no more than 12 months from the date the Drug Administration of Vietnam signs and issues the official dispatch approving the applications. in case of changes or additions.

6. In some cases of changes or additions, the drug registration facility or drug manufacturer is responsible for updating the drug label and instructions for use and is not required to submit documents or notify the drug manufacturer. Drug Administration, including the following cases:

a) Carry out labeling of drugs, medicinal ingredients, and instructions for drug use according to the provisions of Clause 2, Article 35 of Circular 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health regulations labeling of drugs, medicinal ingredients and drug use instructions;

b) Make changes and additions to label content and instructions for drug use according to official dispatches from the Drug Administration of Vietnam guiding the Council's policies;

c) In addition to cases where the drug label and instructions for use must be resubmitted when there are changes or additions as prescribed in Appendix II issued with this Circular, other changes related to the above information Drug labels, instructions for use, registration facilities, and manufacturing facilities must update themselves upon approval of these changes and additions by the Drug Administration of Vietnam.

d) Other contents:

- Change the location and information of the facility importing drugs and medicinal ingredients listed on the drug label or instruction sheet;

- Correct spelling errors on drug labels and instructions for use;

- Change the layout of items in the instruction manual but do not change the content of the drug instruction manual that has been approved in accordance with regulations for drug instruction leaflets;

- Supplement information on quality standards on labels and instructions for drug use according to documents approved by the Drug Administration of Vietnam;

- Remove non-mandatory information on drug labels and instructions for use.

Article 39. The procedure for granting drug circulation registration certificates is carried out according to the process of quick appraisal, shortened appraisal and issuance of circulation registration certificates for medicinal ingredients

1. Within 06 months from the date of receipt of complete documents, the Drug Administration of Vietnam shall issue a certificate of registration for circulation of drugs and medicinal ingredients. In case it is not issued or has not been updated, the Drug Administration of Vietnam will respond in writing and clearly state the reason. The time to resolve the steps is specified, specifically as follows:

a) Within 16 working days from the date of receipt of complete dossier, the Drug Administration of Vietnam will classify and send the dossier to experts or appraisal units. Within 03 months from the date of receiving documents from the Drug Administration of Vietnam, experts and appraisal units must complete the appraisal record and send it to the Drug Administration of Vietnam to synthesize and conclude the appraisal record according to prescribed in Clause 4, Article 35 of this Circular ;

b) Within 18 working days from the date of receiving the appraisal record, the Drug Administration of Vietnam shall issue a written response to the unsatisfactory appraisal dossier and clearly state the reason. For appraisal dossiers that meet the requirements, do not meet the requirements or other cases, it is necessary to ask for appraisal opinions and advice from the Advisory Council for issuance of circulation registration certificates for drugs and medicinal ingredients, the Drug Administration of Vietnam. Move the Council Office to organize Council meetings;

c) Within 10 working days from the date of receiving documents from the Drug Administration of Vietnam, the Council Office organizes a Council meeting and sends the minutes of the Council meeting to the Drug Administration of Vietnam;

d) Within 01 month from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall issue a decision to grant a marketing registration certificate for dossiers that meet the requirements; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

2. Within 36 months for cases requiring additional pre-clinical and clinical documents, bioequivalence documents, stability research documents or within 12 months for other cases To supplement other documents, from the date the Drug Administration of Vietnam issues a written notification, the registration facility must submit additional documents as requested. After this deadline, if the registration facility does not submit additional documents, the submitted documents are no longer valid.

The registration facility is allowed to notify the Drug Administration of Vietnam in writing about the registration dossier submitted and under appraisal in cases of updating information related to the safety and effectiveness of the drug. drugs or legal documents of the registration facility, drug manufacturing facility, drug raw materials compared to the submitted dossier.

The time from the date of written notification from the Drug Administration of Vietnam to the time the registration facility submits additional documents is not counted in the time limit specified in Clause 5, Article 56 of the Pharmacy Law .

3. Within 03 months from the date of receipt of complete additional documents, the Drug Administration of Vietnam shall issue a decision to issue a marketing registration certificate for the dossier that meets the requirements; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons. The time to resolve the steps is specified, specifically as follows:

a) Within 10 working days from the date of receiving the dossier, the Drug Administration of Vietnam will review, classify and send the dossier to appraisal experts or appraisal units. Within 16 working days from the date of receiving the dossier from the Drug Administration of Vietnam, the appraisal experts or appraisal units must complete the appraisal record and send it to the Drug Administration of Vietnam to synthesize and propose opinions. comments on the appraisal record as prescribed in Clause 4, Article 35 of this Circular ;

b) Within 08 working days from the date of receiving the appraisal record, the Drug Administration of Vietnam shall issue a written response to the unsatisfactory appraisal dossier and clearly state the reason. For dossiers proposed to be issued by the Drug Administration of Vietnam, not granted or proposed to require review and advice from the Council, the Drug Administration of Vietnam will transfer the Council Office to the Council meeting;

c) Within 10 working days from the date of receiving documents from the Drug Administration of Vietnam, the Council Office organizes a Council meeting and sends the minutes of the Council meeting to the Drug Administration of Vietnam;

d) Within 01 month from the date of receipt of the Council meeting minutes, the Drug Administration of Vietnam shall issue a decision to grant a marketing registration certificate for dossiers that meet the requirements; The Drug Administration of Vietnam shall issue a written response according to the Council's conclusion to the unsatisfactory or unsatisfactory appraisal dossiers and clearly state the reasons.

Chapter V

REVOKING CIRCULATION REGISTRATION PAPER, STOP RECEIVING ISSUANCE DOCUMENTS, RENEWING CIRCULATION REGISTRATION PAPER

Article 40. Authority and procedures for revocation of registration papers for circulation of drugs and medicinal ingredients

1. Authority to revoke and responsibility to notify revocation of circulation registration certificate:

a) The Drug Administration of Vietnam revokes the registration certificate for circulation of drugs and medicinal ingredients in the cases specified in Clause 1, Article 58 of the Pharmacy Law ;

b) Departments of Health of provinces and centrally-run cities and health sectors notify the decision of the Drug Administration of Vietnam on revoking the registration certificate for circulation of drugs and medicinal ingredients in the management area.

2 . Procedures for revocation of registration papers for circulation of drugs and medicinal ingredients are specified in Points a and b, Clause 1, Article 58 of the Pharmacy Law :

Within no more than 30 days from the date of the decision to recall the drug by the competent management agency, the Drug Administration of Vietnam shall issue a decision to revoke the registration certificate for circulation of drugs and medicinal ingredients.

3. Procedures for revocation of registration papers for circulation of drugs and medicinal ingredients specified in Points d and dd, Clause 1, Article 58 of the Pharmacy Law

Within no more than 30 days from the date of the competent management agency's written conclusion that the dossier of the drug that has been granted a circulation registration certificate is a fake dossier or the drug or raw material If the drug is manufactured at the wrong address according to the registration dossier, the Drug Administration of Vietnam issues a decision to revoke the registration certificate for circulation of drugs and medicinal ingredients.

4. Procedures for revocation of registration papers for circulation of drugs and medicinal ingredients specified in Points c and e, Clause 1, Article 58 of the Pharmacy Law

Within no more than 10 days from the date the competent Vietnamese management agency or from the date of receipt of notification from WHO or the country of origin advising that the drug is not safe or effective for users or agencies. Competent foreign authorities revoke the product certificate, and the Drug Administration of Vietnam issues a decision to revoke the registration certificate for circulation of drugs and medicinal ingredients.

5. Procedures for revocation of registration papers for circulation of drugs and medicinal ingredients prescribed at Point g, Clause 1, Article 58 of the Pharmacy Law :

a) The facility submits an application to revoke the registration certificate for circulation of drugs and medicinal ingredients in Vietnam of the manufacturing facility or the facility registering drugs and medicinal ingredients according to Form 1/TT issued with the Circular. this statement;

b) Within no more than 20 days from the date of receipt of the request for recall, the Drug Administration of Vietnam shall issue a decision to revoke the certificate of registration for circulation of drugs and medicinal ingredients.

Article 41. Regulations on stopping receiving applications for issuance and extension of circulation registration certificates for drugs and medicinal ingredients

1. Stop receiving dossiers for issuance and extension of circulation registration certificates for drugs and medicinal ingredients shall comply with the provisions of Clauses 2, 3 and 4, Article 100 of Decree No. 54/2017/ND-CP .

2. The Drug Administration of Vietnam announces the cessation of receiving applications for issuance and extension of registration certificates for circulation of drugs and medicinal ingredients.

Chapter VI

PRINCIPLES OF ORGANIZATION AND OPERATION OF THE ADVISORY COUNCIL FOR ISSUANCE OF CIRCULATION REGISTRATION OF DRUGS, MEDICINAL INGREDIENTS, APPRAISAL UNITS, APPRAISAL EXPERTS

Article 42. Organization and operations of the Council

1. The Minister of Health establishes an Advisory Council to grant circulation registration certificates for drugs and medicinal ingredients. Council members are experts with appropriate professional qualifications and experience to ensure the ability to evaluate documents, criticize the opinions of appraisal experts, suggestions of the Drug Administration of Vietnam and advise the Board of Directors. Minister of Health issues related to pharmaceutical legislation, records on quality, safety, effectiveness of drugs and medicinal ingredients.

2. The Council is responsible for advising the Minister of Health in granting, extending, changing and supplementing circulation registration certificates for drugs and medicinal ingredients; License to import drugs that do not have a registration certificate for circulation in Vietnam based on the appraisal results of experts, suggestions from the Drug Administration of Vietnam and related issues requested by the Minister of Health. The Council is responsible to the Minister of Health for advisory opinions.

3. Operating principles of the Council:

a) The Council operates according to the principles of consensus, democratic centralism, objectivity, openness and transparency. The Council's opinions must ensure legal basis, scientific basis, consider the results of appraisal documents of appraisal experts, be based on clinical practice, and proposals of the Drug Administration of Vietnam;

b) The Council meets when at least 2/3 of the qualified Council members (according to the Regulations on organization and operation of the Council issued by the Ministry of Health) attend, in case Council members do not attend the meeting. But if you send your comments in writing, it will be considered as attending the meeting;

The Chairman of the Council or the person authorized by the Chairman of the Council to chair the meeting, the Council concludes on the basis of at least 2/3 of the opinions of the members participating in the agreement. Opinions that do not agree with the Council's conclusions are reserved.

The opinions of the Council members and the Council's conclusions must be expressed in the Council meeting minutes, including opinions that do not agree with the Council's conclusions.

c) In case a Council meeting is not held, the Chairman of the Council shall collect written opinions from Council members;

In case the deadline for submitting opinions has passed, the Chairman of the Council or an authorized person will make the Council's conclusions when at least 2/3 of the members have sent their opinions to the Standing Council for synthesis. .

The Council's concluding opinion is based on the consensus of at least 2/3 of the members who have sent their opinions to the Standing Council and on the basis of the summary report and proposals of the Drug Administration of Vietnam;

The Council's concluding opinions are expressed in the Concluding Opinion Report of the Council Chairman or the person authorized by the Council Chairman .

d) In case of necessity, council members have the right to review and appraise documents , and the Chairman of the Council has the right to seek additional opinions from independent experts in addition to members of the Council before making a decision. draw final conclusions. These experts

can directly attend Council meetings or give written opinions, and have the same responsibilities and rights as official members of the Council;

d) Do not violate the principles of conflict of interest.

4. The Drug Administration of Vietnam advises and submits to the Minister of Health to promulgate regulations on the organization and operation of the Council, and the coordination mechanism between the Council and appraisal experts in the process of issuance, extension, and change. , supplementing the registration certificate for circulation of drugs, medicinal ingredients, and license to import drugs that do not have a certificate of circulation registration in Vietnam.

5. The Council's operating budget is implemented in accordance with the provisions of law.

6. Standing Council located at the Drug Administration of Vietnam.

Article 43. Organization and activities of appraisal units and experts evaluating dossiers requesting for granting, extending, changing, supplementing drugs and medicinal ingredients, and appraising dossiers requesting import licenses The drug does not have a circulation registration certificate

1. The Drug Administration of Vietnam and the appraisal unit are responsible for establishing subcommittees of experts to assess: legality; quality standards; pharmacological; clinical; preparation, stability; bioequivalence and list of experts in the subcommittees to evaluate applications for issuance, extension, change, supplementation of drugs and medicinal ingredients, and appraisal of applications for licenses to import drugs that do not yet exist. circulation registration certificate. The structure of expert appraisal subcommittees must be consistent with the classification of registered products and registration form or products requested for import license and form of request for import license.

2. Appraisal experts operate according to the principle: appraisal opinions must ensure legal and scientific basis and must be shown in the appraisal record of application for grant, extension or change. , supplementation of drugs, medicinal ingredients or record of appraisal of application for license to import drugs without circulation registration certificate. The appraisal expert is responsible to the Director of the Drug Administration of Vietnam and to the appraisal unit for the appraisal contents and suggestions related to the appraisal of dossiers requesting issuance, extension, or change . i, supplementation of drugs and medicinal ingredients, appraisal of dossiers for import of drugs without circulation registration certificate.

3. Based on the assigned functions and tasks, the Drug Administration of Vietnam shall develop and promulgate regulations on the organization and operation of groups of appraisal experts (including experts of the appraisal unit) for application dossiers. granting, extending, changing, supplementing drugs, medicinal ingredients, and dossiers for importing drugs that do not have a circulation registration certificate; Sign a contract with an appraisal expert or document appraisal unit;

The Drug Administration of Vietnam and the appraisal unit organize training courses for appraisal experts; Conduct an assessment of the professional capacity of appraisal experts established by the unit and compliance with regulations to make appropriate adjustments and additions of appraisal experts.

4. Funding for organizing appraisal of documents is carried out in accordance with the provisions of law.

Chapter VII

TERMS ENFORCEMENT

Article 44. Effectiveness of implementation

first . This Circular takes effect from October 20, 2022

2. Abolish the following regulations:

a) Circular No. 32/2018/TT-BYT dated November 12, 2018 of the Minister of Health regulating drug registration;

b) Clause 3, Article 1 of Circular No. 23/2021/TT-BYT dated December 9, 2021 of the Minister of Health amending and supplementing a number of legal documents issued by the Minister of Health;

c) Clause 5 Article 1 Circular No. 29/2020/TT-BYT dated December 31, 2020 of the Minister of Health amending, supplementing and abolishing a number of legal documents issued by the Minister of Health issued, jointly issued;

d) Point h, Clause 3, Article 14 of Circular No. 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health regulating labeling of drugs, medicinal ingredients and drug use instructions.

Article 45. Transitional provisions

1. Documents submitted before the effective date of this Circular will continue to be implemented according to the regulations at the time of submission, except in cases where the registration facility voluntarily complies with the regulations from the date of application. Sign and promulgate this Circular.

2. Dossiers submitted to the dossier-receiving agency before the effective date of this Circular but are in the process of being resolved shall be subject to relevant regulations in this Circular or regulations before the date of this Circular. This is effective for the convenience of businesses, organizations and individuals.

3. Drugs submitted for registration according to regulations before the effective date of Circular No. 32/2018/TT-BYT and granted a circulation registration certificate or an extension of the circulation registration certificate, the establishment can only produce Manufacture finished drugs from medicinal ingredients produced at production facilities that meet good manufacturing practices with appropriate scope in accordance with the provisions of Article 141 of Decree No. 54/2017/ND-CP . Production facilities and registration facilities must store supporting documents as prescribed in Clause 11, Article 22 of this Circular and present them to relevant competent authorities upon request.

4. Registration for circulation of Covid - 19 vaccines in urgent cases is carried out according to regulations in Circular No. 11/2021/TT-BYT dated August 19, 2021 of the Minister of Health guiding Instructions for registration of circulation of Covid - 19 vaccines in urgent cases.

5. In case WHO publishes an updated CPP form, within 12 months from the date the updated CPP form is published on the WHO website, the registering facility must submit a CPP with all the content according to the CPP form. Updated in drug registration dossier. Accept CPP that has not been updated (old form) if the CPP is still valid at the time of receiving the drug registration application.

6. Content related to reference water management agencies specified in Clause 9, Article 2 of Circular No. 32/2018/TT-BYT referenced in other legal documents will continue to be implemented until the document That legal regulation is amended, supplemented, replaced or annulled.

7. In case the drug has been announced as the original brand name by the Ministry of Health before the effective date of this Circular, the Drug Administration of Vietnam shall be assigned to make adjustments, update changes, and supplement the information announced as the original brand name. at the request of the drug registration facility.

8. In case Annexes I , III , IV issued with this Circular are updated according to Asean common technical requirements, within 06 months from the date the updated documents are published on the Electronic Information Portal. of Asean (https://asean.org/our-communities/economic-community/standard-and-comformance/key-documents-publications/), the Drug Administration of Vietnam organizes the translation and publishes updated content on C Electronic information page of the Ministry of Health and electronic information page of the Drug Administration of Vietnam.

Within 06 months from the date the Drug Administration of Vietnam publishes updated content on the electronic information portal of the Ministry of Health and the website of the Drug Administration of Vietnam, the registration facility, and the manufacturing facility. must be updated in the drug registration dossier.

9. Drugs registered to be manufactured in Vietnam in the form of technology transfer, drugs with secondary packaging continue to comply with the provisions of Circular 32/2018/TT-BYT until the Circular regulates registration. Circulation registration for processed drugs and technology transferred drugs in Vietnam by the Ministry of Health is issued and takes effect.

Article 46. Implementation roadmap

1. From the effective date of this Circular, a manufacturing facility has more than 02 drugs with the same pharmaceutical substance or medicinal ingredient, dosage form, route of administration, content or concentration in one unit of dosage. dose has been granted a circulation registration certificate, when submitting the application for extension of the circulation registration certificate, the manufacturing facility coordinates with the drug registration facility to select and request the extension of the circulation registration certificate for 2 doses. drugs as prescribed in Clause 6, Article 8 of this Circular , the remaining drugs that have been granted circulation registration will have the validity of their circulation registration extended until December 3, 2025 .

2. For drugs and medicinal raw materials produced domestically that have been granted circulation registration certificates before the effective date of this Circular and establishments wishing to import medicinal raw materials are excipients. Pharmaceuticals and capsule shells to Vietnam: Before the first import to Vietnam, the registration facility updates all information about medicinal ingredients such as excipients and capsule shells in the approved dossier to the service system. Online public service of the Drug Administration of Vietnam. Within 05 working days from the date the facility updates information to the system, the Drug Administration of Vietnam must complete the announcement. The registration facility is responsible for the accuracy of the updated information compared to the information in the approved registration dossier and is not required to update the information again at the next import.

3. The application of registration numbers according to the structure specified in Appendix VI issued with this Circular when issuing or renewing marketing registration certificates will be implemented from January 1, 2023. For drugs that have been issued If the registration number is issued before January 1, 2023, and the marketing registration certificate is renewed, you can continue to use the registration number issued before the extension for a maximum period of 12 months from the date of issuance of the registration number. according to the structure specified in Appendix VI issued with this Circular.

Article 47. Terms of reference

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

Article 48. Responsibility for implementation

1. The Drug Administration of Vietnam, based on its assigned functions, tasks and roadmap for ASEAN harmonization in drug registration, is responsible for:

a) Organize guidance and implementation of the provisions of this Circular;

b) Update the list of issued drugs and medicinal ingredients, renew the circulation registration certificate within 05 days from the date of issuance, extend the circulation registration certificate and registration information of drugs and raw materials making other drugs on the website of the Drug Administration of Vietnam;

c) Announce and update the list of drugs with proven bioequivalence, drugs with declared original brand name, reference biological products within 05 days from the date of issuance of circulation registration certificate and change information. Changes and additions of drugs with proven bioequivalence, drugs with declared original brand name, reference biological products within 07 days from the date of approval of changes and additions to the drug registration and circulation certificate on the website. Electronic information of the Drug Administration of Vietnam;

d) Review and review drugs that have proven bioequivalence, drugs that have been declared original brand names, and reference biological products that no longer meet the prescribed criteria;

d) Develop, promulgate and organize the implementation of standard procedures (SOPs) in drug registration and drug registration manual (QM);

e) Coordinate with the Department of Traditional Medicine and Pharmacy Administration in extending, changing and supplementing circulation registration certificates for traditional drugs and medicinal materials that have been granted circulation registration certificates according to the provisions of Circular No. 44/2014/TT-BYT dated November 25, 2014 of the Minister of Health regulating drug registration;

g) In case the drug registration facility has an act of falsifying or arbitrarily modifying records, documents, and legal papers of Vietnamese or foreign authorities; Using fake seals or forging signatures or seals of the registration facility , manufacturing facility and related facilities in the drug registration dossier, the Drug Administration of Vietnam will issue an official dispatch to warn the facility and stop accepting Dossier for issuance and extension of registration for circulation of drugs and medicinal ingredients according to the provisions of Clauses 2, 3 and 4, Article 100 of Decree

54/2017/ND-CP dated May 8, 2017 of the Government regulating expenses details a number of articles and measures to implement the Pharmacy Law .

In addition to the above forms, the Drug Administration publicizes the violation content of the facility on the Drug Administration's website, and at the same time notifies the Inspectorate and competent authorities for action. Consider and handle according to the provisions of law;

h) In case the drug manufacturing facility commits acts of falsifying or arbitrarily modifying records, documents, and legal papers of Vietnamese or foreign authorities; If you provide documents to a drug registration facility to register for circulation in Vietnam that are not based on actual research or production, the Drug Administration of Vietnam will issue an official dispatch to warn the facility and stop receiving applications and renewals. Certificate of registration for circulation of drugs and medicinal ingredients according to the provisions of Clauses 2, 3 and 4, Article 100 of Decree 54/2017/ND-CP dated May 8, 2017 of the Government detailing a number of articles and measures. enforcement of the Pharmacy Law .

In addition to the above forms, the Drug Administration publicizes the violation content of the facility on the Drug Administration's website, and at the same time notifies the Inspectorate and competent authorities for action. Consider and handle according to the provisions of law;

i) In case of necessity, the Drug Administration of Vietnam organizes a meeting with the registration facility, manufacturing facility, and appraisal experts to clarify problems related to the appraisal of drug registration dossiers and raw materials. stain material ;

k) Publish on the website of the Drug Administration of Vietnam the list of registered establishments and establishments producing drugs and medicinal ingredients according to the provisions of Clauses 10 and 14, Article 22 of this Circular ;

l) Develop regulations on the application of bar codes, QR codes, and DataMatrix Codes (DMC) on the outer packaging of drugs and medicinal ingredients of manufacturing facilities to manage, identify, and trace. Origin of drugs and medicinal ingredients circulating on the market and implementation roadmap according to regulations of the Minister of Health;

m) Within 30 days from the date of issuance or renewal of the registration certificate for circulation of drugs and medicinal ingredients, the Drug Administration of Vietnam shall return the labels and instructions for use of the drugs to the registering facility ;

n) Within 15 days from the date of issuance or extension of the registration certificate for circulation of drugs and medicinal ingredients, 07 days from the date of approval of changes or additions to the certificate of registration for circulation of drugs and medicinal ingredients, The Drug Administration of Vietnam announces the source of medicinal raw materials for drugs manufactured in Vietnam on the website of the Drug Administration of Vietnam.

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

3. Units under the Ministry of Health, Vietnam Pharmaceutical Corporation - Joint Stock Company, and drug trading establishments are responsible for implementing this Circular.

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

KT. MINISTER
DEPUTY MINISTER

Do Xuan Tuyen

Recipient:
- Social Committee of the National Assembly;
- Government Office (Gazette Office, Government Electric Information Portal; Department of KGVX);
- Q. Minister of Health (to report);
- Deputy Ministers of Health;
- Ministry of Justice (Department of Inspection of Legal Documents);
- Science and technology;
- Ministry of Industry andTrade;
- Ministry of National Defense (Military Medical Department);
- Ministry of Public Security (Department of Health);
- Ministry of Transport (Department of Health and Transport);
- Ministry of Finance (General Department of Customs);
- Departments, Bureaus, and Inspectorates of the Ministry of Health;
- Department of Health of provinces and centrally run cities;
- Advisory Council for issuance of medical approval for drugs and medicinal ingredients;
- Vietnam Pharmaceutical Corporation - Joint Stock Company;
- Pharmaceutical business associations Vietnam;
- Vietnam Pharmaceutical Association;
- General Department of Customs;
- Electronic information portal of MOH, Website of Department of Management;
- Domestic and foreign drug production and trading enterprises;
- Central Institute of Drug Testing; City Drug Testing Institute. HCM; National Institute for Testing Vaccines and Medical Biologicals;
- Save: VT, PC, QLD (5).