MINISTRY OF HEALTH -------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 32/2018/TT-BYT	*Hanoi, November 12, 2018*

CIRCULAR

MARKETING AUTHORIZATION OF DRUGS AND MEDICINAL INGREDIENTS

Pursuant to the Law on Pharmacy April 06, 2016;

Pursuant to the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 on elaboration of the Law on Pharmacy;

Pursuant to the Government's Decree No. 75/2017/ND-CP dated June 20, 2017 defining functions, tasks, entitlements and organizational structure of the Ministry of Health;

Pursuant to the Government's Decree No. 155/2018/ND-CP dated November 12, 2018 amending some regulations on conditions for doing business under management of the Ministry of Health;

At the request of the Director of the Drug administration of Vietnam,

The Minister of Health promulgates a Circular on marketing authorization of drugs and medicinal ingredients

Chapter I

GENERAL PROVISIONS

Article 1. Scope

1. This Circular provides for:

a) Documents procedures for issuance, renewal, revision and revocation of the marketing authorization (also called licensing, registration, approval, etc.) of modern medicines, vaccines, biologicals, herbal ingredients and medicinal ingredients (active ingredients, semi-finished herbal ingredients, excipients, capsule shells) for human use in Vietnam;

b) Required clinical data for assurance of safety and efficacy in the application;

c) Requirements for exemption from clinical trial or certain stages thereof in Vietnam; drugs that have to undergo Stage 4 clinical trial;

d) Rules for validating applications for the marketing authorization of drug/medicinal ingredient (hereinafter referred to as "marketing application"), renewal and revision thereof;

dd) Rules for validating applications for the license to import drugs that are yet to be approved for marketing authorization (hereinafter referred to as "unapproved drugs") in the cases specified in Point a Clause 43 Article 5 of Decree No. 155/2018/ND-CP;

e) Rules for organization and operation of Marketing Authorization Advisory Board (hereinafter referred to as "the Advisory Board");

g) Procedures for validating marketing applications, renewal and revision thereof; application for the license to import unapproved drugs.

2. This Circular does not apply to the cases mentioned in Clause 2 Article 54 of the Law on Pharmacy, which provides for medicinal ingredients that are not required to be registered before marketing authorization in Vietnam, and semi-finished herbal ingredients produced by the same producer of the drug products.

Article 2. Definitions

For the purpose of this Circular, the terms below are construed as follows:

1. *ASEAN common technical dossier (ACTD)* means the document providing guidelines for registration of drugs that satisfy ASEAN Common Technical Requirements (ACTR), which are specified in Appendix I hereof.

2. *ICH-CTD* means the common technical document provided by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

3. *"major variations"* are variations that clearly and directly affect the quality, safety and efficacy of the drug, specified in Appendix II hereof.

4. *""minor variations" are variations that do not affect or barely affect the quality, safety and efficacy of the drug, specified in Appendix II hereof.*

5. *"applicant" or "authorization holder"* means the establishment that applies for the marketing authorization, renewal or revision thereof.

6. *"manufacturer"* means the establishment that carry out one or some or all of the manufacturing processes or release of the batch of drug.

7. *"ingredient manufacturer" means the establishment that manufactures or releases the ingredient(s) of the drug product.*

8. *"product license holder" or "product owner"* of a foreign drug means the establishment responsible for the drug product and is written on the Certificate of pharmaceutical product (CPP).

9. *"reference authorities"* mentioned in this Circular include: European Medicines Agency (EMA), drug regulatory authorities of the USA, Japan, France, Germany, Sweden, England, Switzerland, Australia, Canada, Belgium, Austria, Ireland, Denmark and Netherland

10. *Stringent Regulatory Authorities (SRA)* area drug regulatory authorities that are considered SRA by WHO. A SRA is:

a) a member of ICH before October 23, 2015, including: US-FDA, drug regulatory authorities of European Commission, the UK's Medicines and Healthcare products Regulatory Agency (MHRA), and Japan's Pharmaceuticals Medical Devices Agency (PMDA);

b) an ICH observers before October 23, 2015, including: European Free Trade Association (EFTA), Swissmedic and Health Canada;

c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement before October 23, 2015, including: Australia, Iceland, Liechtenstein and Norway.

11. *"Certificate of pharmaceutical product (CPP)"* means a certificate issued in the format recommended by WHO according to WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

12. *"semi-finished herbal ingredients"* are medicinal ingredients derived from herbs in the form of glue, granule, powder, extract, essential oil, resin, gum, jelly.

Article 3. Responsibilities of applicants/authorization holders

1. Take responsibility for any revision to the label or package insert; comply with update request of the Ministry of Health (Drug Administration of Vietnam) during the effective period of the marketing authorization without having to submit an application for revision.

2. Apply for revision according to Clause 4 Article 28 and Article 40 of this Circular during effective period of the marketing authorization.

3. Ensure quality, safety and efficacy of the drugs/medicinal ingredients as declared in the application.

4. Take responsibility for legitimacy and accuracy of every document in the application. Cooperate with the foreign authority and manufacturer in responding to inquiries of Drug

administration of Vietnam regarding the authenticity of legal documents in the application.

5. Send a written notice to Drug Administration of Vietnam within 30 days from the day on which the marketing authorization is revoked in any country if the drugs/medicinal ingredients have been granted the marketing authorization in Vietnam, and specify the reason for such revocation.

6. At the request of a competent authority, cooperate with the manufacturer in ensuring that at least one of the two studies or provides additional information about the to-be-marketed drug when there is information or evidence about the safety and efficacy of the drug during the effective period of its market authorization.

7. Cooperate with the manufacturer, importer and distributor in monitoring, collecting and analyzing information, and send a report to Drug Information and Adverse Reaction Center (DI&ADR) on post-vaccination reactions and adverse reaction of the drug in accordance with Clause 5 Article 77 of the Law on Pharmacy, guidelines for Good Pharmacovigilance Practices, national guidelines for pharmacovigilance and relevant regulations.

8. Maintain the marketing authorization holder's eligibility for operation during the effective period of the marketing authorization. In cases where the current authorization holder is no longer eligible for operation, it shall follow procedures for changing the authorization holder in accordance with Clause 4 Article 28 and Article 40 of this Circular within 30 days from the day on which the marketing authorization holder no longer qualifies for operation.

9. Take responsibility for issues relevant to intellectual property rights of the drugs/medicinal ingredients registered in Vietnam.

10. Cooperate with the manufacturer in updating specifications of drugs/medicinal ingredients in accordance with Circular No. 11/2018/TT-BYT and Circular No. 13/2018/TT-BYT.

11. Implement the approved risk management plan in the application for issuance or renewal of the marketing authorization for vaccines.

12. Take responsibility in accordance with Clause 2 Article 57 of the Law on Pharmacy and provisions of this Article for the proposed drugs/medicinal ingredients from the day on which Drug Administration of Vietnam signs the permission for changing the marketing authorization holder, including the drugs/medicinal ingredients approved for marketing authorization before such permission is signed.

13. Assume other responsibility specified in this Circular and relevant regulations of law.

Article 4. Responsibilities of manufacturers of drugs/medicinal ingredients

1. Manufacture the drugs/medicinal ingredients at the factory having the manufacture license issued by a competent authority.

2. Request revocation of the marketing authorization in case the drug/medicinal ingredient may affect users' health in terms of their quality, safety or efficacy (Form No. 1/TT enclosed herewith)

3. Cooperate with the applicant/authorization holder in implementation of Clause 1, 2, 3 Article 3 of this Circular.

4. Cooperate with the applicant/authorization holder in fulfilling competent authorities' request for inspection or evaluation of the manufacturing facility.

5. Maintain the operating conditions of the manufacturing facility throughout the effective period of the marketing authorization.

6. Follow procedures for changing the authorization holder within 30 days from the day on which Drug Administration of Vietnam signs the notice that the current authorization holder is no longer qualified for operation.

7. Update specifications of drugs/medicinal ingredients in accordance with Circular No. 11/2018/TT-BYT.

Article 5. Reporting monitoring and evaluation of safety and efficacy

1. Pharmaceutical-trading establishments and health facilities shall monitor, collect information, and submit reports to competent authorities on post-vaccination reactions and adverse reaction of the drug in accordance with Article 77 and Article 78 of the Law on Pharmacy, guidelines for Good Pharmacovigilance Practices, national guidelines for pharmacovigilance and relevant regulations.

2. The authorization holders shall submit reports on safety and efficacy of the drugs specified in Clause 2 Article 8 of this Circular (Form No. 2A/TT for drugs or 2B/TT for vaccines):

a) to DI&ADR every 6 months throughout the effective period of the marketing authorization.

b) when applying for renewal of the marketing authorization at Drug Administration of Vietnam.

3. Health facilities using the drugs specified in Clause 2 Article 8 of this Circular shall submit the report on the use of drugs (Form No. 2C/TT) to DI&ADR every 6 months throughout the effective period of the marketing authorization.

Article 6. Language, format, quantity of documents

1. Language of documents in the marketing application

Every document in the marketing application shall be written in Vietnamese or English language. The package insert and summary shall be written in Vietnamese language.

2. Documents in the marketing application shall be A4 papers and firmly bound (except online applications). The application shall have covers (Form No. 3/TT), product information sheet (Form No. 4/TT) and arranged in the order specified in the Table of Contents (Form No. 5/TT). Different sections are separated from each other. The sections shall be numbered and bear the applicant's or manufacturer's seal on the first page (for foreign drug, the seal of the representative office is acceptable).

The following documents shall be bound separately and enclosed with 01 product information sheet:

a) Bioequivalence study documents;

b) Non-clinical and clinical documents;

c) Documents serving GMP evaluation according to Article 95 and Article 98 of the Government's Decree No. 54/2017/ND-CP dated May 08, 2017 on elaboration of the Law on Pharmacy.

3. Different drugs (except vaccines) may be included in the same application if the following elements are the same: Drug name, dosage form, route of administration, specifications; manufacturer's name and address, formula, content active ingredient per unit dose (for metered-dose solid drugs), content or concentration of active ingredient (for non-metered solid drugs, liquid drugs or semi-solid drugs; concentration or content of active ingredient and material of the primary package (for parenteral drugs).

4. Quantity of mandatory documents in the application for issuance or renewal of the marketing authorization:

a) For modern drugs, vaccines, biologicals: 01 set of documents specified in Clauses 1, 2, 3, 5, 6, 7 Article 28 of this Circular; For herbal ingredients and medicinal ingredients: the documents specified in Clause 1 and Clause 2 Article 31, Clause 1 and Clause 2 Article 33 of this Circular;

b) For vaccines: 01 copy of every document; For other cases: 02 copies of the following documents: application form, specifications, test method;

c) 02 set of samples of the label of the drug/medicinal ingredient and the package insert bearing the seal of the applicant (or seal of the representative office for foreign drugs) or manufacturer. The labels shall be attached to or presented on A4 papers.

5. Quantity of mandatory documents in the application for revision of the marketing authorization:

a) For modern drugs, vaccines, biologicals and the cases mentioned in Clause 3 Article 31: 01 set of documents specified in Clause 4 Article 28 of this Circular; For herbal ingredients and medicinal ingredients: the documents specified in Clause 1 Article 31 and Clause 3 Article 33 of this Circular.

b) For revision to the label or package insert: 02 sets of samples of the label and the package insert bearing the seal of the applicant (or seal of the representative office for foreign drugs) or manufacturer. The labels shall be attached to or presented on A4 papers.

6. Online application:

a) 01 set of documents specified in this Circular shall be submitted online and 01 set of physical documents (except labels and package inserts) shall be sent to Drug Administration of Vietnam;

b) The online application roadmap shall be announced by the Ministry of Health.

Article 7. Marketing authorization fees

Applicants shall pay the fees for issuance of the marketing authorization in accordance with applicable regulations of law on fees and charges.

Article 8. Effective periods, symbols of the marketing authorization and deadline for renewal

1. The effective period of a marketing authorization is 05 years from the issuance date or renewal date, except for the case specified in Clause 2 of this Article.

2. The effective period of the marketing authorization for the following drugs is 03 years:

a) New drugs and vaccines that apply for the marketing authorization for the first time, reference biologicals and similar biologicals that apply for the marketing authorization in Vietnam for the first time;

b) Drugs having the same active ingredient(s), concentration, content or dosage form as that of the new drug which has not been granted a 5-year marketing authorization;

c) Any drug other than those mentioned in Point a and Point b of this Clause if a report on their safety and efficacy is not submitted when applying for renewal of the marketing authorization because the drug has not been marketed in reality or the quantity of drug used, quantity of patients or use duration is insufficient according to the Advisory Board, or the health facility recommends extension of monitoring of the safety and efficacy of the drug;

d) The cases in which the monitoring of safety and efficacy of the drug should be continued as recommended by the Advisory Board.

3. Within 12 months before the expiration date of the marketing authorization, its holder may apply for renewal. The marketing authorization cannot be renewed after it expires, in which case an application for issuance of a new marketing authorization shall be submitted.

4. Each marketing authorization has a separate number, which helps recognize domestically manufactured and import drugs, medicinal ingredients, vaccines, biologicals, drugs under technology transfer agreements, drugs undergoing secondary packaging in Vietnam.

5. If a new marketing authorization is granted during the effective period of the old marketing authorization, both of them can be simultaneously effective and the latter will be effective for 06 months from the effective date of the former.

Article 9. Criteria for recognition of proprietary drugs

1. The drug proposed as proprietary drug (except biologicals) shall be specified in the marketing application and satisfy all of the following criteria:

a) The safety and efficacy data is sufficient as prescribed in Article 13 of this Circular;

b) The drug is approved for marketing authorization by one of the regulatory authorities mentioned in Clause 9 and Clause 10 Article 2 of this Circular, except for new drugs that are manufactured in Vietnam.

In case of change of manufacturer or technology transfer of the proprietary drug in Vietnam according to Clause 2 or Clause 3 of this Article, it will be still recognized as a proprietary drug.

2. In cases where a proprietary drug is declared by the Ministry of Health as prescribed in Clause 1 of this Article and one, some or all of its manufacturing processes is transferred to a manufacturer in Vietnam, the proprietary drug and the drugs manufactured in Vietnam must satisfy all of the following criteria:

a) The formulae are the same;

b) The manufacturing processes are the same;

c) The material quality specifications are the same;

d) The drug product specifications are the same;

dd) In case of any changes to the criteria mentioned in Point a, b, c or d of this Clause, the applicant shall provide data proving that the quality of the drugs manufactured in Vietnam is equivalent to that of the proprietary drug before carrying out the transfer.

3. In case of change of the manufacturer of a recognized proprietary drug, the drug granted the new marketing authorization of the new manufacturer will also be recognized as a proprietary drug if the applicant makes a written request and all of the following criteria are satisfied:

a) The drug is approved for market authorization by one of the regulatory authorities mentioned in Clause 9 and Clause 10 Article 2 of this Circular;

b) The drugs satisfy all of the criteria specified in Point a through d Clause 2 of this Article.

Article 10. Requirements for marketing authorization of domestically manufactured drugs under technology transfer agreements and drug undergoing secondary packaging in Vietnam

1. Requirements for marketing authorization of drugs under technology transfer agreements:

a) The technology transfer may involve one, some or all of the manufacturing processes of the drug product. This does not include secondary packaging transfer;

b) The to-be-marketed drug and the original drug shall satisfy all of the following criteria:

- The formulae are the same;

- The manufacturing processes are the same;

- The material quality specifications are the same;

- The drug product specifications are the same;

In case of any changes to the aforementioned requirements, the applicant shall provide data proving that the quality of the drugs manufactured in Vietnam is equivalent to that of the original drug.

c) Regarding generic drugs with systemic action, the original drug must have demonstrated bioequivalence, unless the drug has a dosage form that is exempt from bioequivalence testing according to Circular No. 08/2010/TT-BYT.

d) The documents satisfy the requirements specified in Clause 5 Article 28 of this Circular.

2. Drugs undergoing secondary packaging in Vietnam

a) Within 05 years from the issuance date of the marketing authorization, the authorization holder and the manufacturer shall complete the technology transfer under the conditions specified in Clause 1 of this Article. Within 03 years from the issuance date of the marketing authorization, the authorization holder shall submit a report on the technology transfer progress (Form No. 6/TT enclosed herewith);

b) The documents satisfy the requirements specified in Clause 6 Article 28 of this Circular.

3. The drug before technology transfer and secondary packaging may be marketed until expiration of the marketing authorization.

Article 11. Confidentiality of information in the marketing application dossier

The applicant that wishes to keep the information in the marketing application dossier confidential shall follow instructions in Circular No. 05/2010/TT-BYT and specify the request in Form No. 6/TT enclosed herewith.

Article 12. Verification of information on legal documents

1. Drug Administration of Vietnam shall cooperate with diplomatic agencies and relevant domestic and overseas authorities in verifying the authenticity of legal documents in marketing application dossiers. Such legal documents include:

a) The CPP of every application for issuance, renewal or revision of the marketing authorization;

b) For foreign applicants that apply for marketing authorization in Vietnam for the first time: legal documents issued by overseas competent authorities.

2. The verification shall be simultaneous with validation of the marketing application dossier and within the time limit specified in Clause 5 Article 56 of the Law on Pharmacy.

Chapter II

MANDATORY CLINICAL DATA FOR ASSURANCE OF SAFETY AND EFFICIACY; CRITERIA FOR EXEMPTION FROM CLINICAL TRIAL OR CERTAIN STAGES THEREOF IN VIETNAM; DRUGS THAT HAVE TO UNDERGO STAGE 4 CLINICAL TRIAL

Article 13. Clinical data in an application for marketing authorization of a new modern drug, vaccine or biological

1. Mandatory clinical data in an application for marketing authorization of a new modern drug, vaccine or biological

a) Clinical studies of the drug, data in clinical documents shall be conformable with ICH guidelines, the Ministry of Health of Vietnam or guidelines of other organizations recognized by Vietnam (international organizations to which Vietnam is a member, reference agencies specified in Clause 9 Article 2 of this Circular), except for the case specified in Clause 2 of this Article;

b) Clinical database (except similar biologicals and reference biologicals, similar vaccines and vaccines approved for marketing authorization in Vietnam) shall be sufficient for analysis and justification of the safety and efficacy of the drug in Asian populations for extrapolating clinical data from Asian populations according to instructions in Point a Clause 1 of this Article, or bridging study data according to ICH-E5 for extrapolating clinical data from Asian populations;

c) If the vaccine has been approved for market authorization according to Point g Clause 4 Article 23 of this Circular and has sufficient clinical data for safety and efficacy according to Point a and Point b Clause 1 of this Article but its manufacturing process is not entirely carried out in Member States specified in Clause 10 Article 2 of this Circular, it is required to have clinical data pertinent to safety and immunogenicity in the intended population in Vietnam before market authorization

d) If the vaccine has sufficient clinical data for safety and efficacy as prescribed in Point a and Point b Clause 1 of this Article but a requirement specified in Point g Clause 4 Article 23 of this Circular is not satisfied, it is required to have clinical data pertinent to safety and immunogenicity in the intended population in Vietnam before market authorization.

2. If the study is carried out before the effective date of the regulations or instructions mentioned in Point a Clause 1 of this Article, data of the study is acceptable.

Article 14. Mandatory clinical data for safety and efficacy in the application for marketing authorization of a drug with new combination of similar biologicals or active ingredients

1. A drug with new combination of active ingredients shall have sufficient clinical data according to guidelines of US FDA, EMA or WHO for clinical development of fixed-dose combinations according to Appendix IV hereof.

2. Similar biologicals shall have sufficient clinical data according to the guideline of the Ministry of Health or WHO for development of similar biologicals. Guidelines of US FDA and EMA that are developed based on the aforementioned guidelines are acceptable. Guidelines of WHO, US FDA, EMA are provided in Appendix IV hereof.

Article 15. Mandatory clinical data for safety and efficacy in the application for marketing authorization of a new non-proprietary drug

1. If the drug that has been approved for market authorization in its home country is a prescription drug (except drugs manufactured in Vietnam) and at least a similar drug (with the same active ingredient, content, concentration thereof, dosage form and route of administration) has been approved for market authorization by one of the regulatory bodies specified in Clause 10 Article 2 of this Circular, the clinical data shall satisfy one of the following requirements:

a) The use of clinical data of the similar drug is permitted by its owner. The clinical data shall satisfy the requirements in Article 13 of this Circular;

b) There is clinical data from published researches and bioequivalence studies (unless the drug does not require bioequivalence test according to regulations of the home country).

2. If the drug that has been approved for market authorization in its country of origin is a prescription drug (except drugs manufactured in Vietnam and the case specified in Clause 3 of this Article) and at least a similar drug (with the same active ingredient, content, concentration thereof, dosage form and route of administration) has been approved for market authorization by one of the regulatory bodies specified in Clause 10 Article 2 of this Circular, the clinical data shall satisfy one of the following requirements:

a) The use of clinical data of the similar drug is permitted by its owner. The clinical data shall satisfy the requirements in Article 13 of this Circular;

b) There is clinical data from published researches and bioequivalence studies (unless the drug does not require bioequivalence test according to regulations of the country of origin).

3. If the drug that is approved for marketing authorization is classified as non-proprietary by one of the reference authorities mentioned in Clause 9 Article 2 of this Circular, it is required to have justification and evidence that the use of the active ingredients (indications, dose, route, users) is specified in Vietnam's National Pharmacopoeia, other pharmacopoeia accepted by any of the reference authorities specified in Clause 9 Article 2 of this Circular.

Article 16. Mandatory clinical data for safety and efficacy in the application for marketing authorization of a new drug with content, concentration, dose, route, indications or intended users that are different from the proprietary drug which has been approved for market authorization in Vietnam

Clinical documents specified in Article 13 of this Circular are mandatory for a modern drug whose content, concentration, dose, route, indications or intended users that are different from the proprietary drug which has been approved for market authorization in Vietnam, or has a new dosage form that might affect its biopharmaceutics.

Article 17. Mandatory clinical data for drugs approved for marketing authorization in Vietnam in case of changes in clinical data thereof

In case of changes to clinical data for a modern drug, vaccine, biological or herbal drug that has been approved for marketing authorization in Vietnam, the applicant shall provide the additional clinical data in accordance with Appendix II of this Circular.

Article 18. Criteria for exemption of one or some stages of clinical trial of new modern drugs, vaccines, biologicals before marketing authorization

In one of the following cases, the Ministry of Health is entitled to exempt one or several stages of clinical trial (including clinical data) of a drug that fails to meet the requirements specified in Article 13 of this Circular on the basis of opinions given by the Advisory Board:

1. The drug is meant to serve urgent needs for national defense and security, epidemic control, disaster relief and cannot be replaced by any other drug on the market.

2. The drug is approved for market authorization by at least two of the reference authorities specified in Clause 9 Article 2 of this Circular, or approved for market authorization by US FDA or EMA based on the reduced clinical documents they require.

3. The drug is meant to treat a rare or fatal disease.

4. Vaccines and biologicals manufactured in Vietnam through technology transfer of one, some or all of the manufacturing processes of the finished vaccine or biological whose clinical data satisfies the requirements in Clause 1 Article 13 and Article 14 of this Circular.

Article 19. Mandatory clinical data in an application for marketing authorization a new herbal drug

1. Mandatory clinical data for assurance of safety and efficacy in the application; for marketing authorization a new herbal drug:

a) Clinical studies of the drug, data in clinical documents shall be conformable with guidelines of the Ministry of Health of Vietnam or other organizations recognized by Vietnam, including: WHO’s Research guidelines for evaluating the safety and efficacy of herbal medicines or guidelines of a regulatory body specified in Clause 10 Article 2 of this Circular. If the study is carried out before the effective date of the aforementioned regulations or instructions, data of such study is acceptable;

b) Data extracted from the following documents is acceptable as clinical data for consideration of safety and efficacy of the drug:

- The treatises about safety and efficacy of the drug mentioned in pharmacopoeias of Vietnam and other countries;

- Evaluations of safety and efficacy of the drug published on SCI (Science Citation Index) journals and clinical data collected from other medical publications;

- Evaluations of safety and efficacy in a national, ministerial or provincial research which has been accepted.

2. Clinical data mentioned in Clause 1 of this Article is not required if the herbal drug satisfies any of the following requirements:

a) The drug has the same composition, content of herbal ingredients, indications and route of administration as those of another herbal drug which has been approved for marketing authorization (even if it has expired) except traditional drugs the indications of which do not include any of the diseases on the list of diseases published by the Ministry of Health according to Point b Clause 1 Article 89 of the Law on Pharmacy;

b) The drug has the same composition, content of herbal ingredients, indications and route of administration as those of another herbal drug which has been approved for marketing authorization in Vietnam for at least 05 years, has sufficient clinical data as prescribed in Clause 1 of this Article and is not meant to treat the diseases on the list of diseases published by the Ministry of Health according to Point b Clause 1 Article 89 of the Law on Pharmacy.

Article 20. Criteria for exemption of one or some stages of clinical trial of herbal drugs before marketing authorization

In one of the following cases, the Ministry of Health is entitled to exempt one or several stages of clinical trial (including clinical data) of a herbal drug that fails to meet the requirements specified in Article 19 of this Circular on the basis of opinions given by the Advisory Board:

1. The drug is meant to serve urgent needs for national defense and security, epidemic control, disaster relief and cannot be replaced by any other drug on the market.

2. The drug is approved for market authorization by at least one of the reference authorities specified in Clause 9 and Clause 10 Article 2 of this Circular according to the reduced clinical documents they require.

3. The drug is meant to treat a disease on the list of diseases published by the Minister of Health according to Point b Clause 1 Article 89 of the Law on Pharmacy but is not exempt from clinical trial as prescribed in Clause 3 Article 21 of this Circular.

4. The drug is new combination of herbal ingredients that have been used in Vietnam and the indications of which do not include any of the diseases on the list of diseases

published by the Minister of Health according to Point b Clause 1 Article 89 of the Law on Pharmacy.

Article 21. Criteria for exemption of clinical trial in Vietnam before marketing authorization

1. A generic drug has the same active ingredients, content and concentration thereof, route of administration, uses, doses, indications, intended users and dosage form as those of another drug that has been approved for market authorization.

2. A new drug (except vaccines), has been approved for market authorization in at least another country and has sufficient clinical data according to Article 13 and Article 19 of this Circular.

3. An herbal drug is granted the marketing authorization before the effective date of the Law on Pharmacy and the indications of which do not include any of the diseases on the list of diseases published by the Ministry of Health.

4. A vaccine has been approved for market authorization and satisfies the requirements specified in Point g Clause 4 Article 23 of this Circular, all of the manufacturing processes of which are carried out in the Member States specified in Clause 10 Article 2 of this Circular, and the clinical data is sufficient according to Article 13 of this Circular.

Article 22. When to carry out a State IV clinical trial in Vietnam

The drug has been approved for market authorization but its safety and efficacy needs additional evaluation as proposed by the Advisory Board.

Chapter III

MARKETING APPLICATION

Section 1. APPLICATION FOR ISSUANCE, RENEWAL, REVISION OF MARKETING AUTHORIZATION FOR DRUGS/MEDICINAL INGREDIENTS

Article 23. Documents in the application for issuance, renewal, revision of marketing authorization for drugs/medicinal ingredients

1. Documents issued by foreign regulatory authorities shall be consularly legalized in accordance with regulations of law on consular legalization, except for the cases in which consular legalization is exempted by law.

2. Licenses, certificates, confirmations, registration certificates (hereinafter referred to as "legal documents") must be effective on the date of receipt of the application (according to the receipt note) and written in English or Vietnamese language. If the expiration date is not written on the CPP, its effective period will be 24 months from its issuance date.

3. Original copies or certified true copies of legal documents:

a) The original copy shall bear the signature, name of the signer and seal of the issuing authority;

b) The certified true copy shall be authenticated by a Vietnamese competent authority in accordance with Vietnam's regulations of law on document authentication. The original copy may be required;

c) If an electronic document does not bear the signature, full name of the signer and seal of the issuing authority, the applicant shall send a document specifying the link to the website (English) of the issuing authority and assume responsibility for the legitimacy of such document.

4. CPP:

a) A CPP shall bear the signature, name of the signer and seal of the issuing authority;

b) The CPP shall be issued by a national-level drug regulatory authority.

In the cases where the CPP is issued by a drug regulatory authority other than a national-level authority, the applicant shall provide legal documents proving that the issuing authority is fully competent and that the national-level drug regulatory authority of the home country does not issue CPPs according to its domestic law.

In the cases where the CPP is issued by an authority other than a drug regulatory authority, the applicant shall provide legal documents proving that the issuing authority is fully competent and that drug regulatory authorities of the home country does not issue CPPs according to its domestic law.

c) The signature, the signer's name and seal of the issuing authority shall be authenticated by a competent authority; If the authentication content is not written in English, a notarized Vietnamese or English translation shall be provided.

d) The CPP shall contain sufficient information required in Form No. 7/TT enclosed herewith and the following information:

- The formula of the drug, which specifies the name, composition, concentration and content of each active ingredient, herbal ingredient and excipient; formula of the capsule shell (for capsules);

- Specifications of the drug product, active ingredients and herbal ingredients; name and address of the manufacturers of the active ingredients and herbal ingredients;

- If the drug product is manufactured by more than one manufacturer, the name and address of each manufacturer shall be written on the CPP;

- If the CPP does not specify which manufacturer satisfies GMP requirements, the applicant shall enclose with the application the GMP certificate of every manufacturer that does.

- Every appendix to the CPP (if any) shall be certified by the CPP issuer.

dd) For generic drugs, herbal drugs and probiotics; drugs whose marketing authorization is renewed or revised: the CPP shall specify that the drug is approved for marketing authorization in the country of origin. If the drug is not approved for market authorization in the country of origin or approved for market authorization but has not been marketed in reality in the country of origin, the applicant shall provide a CPP which certifies that the drug is approved for market authorization and marketed in any of the countries specified in Clause 10 Article 2 of this Circular;

e) For imported modern drugs and biologicals other than probiotics: the CPP issued in the country of origin and the CPP issued by any of the other regulatory authorities specified in Clause 10 Article 2 of this Circular certifies that the drug is approved for marketing authorization and has been marketed in reality;

g) For imported vaccines: the CPP issued in the country of origin and the CPP issued by any of the other regulatory authorities specified in Clause 9 Article 2 of this Circular certifies that the vaccine is approved for marketing authorization and has been marketed in reality;

h) For generic drugs having a bioequivalence study report: the CPP issued by any of the regulatory authorities specified in Clause 10 Article 2 of this Circular certifies that the drug is approved for marketing authorization and has been marketed in reality;

If the CPP does not satisfy this requirement, it is required to have the bioequivalence study report provided by the bioequivalence laboratory in Vietnam or any bioequivalence laboratory recognized by Vietnam as prescribed by the Minister of Health or under international agreements to which Vietnam is a signatory.

i) For drug proposed as proprietary drug, the CPP shall be issued by one of the regulatory authorities mentioned in Clause 9 and Clause 10 Article 2 of this Circular, except for drugs that are manufactured in Vietnam;

k) In cases where an imported drug/vaccine/biological does not have a CPP that satisfies the requirements specified in Point dd, e, g, h of this Clause, the Minister of Health, on the basis of opinions provided by the Advisory Board, shall make the decision if the drug/vaccine/biological is approved for market authorization by at least one regulatory authority in any country and satisfies any of the following requirements:

- The drug/vaccine/biological is meant to serve national defense and security, epidemic control, disaster relief or a state-level health program;

- The vaccine is meant for the national expanded immunization program and another substitute vaccine with equivalent quantity, safety, efficacy or cost is not available on the domestic market;

- In other cases under a mutual recognition agreement between drug regulatory authorities regarding conditions for manufacturing and marketing of drugs, vaccines and biologicals.

l) The information on the CPP shall be consistent with information in the marketing application.

5. The application form and other administrative documents shall bear the signature and seal of the President of the Member Assembly, Board of Directors, General Director or Director or a person authorized by them (signature stamp is not acceptable).

6. An authorization letter (Form No. 8/TT enclosed herewith) is required in the following cases:

a) A person is authorized to act as the applicant (Form No. 8A/TT enclosed herewith). An authorization letter of a foreign applicant shall bear an authenticated signature and be consularly legalized as prescribed.

Each application dossier shall contain an original copy or certified true copy of the authorization letter.

b) A person is authorized to sign the application (Form No. 8B/TT enclosed herewith); if the authorized person is not the representative office manager, the authorization letter shall bear the seal and signature of the representative office manager in Vietnam.

Each application dossier shall contain an original copy or certified true copy of the authorization letter which bear the seal of the representative office (for foreign applicants) or the Vietnamese applicant.

7. A copy of the technology transfer agreement certified by the applicant, manufacturer or representative office (for foreign applicants).

8. The Certificate of Eligibility for Pharmacy Business which permits manufacture, wholesaling, export or import of drug/medicinal ingredient (for Vietnamese applicants).

9. The license to establish a representative office in Vietnam.

If the name or address of the applicant on the license to establish a representative office in Vietnam is different from those on the legal documents issued by foreign authorities, proof must be provided.

10. For foreign applicants: Legal documents issued by foreign authorities permitting at least one of the following: manufacture, wholesaling, export, import of drugs/medicinal ingredients.

In cases where the applicant is also the manufacturer written on the CPP, the legal documents mentioned in this Clause are not required.

In cases where the license for manufacture, wholesaling, export or import of drugs/medicinal ingredients is not issued in any country, it is required to have the business license for business registration certificate that permits manufacture, wholesaling, export or import of drugs/medicinal ingredients and a certification issued by a competent authority that the applicant is qualified and is operating in the pharmaceutical field, or a certificate of Good Manufacturing Practice, Good Distribution Practice, Good Supply Practice or Good Storage Practice.

In case of medicinal ingredients: if the home country does not grant licenses to traders of medicinal ingredients, other licenses available in the home country may be accepted if they permit manufacture, wholesaling, export or import of medicinal ingredients.

11. If the applicant is already included in the list of applicants for drugs/medicinal ingredients posted on the website of Drug Administration of Vietnam, the documents mentioned in Clause 8, 9, 10 of this Article are not required.

12. Legal documents proving compliance with GMP submitted by a manufacturer of active ingredients, excipients, capsule shells, semi-finished herbal ingredients and herbal ingredients (for manufacture of herbal drugs) may be any of the following documents:

a) The GMP certificate;

b) The manufacture license that certifies GMP compliance;

c) The CPP if the active ingredient is conformable with GMP;

d) The Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP).

13. Samples of the label of the drug/medicinal ingredient and the package insert of the drug that has been marketed in the country of origin or the country in which the CPP is issued which bears the seal of the representative office or applicant or manufacturer. If the package insert of the drug is marketed in the country of origin is not written in English, a Vietnamese translation bearing the seal of the representative office, applicant or manufacturer is required.

14. The label sample, the package insert of the to-be-marketed drug shall comply with regulations of the Minister of Health on labeling of drugs/medicinal ingredients and the following requirements:

a) The label sample and package insert shall bear the seal of the representative office, applicant or manufacturer;

b) The secondary package shall have a bar code, QR code or DataMatrix Code (DMC) in accordance with Point 1 Clause 1 Article 50 of this Circular.

15. If the manufacturer is already included in the list of GMP manufacturers posted on the website of Drug Administration of Vietnam, the GMP documents are not required.

16. Specifications, test method, test report and stability study documents (for both active ingredients and drug product) shall be original copies bearing the signature and seal of the manufacturer; copies shall bear the seal of the applicant (or representative office of the foreign applicant).

The test report shall contain: name and address of the manufacturer, certificate number, name and signature of the responsible person, issuance date of the certificate), information about the drug/medicinal ingredient (name, batch number, expiry date, applied standards, specifications, analysis result, conclusion on quality of the batch)

17. The test report, results of validation of specifications and test method in Vietnam:

The test report, results of validation of specifications and test method in Vietnam (for manufacturers that have not applied GMP under the roadmap of the Ministry of Health or those required by Drug Administration of Vietnam according to Appendix III hereof) shall be certified by a state-owned drug testing laboratory that satisfies GLP requirements or a profitable drug testing laboratory that has a certificate of eligibility (original copy or certified true copy).

18. The certificate that the medicinal ingredient is permitted to be manufactured or marketed in the country of origin, on which the following information is mandatory: name of the ingredient, name and address of the manufacturer, the country of origin, signature and full name of the signer.

Article 24. Administrative documents in the application for issuance, renewal, revision of marketing authorization for drugs/medicinal ingredients

Administrative documents include:

1. The application form (Form No. 6/Circular) enclosed herewith.

2. The authorization letter (Form No. 8/TT enclosed herewith).

3. The Certificate of Eligibility for Pharmacy Business (for Vietnamese applicants).

4. Legal documents (for foreign applicants).

5. The license to establish a representative office in Vietnam (for foreign applicants).

6. The CPP (Form No. 7/TT enclosed herewith).

7. The label sample, the package insert of the to-be-marketed drug.

8. The label sample, the package insert of the drug marketing in the country of origin or the country in which the CPP is issued.

9. Summary of product properties for new modern drugs, vaccines and biologicals (Form No. 9/TT enclosed herewith).

10. Assessment of GMP compliance in the cases mentioned in Article 95 of Decree No. 54/2017/ND-CP (for foreign drug/medicinal ingredient manufacturers applying for the marketing authorization in Vietnam).

11. Legal documents of the manufacturer of active ingredients, excipients, capsule shells, semi-finished and finished herbal ingredients.

12. The certificate that the medicinal ingredient is permitted to be manufactured or marketed in the country of origin.

13. The GLP certificate of the testing laboratory in the cases mentioned in Clause 17 Article 23 of this Circular.

14. The risk management plan (Form No. 10/TT enclosed herewith).

15. The technology transfer agreement (in case of pharmaceutical technology transfer).

16. The safety and efficacy report (Form No. 2/TT enclosed herewith).

17. The marketing report (Form No. 11/TT enclosed herewith).

18. Any certificate, patent, industrial property transfer agreement, document proving the origin of ingredients (GACP, CEP, domestic herbal ingredients, imported herbal ingredients, etc.) and relevant documents.

19. A copy of the marketing authorization granted in Vietnam.

Section 2. APPLICATION FOR ISSUANCE, RENEWAL, REVISION OF MARKETING AUTHORIZATION FOR MODERN DRUGS, VACCINES AND BIOLOGICALS

Article 25. Quality documents in the application dossier

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

1. For vaccines, antiserum, blood extracts and human plasma:

a) The batch release certificate issued by a competent authority of the country in which the CPP is issued;

b) The test report, specifications and test method certified by National Institute for Control of Vaccines and Biologicals (NICVB);

2. For rare drugs and drugs serving special treatment:

a) Rare drugs for treatment of rare diseases: existing stability studies according to ASEAN's or ICH guidelines;

b) Drugs serving special treatment: existing stability studies according to ASEAN's or ICH guidelines, or decision of the Minister of Health, which is made on the basis of opinions provided by the Advisory Board if the applicant proves that the drug cannot be stored in climatic zone IVb according to ASEAN guidelines.

3. If the manufacturer uses medicinal ingredients that are have been approved for marketing authorization in Vietnam:

a) Quality documents of the ingredients and the documents mentioned in Clause 11 Article 24 of this Circular are not required in the application for marketing authorization of the drug product.

b) The applicant shall submit the following documents:

- 01 test report of the medicinal ingredients provided by the manufacturer of the drug product the specifications in which are equivalent to or higher than those of the manufacturer of the medicinal ingredients.

- 01 test report of the medicinal ingredients provided by the manufacturer of the ingredients.

4. Pharmaceutical technology transfer

a) All quality documents of the original drug shall comply with Part II of ACTD (Appendix I hereof) or 3-ICH-CTD (if original drug does not have a marketing authorization in Vietnam);

b) A tabular listing of changes between the original drug and the to-be-marketed drug (Appendix II hereof);

c) Documents about active ingredients of the to-be-marketed drug provided by the transferee if the manufacturer of the active ingredients is different from that of the original drug;

d) Documents prepared by the transferee include:

- Manufacturing process of the to-be-marketed drug.

- Report on validation of the manufacturing process (regarding the processes carried out by the transferee).

- A report on conformity assessment of the analysis process (can be replaced with documents about transfer of the analysis process prepared by both the transferor and the transferee).

- Batch analysis data (test report of drug product).

- Stability studies of the to-be-marketed drug. If the original drug already has a marketing authorization in Vietnam or its stability studies are conformable with ASEAN guidelines of stability studies, such stability studies may be applied to major variations or minor variations (depending on the differences between the original drug and the to-be-marketed drug)

- The bioequivalence studies of the to-be-marketed drug (if the to-be-marketed drug is a proprietary drug or a drug requiring bioequivalence studies according to Circular No. 08/2010/TT-BYT, or the applicant claims that the drug has demonstrated bioequivalence). If all the requirements are met, they can be replaced with studies on equivalent solubility between the to-be-marketed drug and the original drug:

+ The original drug is already granted the marketing authorization in Vietnam and declared as a proprietary drug or drug with demonstrated bioequivalence.

+ The to-be-marketed drug shall be similar to the original drug in terms of formula, medicinal ingredient manufacturers, specifications, processes of analysis of medicinal ingredients, manufacturing process, manufacturing devices and manufacturing environment. Any variation to these contents must not require submission of the bioequivalence study after changes according to instructions on batch size increase and changes after marketing authorization for solid oral drugs of US-FDA (SUPACs), and documents for each variation shall be included.

5. Secondary packaging in Vietnam

a) All quality documents of the original drug shall comply with Part II of ACTD (Appendix I hereof) or 3-ICH-CTD (if original drug does not have a marketing authorization in Vietnam);

6. For simplified validation procedures:

a) Documents about active ingredients:

- Names of the active ingredients (international nonproprietary names);

- Name and address of the manufacturer of the active ingredients and semi-finished that contain the active ingredients;

- Specifications and method for testing of the active ingredients and semi-finished that contain the active ingredients. If a Vietnam's pharmacopoeia or a reference pharmacopoeia accepted by the Ministry of Health is applied, only the name of the pharmacopoeia is required;

- 01 test report of active ingredients and semi-finished ingredients provided by the manufacturer thereof, and 01 test report of active ingredients and semi-finished ingredients provided by the manufacturer of the drug product;

- For semi-finished active ingredients, the manufacturer shall provide their formula and manufacturing process.

b) Documents about the drug product:

- The description and composition shall comply with Part 1 of ACTD;

- Specifications and method for testing of the drug product. If Vietnam's pharmacopoeia or a reference pharmacopoeia accepted by the Ministry of Health is applied, only the name of the pharmacopoeia is required;

- Manufacture of the drug product: batch formula, manufacturing process and process controls; control of critical steps and intermediates.

- Test report of drug product;

- Primary package: appearance, materials and specifications.

- Stability of the drug product.

c) Other quality documents shall comply with Part II of ACTD or 3-ICH-CTD and shall be retained by the authorization holder or manufacturer.

7. The documents mentioned in this Article shall:

a) comply with regulations of Appendix I hereof, including:

- ACTD;

- Guideline for stability study;

- Guideline for manufacturing process validation;

- Guideline for analytical method validation;

- Guideline on bioavailability and bioequivalence study;

b) Documents that are prepared according to ICH-CTD and guidelines thereof are not required to be converted to the requirements in Point a of this Clause;

Article 26. Non-clinical documents in the application for issuance, renewal or revision of marketing authorization of modern drugs, vaccines or biologicals

Non-clinical documents shall comply with Part III or ACTD or 4-ICH-CTD.

Non-clinical documents are not required for probiotics with origins, bacterial strain, concentration or content, indications, doses that are similar to biologicals licensed by one of the regulatory bodies specified in Clause 9 and Clause 10 Article 2 of this Circular.

Article 27. Clinical documents in the application for issuance, renewal or revision of marketing authorization of modern drugs, vaccines or biologicals

Clinical documents shall comply with Part IV or ACTD or 5-ICH-CTD.

Clinical documents are not required for probiotics with origins, bacterial strain, concentration or content, indications, doses that are similar to biologicals licensed by one of the regulatory bodies specified in Clause 9 and Clause 10 Article 2 of this Circular.

Article 28. Application for issuance, renewal or revision of marketing authorization of modern drugs, vaccines or biologicals

1. An application for issuance of marketing authorization for a new modern drug, vaccine or biological consists of:

a) The primary documents specified in Clauses 1, 2, 7, 9, 11, 13, 14, 18 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 and Clause 5 Article 24 of this Circular;

- For foreign drugs: the documents specified in Clause 6, Clause 8 and Clause 10 Article 24 of this Circular.

b) The quality documents specified in Article 25 of this Circular;

c) The non-clinical documents specified in Article 26 of this Circular;

d) The clinical documents specified in Article 27 of this Circular;

dd) For proprietary drugs: the documents specified in Point a, b, c, d Clause 1 of this Article and Point b Clause 1 Article 9 of this Circular.

2. An application for issuance of marketing authorization for a generic drug consists of:

a) The administrative documents specified in Clauses 1, 2, 7, 9, 11, 13, 18 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 and Clause 5 Article 24 of this Circular;

- For foreign drugs: the documents specified in Clause 6, Clause 8 and Clause 10 Article 24 of this Circular.

b) The quality documents specified in Article 25 of this Circular.

3. An application for renewal of the marketing authorization:

a) The administrative documents specified in Clauses 1, 2, 14, 16, 17, 18, 19 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 and Clause 5 Article 24 of this Circular;

- For foreign drugs: the documents specified in Clause 6 and Clause 10 Article 24 of this Circular.

b) The documents specified in Appendix II hereof if there are changes to the administrative documents when the renewal is applied for.

If the applicant has submitted the new administrative documents before the renewal application, they are not required in the renewal application even if they are yet to be approved.

4. An application for revision of the marketing authorization consists of:

a) The application form No. 6/TT enclosed herewith;

b) Documents suitable for the major variations and minor variations specified in Appendix II hereof. For vaccines of the same product owner, manufacturer or product license holder, the manufacturing location may be changed within or outside the country in which the marketing authorization is granted.

5. Application for marketing authorization of pharmaceutical technology transfer

a) An application for marketing authorization of technology transfer of a drug that has an unexpired marketing authorization in Vietnam consists of:

- The administrative documents specified in Clauses 1, 2, 7, 13, 14, 15, 16, 17, 18, 19 Article 24 of this Circular and the following documents:

+ For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

+ For foreign applicants: the documents specified in Clause 4 and Clause 5 Article 24 of this Circular.

- The quality documents specified in Clause 4 Article 25 of this Circular;

- Relevant documents specified in Appendix II hereof if there are changes to the original drug which has been approved for market authorization.

b) The application for marketing authorization of technology transfer of a drug that does not have marketing authorization in Vietnam or an unexpired marketing authorization in Vietnam.

- The documents about the original drug specified in Clause 1 or Clause 2 of this Article and Clause 15 Article 24 of this Circular;

- The quality documents specified in Clause 4 Article 25 of this Circular.

6. Application for the marketing authorization of a drug undergoing secondary packaging in Vietnam

a) If the drug undergoing secondary packaging has an unexpired marketing authorization in Vietnam: follow instructions on change of secondary packaging facility in Appendix II hereof;

b) If the drug undergoing secondary packaging in Vietnam does not have marketing authorization in Vietnam or its marketing authorization in Vietnam has expired:

- Documents of the drug before secondary packaging: follow instructions in Clause 1 or Clause 2 of this Article;

- The GMP certificate of the secondary packaging facility in Vietnam;

- The quality documents specified in Clause 5 Article 25 of this Circular.

7. Application for the marketing authorization following simplified procedures

a) The administrative documents specified in Clauses 1, 2, 7, 11, 13, 18 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 an Clause 5 Article 24 of this Circular;

- For foreign drugs: the documents specified in Clause 6 and Clause 8 Article 24 of this Circular.

b) The quality documents specified in Point a and Point b Clause 6 Article 25 of this Circular.

Section 3. APPLICATION FOR ISSUANCE, RENEWAL, REVISION OF MARKETING AUTHORIZATION FOR HERBAL DRUGS

Article 29. Quality documents in the application for issuance, renewal or revision of the marketing authorization for herbal drugs

1. Ingredients

a) The manufacturing process (only applied to herbal ingredients): describe in details the preparation and processing of herbal ingredients. For semi-finished herbal ingredients and bone glue, it is required to describe in details the manufacturing process thereof, except for those that are already approved for marketing authorization;

b) Specifications and test method

- For herbal ingredients other than semi-finished herbal ingredients: follow instructions in Circular No. 13/2018/TT-BYT.

- Regulations on specifications and test methods for herbal ingredients other than semi-finished herbal ingredients specified in Circular No. 13/2018/TT-BYT shall also be applied to semi-finished herbal ingredients.

c) Test report of ingredients

- 01 test report of herbal ingredients provided by the manufacturer of the drug product.

- 01 test report of semi-finished herbal ingredients and bone glue provided by the manufacturer thereof, and 01 test report of semi-finished herbal ingredients and bone glue provided by the manufacturer of the drug product.

2. Drug product

a) Manufacturing process

- Formula of a smallest packaging unit: name, content, concentration, weight, specs of each ingredient in a smallest packaging unit. If the drug product is made of semi-finished herbal ingredients or bone glue, it is required to specify the ratio of herbal ingredients to total weight of semi-finished herbal ingredients or bone glue, the ratio of bone glue or semi-finished herbal ingredients to the initial herbal ingredients and content (%) of the active ingredients or substances therein.

- Batch formula: names, weights, volumes of each ingredient in the formula.

- Manufacturing process diagram: present all stages in the manufacturing process, including the path of ingredients and its consistency with the manufacturing process description.

- Manufacturing process description: describes in details every step of the manufacturing process, including specifications thereof.

- Equipment list: names, specifications and uses of each piece of equipment.

- Control of manufacturing process: Describe in details control criteria for each stage, including the criterion, specifications, control method, control frequency and sample size.

b) Specifications and test method

- Formula of a smallest packaging unit: name, content, concentration, weight, specs of each ingredient in a smallest packaging unit. If the drug product is made of semi-finished herbal ingredients or bone glue, it is required to specify the ratio of herbal ingredients to total weight of semi-finished herbal ingredients or bone glue, the ratio of bone glue or semi-finished herbal ingredients to the initial herbal ingredients and content (%) of the active ingredients or substances therein.

- Specifications of the drug product shall comply with Circular No. 11/2018/TT-BYT.

c) The test report of drug product.

d) Specifications of packages: Describe in details the material, specifications, quality and test method.

dd) A stability study according to the guidelines for stability study in Appendix I hereof.

Article 30. Safety and efficacy documents in the application for issuance, renewal or revision of the marketing authorization for herbal drugs

1. Safety and efficacy documents of herbal drugs shall comply with regulations in Appendix V hereof, ACTD or ICH-CTD.

2. The documents specified in Point b Clause 1 Article 19 of this Circular (if any).

Article 31. Application for issuance, renewal, revision of marketing authorization for herbal drugs

1. An application for issuance of marketing authorization for an herbal drug consists of:

a) The administrative documents specified in Clauses 1, 2, 7, 11, 13, 18Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 an Clause 5 Article 24 of this Circular;

- For foreign drugs: the documents specified in Clause 6, Clause 8 and Clause 10 Article 24 of this Circular.

b) The quality documents specified in Article 29 of this Circular;

c) The safety and efficacy documents specified in Article 30 of this Circular;

2. Application for renewal of marketing authorization of an herbal drug consists of:

a) The administrative documents specified in Clauses 1, 2, 16, 17, 18, 19 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 an Clause 5 Article 24 of this Circular;

- For foreign drugs: the documents specified in Clause 6 and Clause 10 Article 24 of this Circular.

b) Relevant documents according to Section D of Appendix II hereof if there are changes to the administrative documents when the renewal is applied for.

If the authorization holder has submitted the new administrative documents before the renewal application, they are not required in the renewal application even if they are yet to be approved.

3. An application for revision the marketing authorization for a generic drug consists of:

a) The application form No. 6/TT enclosed herewith;

b) Documents about major variations and minor variations according to Section D Appendix II hereof.

Section 4. APPLICATION FOR MARKETING APPLICATION OF MEDICINAL INGREDIENTS

Article 32. Quality documents in the application for issuance, renewal or revision of the marketing authorization for medicinal ingredients

1. For active ingredients: Documents of active ingredients specified in ACTD. Submit the Drug Master File if the manufacturer’s specifications are applied.

2. For semi-finished active ingredients: The same documents specified in ACTD as those of drug products, in which the documents about the drug product will be replaced with documents about the semi-finished products; the formula of a single dose or smallest packaging unit will be replaced with the batch formula.

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

a) Formulae of the semi-finished herbal ingredients, pre-mixed excipients, capsule shells: composition, weight, volume, specifications of each component of the formula. For ingredients derived from animals, information should be provided regarding adventitious agents (viral safety data).

b) Manufacturing process

- Manufacturing process diagram: describes all stages in the manufacturing process, including the path of ingredients and its consistency with the manufacturing process description.

- Manufacturing process description: describes in details every step of the manufacturing process, including specifications thereof.

- Equipment list: names, specifications and uses of each piece of equipment.

- Control of manufacturing process: Describe in details control criteria for each stage, including the criterion, specifications, control method, control frequency and sample size.

c) Specifications and test method

- Regulations on specifications and test methods for herbal ingredients other than semi-finished herbal ingredients specified in Circular No. 13/2018/TT-BYT shall also be applied to semi-finished herbal ingredients.

- Specifications of excipients and capsule shells shall comply with Circular No. 11/2018/TT-BYT.

d) The test report.

dd) Specifications of packages: Describe in details the material, specifications, quality and test method.

e) The stability study, including the stability study rationales, data, result and discussion.

Article 33. Application for issuance, renewal, revision of marketing authorization for medicinal ingredients

1. An application for issuance of marketing authorization for a medicinal ingredient consists of:

a) Part I: Administrative documents

- The administrative documents specified in Clauses 1, 2, 7, 11, 13, 18 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 an Clause 5 Article 24 of this Circular;

- For foreign ingredients: the documents specified in Clause 8, Clause 10 and Clause 12 Article 24 of this Circular.

b) The quality documents specified in Article 32 of this Circular;

2. Application for renewal of marketing authorization of a medicinal ingredient consists of:

a) The administrative documents specified in Clauses 1, 2, 11, 17, 18, 19 Article 24 of this Circular and the following documents:

- For Vietnamese applicants: the documents specified in Clause 3 Article 24 of this Circular;

- For foreign applicants: the documents specified in Clause 4 an Clause 5 Article 24 of this Circular;

- For foreign ingredients: the documents specified in Clause 8, Clause 10 and Clause 12 Article 24 of this Circular.

b) Relevant documents according to Section D of Appendix II hereof if there are changes to the administrative documents when the renewal is applied for.

If the authorization holder has submitted the new administrative documents before the renewal application, they are not required in the renewal application even if they are yet to be approved.

3. An application for revision the marketing authorization for a medicinal ingredient consists of:

a) The application form No. 06/TT enclosed herewith;

b) Documents about major variations and minor variations according to Section B Appendix II hereof.

Chapter IV

PROCEDURES FOR ISSUANCE, RENEWAL, REVISION OF MARKETING AUTHORIZATION FOR DRUGS AND MEDICINAL INGREDIENTS PROCESSING OF APPLICATIONS FOR IMPORT OF DRUGS WITHOUT MARKETING AUTHORIZATION

Article 34. Drugs eligible for quick validation

1. Rare drugs listed by the Minister of Health.

2. Drugs serving urgent needs for national defense and security, epidemic control or disaster relief.

3. Domestic drugs that are manufactured by production lines that satisfy GMP, GMP-EU, GMP-PIC/S standards and equivalent standards within 18 months from the issuance date of the GMP certificate.

4. Vaccines that are approved by WHO; vaccines used for national expanded immunization programs.

5. Specialty drugs, drugs with special dosage forms where not more than 02 similar drugs (with the same active ingredients, dosage form, content or concentration) have an unexpired marketing authorization in Vietnam when the application is submitted, including:

a) Antineoplastic drugs;

b) Next-gen antiviral drugs

c) Next-gen antibiotics;

d) Drugs for treatment of hemorrhagic fever, tuberculosis, malaria.

6. Drugs that can be domestically manufactured, including:

a) Antineoplastic drugs, vaccines, biologicals, next-gen antiviral drugs that are manufactured in Vietnam under a processing agreement or technology transfers agreement;

b) Herbal drugs under a national, ministerial or provincial research which has been accepted; drugs wholly obtained from domestic herbal ingredients that satisfy GACP standards;

c) New domestic drugs that have undergone clinical trial in Vietnam;

7. New antineoplastic drugs, next-gen antiviral drugs, next-gen antibiotics, biologicals.

8. Proprietary drugs that are manufactured in Vietnam under a processing agreement or technology transfer agreement.

Article 35. Drugs eligible for simplified validation procedures

A marketing application will be eligible for simplified validation procedures if all of the following conditions are satisfied:

1. The drug is manufactured in a factory that periodically undergoes GMP inspection by Drug Administration of Vietnam.

2. The drug is included in the list of OTC drugs.

3. The dosage form of the drug is not modified-release.

4. The drug is not directly applied to the eye.

Article 36. Power to grant issuance, renewal, revision of marketing authorization for drugs and medicinal ingredients

1. Drug Administration of Vietnam shall validate and consider granting applications for issuance and renewal of marketing authorization; consider granting approval for major variations to marketing authorization, including indications, dose, intended users, declaration of proprietary drug, drugs with demonstrated bioequivalence on the basis of opinions offered by the Advisory Board.

2. Drug Administration of Vietnam shall validate and consider granting applications for revision of marketing authorization for drugs and medicinal ingredients, except for the major variations mentioned in Clause 1 of this Article.

Article 37. General provisions

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

2. After receiving adequate documents, Drug Administration of Vietnam shall issue the receipt note (form No. 12/TT enclosed herewith).

3. Receipt of applications for import of unapproved drugs shall comply with Point b Clause 1 Article 77 of Decree No. 54/2017/ND-CP.

4. Validation of applications for issuance, renewal, revision of marketing authorization of drugs/medicinal ingredients and applications for import of unapproved drugs:

a) Drug Administration of Vietnam shall send the applications to validating officials or units assigned by the Minister of Health (hereinafter referred to as “validating units”).

b) On the basis of comments offered by the validating officials and validating units mentioned in Point a of this Clause and relevant information, Drug Administration of Vietnam shall propose grant or rejection of the applications. The proposal of Drug Administration of Vietnam shall be written on the validation record.

c) Drug Administration of Vietnam shall consult with the Advisory Board about:

- Whether to grant the marketing authorization;

- Whether to renew the marketing authorization;

- Whether to approve the major variations of the marketing authorization in terms of indications, dose, intended users;

- Whether to declare the proprietary drug or drug with demonstrated bioequivalence;

- Whether to grant the license to import an unapproved drug;

- Other cases proposed by Drug Administration of Vietnam to serve urgent treatment.

Article 38. Procedures for granting marketing authorization and import of unapproved drugs

1. Within 12 months from the day on which adequate documents are received (except for the case specified in Article 41 of this Circular), Drug Administration of Vietnam shall issue marketing authorization. If the application is rejected, Drug Administration of Vietnam shall respond in writing and provide explanation. Deadlines:

a) Within 03 months from the day on which adequate documents are received, Drug Administration of Vietnam shall transfer it to the validating official or validating unit. Within 06 months from the receipt of the application from Drug Administration of Vietnam, the validating official or validating unit shall send a validation record to Drug Administration of Vietnam in accordance with Clause 4 Article 37 of this Circular;

b) Within 02 months from the receipt of the validation record, Drug Administration of Vietnam shall make a written response if the application is rejected and provide explanation. Drug Administration of Vietnam shall make the proposals or obtain comments from the Advisory Board in the nearest meeting;

c) Within 30 days from the meeting, Drug Administration of Vietnam shall issue the decision to grant the marketing authorization to the satisfactory application; Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

2. Within 36 months from the day on which Drug Administration of Vietnam requests submission of additional non-clinical and clinical documents, bioequivalence documents, stability study documents are required (or 12 months for other documents), the applicant shall provide the additional documents. Otherwise, the application will be rejected.

The applicant shall send a written notification to Drug Administration of Vietnam of updated information about safety and efficacy of the drug during validation period.

The period from the date Drug Administration of Vietnam issues the request to the date the applicant submits the additional documents is not included in the time limit specified in Clause 5 Article 56 of the Law on Pharmacy.

3. Within 06 days from the receipt of additional documents, Drug Administration of Vietnam shall issue the decision to grant the marketing authorization if the application is satisfactory; Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

Additional documents shall be examined in accordance with Clause 1 of this Article.

4. Validation of applications for import of unapproved drugs:

a) Within 05 working days from the day on which adequate documents are received, Drug Administration of Vietnam shall transfer it to the validating officials or validating units.

The validation shall not exceed 30 days if clinical data or bioequivalence documents for reference biologicals are not mandatory; 60 days if clinical data or bioequivalence documents for reference biologicals are mandatory;

b) Within 20 days from the day on which the validation record is received:

- Drug Administration of Vietnam shall gather comments from the validating officials or validating units and consider relevant information to decide whether to propose the grant of the import license.

- Drug Administration of Vietnam shall present the documents mentioned in Point c Clause 4 Article 37 of this Circular to the Advisory Board in the nearest meeting;

- If the rejection is proposed, Drug Administration of Vietnam shall respond in writing and provide explanation.

c) Within 5 working days from the day on which the meeting is held or comments are given by the Advisory Board, Drug Administration of Vietnam shall grant the import license if the application is satisfactory, or send a notice of rejection and provide explanation if the application is not satisfactory.

d) After receiving the supplementary application from the applicant, Drug Administration of Vietnam shall follow instructions in Point a through c of this Clause.

If the Advisory Board requests supplementation of the application without re-submission of the application, Drug Administration of Vietnam shall inform the applicant and, if the supplemented application is satisfactory, grant the license without resubmitting to the Advisory Board.

Article 39. Procedures for renewal of marketing authorization

1. Within 03 months from the receipt of adequate documents, Drug Administration of Vietnam shall renew the marketing authorization if the application is satisfactory. If the renewal application is rejected or yet to be granted, Drug Administration of Vietnam shall respond in writing and provide explanation. Deadlines:

a) Within 10 working days from the receipt of adequate documents, Drug Administration of Vietnam shall classify the applications and send them to validating units. Within 01 month from the receipt of the application from Drug Administration of Vietnam, the

validating unit shall send a validation record to Drug Administration of Vietnam in accordance with Clause 4 Article 37 of this Circular;

b) Within 15 working days from the receipt of the validation record, Drug Administration of Vietnam shall make a written response if the application is rejected and provide explanation. If the application is satisfactory or comments of the Advisory Board are necessary, Drug Administration of Vietnam shall present them in the nearest meeting;

c) Within 15 days from the meeting, Drug Administration of Vietnam shall issue the decision to renew the marketing authorization if the application is satisfactory; Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

2. The authorization holder shall provide additional documents within 12 months from the day on which a request is issued by Drug Administration of Vietnam. Otherwise, the application will be rejected.

The authorization holder shall send a written notification to Drug Administration of Vietnam of updated information about safety and efficacy of the drug during validation period.

The period from the date Drug Administration of Vietnam issues the request to the date the authorization holder submits the additional documents is not included in the time limit specified in Clause 5 Article 56 of the Law on Pharmacy.

3. Within 03 months from the receipt of additional documents, Drug Administration of Vietnam shall issue the decision to renew the marketing authorization if the application is satisfactory; Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

Additional documents shall be examined in accordance with Clause 1 of this Article.

Article 40. Procedures for revision of unexpired marketing authorization

1. Revision in case of major variations in terms of indications, dose, intended users; recognition of proprietary drugs, drugs with demonstrated bioequivalence:

Within 03 months from the receipt of adequate documents, Drug Administration of Vietnam shall issue the declaration of proprietary drug or drug with demonstrated bioequivalence, or approve the major variations in terms of indications, dose, intended users. If the revision application is rejected or yet to be granted, Drug Administration of Vietnam shall respond in writing and provide explanation. Deadlines:

a) Within 10 working days from the receipt of adequate documents, Drug Administration of Vietnam shall classify the applications and send them to validating units. Within 01 month from the receipt of the application from Drug Administration of Vietnam, the

validating unit shall send a validation record to Drug Administration of Vietnam in accordance with Clause 4 Article 37 of this Circular;

b) Within 15 working days from the receipt of the validation record, Drug Administration of Vietnam shall make a written response if the application is rejected and provide explanation. If the application is satisfactory or comments of the Advisory Board are necessary, Drug Administration of Vietnam shall present them in the nearest meeting;

c) Within 15 working days from the meeting, Drug Administration of Vietnam shall issue the declaration of proprietary drug or drug with demonstrated bioequivalence, or approve the major variations in terms of indications, dose, intended users if the application is satisfactory. Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

2. Revision of the marketing authorization, except for the cases specified in Clause 1 and Clause 3 of this Article

Drug Administration of Vietnam shall process the revision application within 03 months from the receipt of adequate documents. If the revision application is rejected or yet to be granted, Drug Administration of Vietnam shall respond in writing and provide explanation. Deadlines:

a) Within 10 working days from the receipt of adequate documents, Drug Administration of Vietnam shall classify the applications and send them to validating units. Within 60 days from the receipt of the application from Drug Administration of Vietnam, the validating unit shall send a validation record to Drug Administration of Vietnam in accordance with Clause 4 Article 37 of this Circular;

b) Within 20 days from the receipt of the validation record, Drug Administration of Vietnam shall approve the revision if the application is satisfactory, or make a written response if the application is rejected and provide explanation.

3. Minor variations that only require notification

Within 15 days from the receipt of adequate documents, Drug Administration of Vietnam shall approve the revision if the application is satisfactory, or make a written response if the application is rejected and provide explanation.

4. Within 36 months from the day on which Drug Administration of Vietnam requests submission of additional non-clinical and clinical documents, bioequivalence documents, stability study documents are required (or 12 months for other documents), the authorization holder shall provide the additional documents. Otherwise, the application will be rejected.

The authorization holder shall send a written notification to Drug Administration of Vietnam of updated information about safety and efficacy of the drug during validation period.

The period from the date Drug Administration of Vietnam issues the request to the date the authorization holder submits the additional documents is not included in the time limit specified in Clause 5 Article 56 of the Law on Pharmacy.

5. Within 02 months from the receipt of the additional documents specified in Clause 1 of this Article, 01 month for the documents specified in Clause 2 of this Article, 10 working days for the documents specified in Clause 3 of this Article, Drug Administration of Vietnam shall approve the revision if the application is satisfactory, or make a written response and provide explanation if the application is rejected.

Additional documents shall be examined in accordance with Clause 1 through 3 of this Article.

6. Time limits for implementation of the revisions to the marketing authorization: 12 months for vaccines and biologicals, 06 months for other drugs and medicinal ingredients from the day on which Drug Administration of Vietnam signs the approval for revisions, unless otherwise requested by Drug Administration of Vietnam.

7. In the following cases, the applicant or manufacturer may update the label or package insert without submitting an application or notifying Drug Administration of Vietnam:

a) The label or package insert complies with Clause 2 Article 35 of Circular No. 01/2018/TT-BYT;

b) The label or package insert is revised in accordance with the written request of Drug Administration of Vietnam;

c) Unless the sample label or package insert has to be submitted in case of the revisions specified in Appendix II hereof, other revisions to the label or package insert shall be updated by the authorization holder after they are approved by Drug Administration of Vietnam;

d) Other contents:

- Change to information about the importer on the label or package insert;

- Correction of spelling errors on the label or package insert;

- Change in order of information in the package insert without change to information thereof;

- Addition of specifications on the label or package insert approved by Drug Administration of Vietnam;

- Revisions requested by Drug Administration of Vietnam regarding validation of the marketing application.

Article 41. Simplified procedures for validation and grant of marketing authorization

1. Within 06 months from the receipt of adequate documents, Drug Administration of Vietnam shall grant the marketing authorization. If the application is rejected or yet to be granted, Drug Administration of Vietnam shall respond in writing and provide explanation. Deadlines:

a) Within 10 working days from the receipt of adequate documents, Drug Administration of Vietnam shall classify the applications and send them to validating units. Within 03 months from the receipt of the application from Drug Administration of Vietnam, the validating official or validating unit shall send a validation record to Drug Administration of Vietnam in accordance with Clause 4 Article 37 of this Circular;

b) Within 20 working days from the receipt of the validation record, Drug Administration of Vietnam shall make a written response if the application is rejected and provide explanation. If the application is satisfactory or comments of the Advisory Board are necessary, Drug Administration of Vietnam shall present them in the nearest meeting;

c) Within 30 working days from the meeting, Drug Administration of Vietnam shall issue the decision to grant the marketing authorization to the satisfactory application; Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

2. Within 36 months from the day on which Drug Administration of Vietnam requests submission of additional non-clinical and clinical documents, bioequivalence documents, stability study documents are required (or 12 months for other documents), the applicant shall provide the additional documents. Otherwise, the application will be rejected.

The applicant shall send a written notification to Drug Administration of Vietnam of updated information about safety and efficacy of the drug or medicinal ingredient during the validation period.

The period from the date Drug Administration of Vietnam issues the request to the date the applicant submits the additional documents is not included in the time limit specified in Clause 5 Article 56 of the Law on Pharmacy.

3. Within 03 days from the receipt of additional documents, Drug Administration of Vietnam shall issue the decision to grant the marketing authorization if the application is

satisfactory; Drug Administration of Vietnam shall send written response and provide explanation for rejected applications according to comments of the Advisory Board.

Additional documents shall be examined in accordance with Clause 1 of this Article.

Chapter V

REVOCATION OF MARKETING AUTHORIZATION, TEMPORARY REJECTION OF APPLICATIONS FOR ISSUANCE OR RENEWAL OF MARKETING AUTHORIZATION

Article 42. Documents and procedures for revocation of marketing authorization

1. Power to revoke the marketing authorization and responsibility to inform the revocation:

a) Drug Administration of Vietnam is entitled to revoke the marketing authorization in the cases specified in Clause 1 Article 58 of the Law on Pharmacy;

b) Departments of Health shall send the revocation decisions of Drug Administration of Vietnam to the license holder in their provinces.

2. Documents for revocation in the cases specified in Point g Clause 1 Article 58 of the Law on Pharmacy include:

- The written request for revocation of the marketing authorization (Form 1/TT enclosed herewith) prepared by the manufacturer or authorization holder;

- The original marketing authorization;

- Supporting documents (if any).

3. Procedures for revocation in the cases specified in Point a and Point b Clause 1 Article 58 of the Law on Pharmacy

Within 30 days from the issuance date of the decision to recall a drug, Drug Administration of Vietnam shall issue a decision to revoke the marketing authorization of the drug.

4. Procedures for revocation in the cases specified in Point c and Point e Clause 1 Article 58 of the Law on Pharmacy

Within 10 days from the day on which the Vietnamese competent authority receives the notification from WHO or country of origin that the drug is not safe or effective on human, or a foreign competent authority revokes the product certificate, Drug

Administration of Vietnam shall issue a decision to revoke the marketing authorization of the drug or medicinal ingredient.

5. Procedures for revocation in the cases specified in Point d and Point dd Clause 1 Article 58 of the Law on Pharmacy

Within 30 days from the day on which a competent authority issues the conclusion that documents in the marketing application is fraudulent, or the drug/medicinal ingredient is manufactured at an unregistered location, Drug Administration of Vietnam shall issue the decision to revoke the drug/medicinal ingredient.

6. Procedures for revocation in the cases specified in Point g Clause 1 Article 58 of the Law on Pharmacy

Within 20 days from receipt of adequate documents specified in Clause 2 of this Article, Drug Administration of Vietnam shall issue a decision to revoke the marketing authorization of the drug/medicinal ingredient. Drug Administration of Vietnam shall make a written response and provide explanation if the request for revocation is rejected.

Article 43. Suspension from submission of marketing applications

1. Applicants may be suspended from submission of marketing applications according to Clause 2 through 4 Article 100 of Decree No. 54/2017/ND-CP.

2. Such a suspension shall be announced by Drug Administration of Vietnam.

Chapter VI

RULES FOR ORGANIZATION AND OPERATION OF MARKETING AUTHORIZATION ADVISORY BOARD

Article 44. Organization and operation of Marketing Authorization Advisory Board

1. Marketing Authorization Advisory Board is established by the Minister of Health. The Advisory Board consists of experts whose qualifications and experience are appropriate for validating applications, questioning opinions of validating officials and proposals of Drug Administration of Vietnam, provide the Minister of Health with advice regarding about pharmacy laws, safety and efficacy documents of drugs/medicinal ingredients.

2. The Advisory Board has the responsibility to validate applications, provide the Minister of Health with advice on issuance, renewal, revision of marketing authorization; licensing import of drugs without the marketing authorization on the basis of proposals of Drug Administration of Vietnam, and relevant issues at the request of the Minister of Health. The Advisory Board is responsible to the Minister of Health for its advice and comments.

3. Operation of the Advisory Board:

a) The Advisory Board operates according to unanimity, democracy, objectivity and transparency principles. Comments offered by The Advisory Board shall be scientific and lawful with account taken of results given by validating officials, clinical reality and proposals of Drug Administration of Vietnam.

b) Every meeting of The Advisory Board shall be attended by at least 2/3 of its members, including those who send their comments in writing without attending the meeting;

The chairperson or a person authorized by the chairperson to preside over the meeting shall announce the verdict when it is approved of by at least 2/3 of the participants. Dissenting opinions shall be reserved.

Opinions, including dissenting opinions, of the members and the verdict of The Advisory Board shall be written in the meeting minutes, including dissenting opinions.

c) If a meeting is not held, the chairperson shall obtain written comments from the members;

After the deadline for sending comments, the chairperson or a person authorized by the chairperson shall announce a verdict when at least 2/3 of the members have sent their comments.

The verdict shall be based upon consenting opinions of at least 2/3 of the commenting members, the consolidated report and proposal of Drug Administration of Vietnam;

d) Where necessary, the chairperson may seek opinions from independent experts other than Advisory Board members before announcing the verdict. These experts may participate in the Advisory Board meeting or send their comments, have the same responsibilities and interests as those of the members;

dd) Conflict of interest rules are not violated.

4. Drug Administration of Vietnam shall propose to the Minister of Health the regulations on organization and operation of the Advisory Board, the mechanism for cooperation between the Advisory Board and validating officials regarding issuance, renewal and revision of marketing authorizations and licenses for import of unapproved drugs.

5. Operating budget of the Advisory Council shall comply with regulations of law.

6. Standing Committee of Marketing Authorization Advisory Board shall be situated within Drug Administration of Vietnam.

Article 45. Organization and operation of validating official of marketing applications and import license applications

1. Drug Administration of Vietnam shall established validation teams to validate marketing applications and import license applications. The composition of each validation team shall be suitable for the proposed products, registration form or licensing form.

2. The validating officials' comments shall be lawful and scientific, and written in the validation record. Validating officials are responsible to the Director of Drug Administration of Vietnam for their validation works and proposals.

3. Drug Administration of Vietnam shall introduce regulations on organization and operation of validation teams; sign contracts with validating officials or validating units; provide training courses for validating officials; organize assessment of the validating officials' knowledge and conformity, which is the basis for replacement or employment of validating officials.

4. Provision of funding for validation shall comply with regulations of law.

Chapter VII

IMPLEMENTATION CLAUSES

Article 46. Effect

1. This Circular comes into force from September 01, 2019.

2. Circular No. 44/2014/TT-BYT dated November 25, 2014 of the Minister of Health on drug registration, except for regulations on regulations of in vitro diagnostic reagents, shall expire from the effective date of this Circular.

Article 47. Transition clauses

1. Applications submitted before the effective date of this Circular shall be processed in accordance with Circular No. 44/2014/TT-BYT, unless the applicant wishes to apply regulations on this Circular when it comes into force.

2. A marketing authorization that expires during the period from January 01, 2018 to June 30, 2020 will be extended for 12 more months if all of the following requirements are satisfied:

a) The applicant is not suspended from applying for issuance or renewal of the marketing authorization according to Clause 2 Article 100 of Decree No. 54/2017/ND-CP; Clause 54 Article 4 and Point a Clause 53 Article 5 of Decree No. 155/2018/ND-CP;

b) There is no warning against the safety or efficacy of the drug/medicinal ingredient issued by WHO or any drug regulatory authority of Vietnam;

c) The authorization holder submits an application for renewal of the marketing authorization (form No. 6/TT enclosed herewith);

Drug Administration of Vietnam shall send a written response within 20 days from the day on which the application is received.

3. If a new marketing authorization is granted during the effective period of the old marketing authorization, both of them can be simultaneously effective and the latter will be effective for 06 months from the effective date of the former.

4. Proprietary drugs that are recognized by Drug Administration of Vietnam before the effective date of this Circular are still recognized. Authorization holders shall update the categorization of their proprietary drugs in accordance with Appendix II hereof within the effective period of the marketing authorization.

Article 48. Implementation roadmap

1. The duration of marketing authorization for excipients and capsule shells shall comply with Clause 8 Article 143 of Decree No. 54/2017/ND-CP.

2. The duration of marketing authorization for semi-finished herbal ingredients shall comply with Point c Clause 78 Article 5 of Decree No. 155/2018/ND-CP.

3. Regarding applications for renewal or revision of the marketing authorization submitted before January 01, 2020: specifications of the drug product, active ingredients, herbal ingredients, name and address of manufacturers thereof are not requirements in the CPP.

4. The legal documents specified in Clause 11 Article 24 of this Circular are not required for applications for marketing authorization for semi-finished herbal ingredients, semi-finished medicinal ingredients that are herbal ingredients, excipients, capsule shells and ingredients thereof that are submitted before January 01, 2021.

Article 49. Reference clauses

In cases where a legislative document or regulation referred to in this Circular is amended or replaced, the newest one shall apply.

Article 50. Responsibility for implementation

1. Drug Administration of Vietnam, pursuant to the roadmap for ASEAN harmonization of drug registration, has the responsibility to:

a) Organize the implementation of this Circular;

b) Update on its website the list of drugs and medicinal ingredients whose marketing authorizations are granted or renewed within 05 days from the day on which they are granted or renewed, other information about registration of drugs and medicinal ingredients;

c) Update on its website the list of drugs with demonstrated bioequivalence within 05 days from the day on which their marketing authorization is granted, revisions to information about these drugs within 07 days from the day on which the revisions are approved;

d) Update on its website the list of proprietary drugs within 05 days from the day on which their marketing authorization is granted, revisions to information about these proprietary drugs within 07 days from the day on which the revisions are approved;

dd) Review the recognized proprietary drugs after they may no longer satisfy the criteria;

e) Develop, issue and organize implementation of SOPs in drug registration and QM;

g) Cooperate with Traditional Medicine Administration of Vietnam in renewing and revising the marketing authorizations of traditional drugs and herbal drugs that were issued under Circular No. 44/2014/TT-BYT;

h) In the cases where an applicant forges or falsifies legal documents of Vietnamese or foreign authorities, uses a fraudulent seal or signature of an organization in the application, Drug Administration of Vietnam will issue a warning and stop receiving applications from such applicant in accordance with Clause 2 through 4 Article 100 of Decree No. 54/2017/ND-CP.

Other than Drug Administration of Vietnam will make an announcement about the violation on its website, inform inspection authorities and competent authorities for handling as prescribed by law;

i) Where necessary, Drug Administration of Vietnam shall hold a meeting with the applicant, manufacturer or experts to clarify the issues that arise during verification of the application;

k) Publish on its website the list of authorization holders and manufacturers of drugs and medicinal ingredients in accordance with Clause 11 and Clause 15 Article 23 of this Circular.

l) Propose to the Minister of Health regulations and a roadmap for use of bar codes, QR codes and DataMatrix codes on secondary packages of drugs and medicinal ingredients marketed in Vietnam;

m) Return the label and package insert to the authorization holder within 30 days from the date of issue or renewal of the marketing authorization;

n) Publish on its website the origins of medicinal ingredients of domestically manufactured drugs of proprietary drugs within 15 days from the date of issue or renewal of the marketing authorization; within 07 days from the day on which the revisions to the marketing authorization are approved.

2. Departments of Health of provinces shall carry out inspection of the implementation of this Circular by pharmaceutical manufacturers and sellers in their provinces.

3. Affiliated units of the Ministry of Health, Vinapharm and drug sellers have the responsibility for implementation of this Circular.

Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health for consideration./.

PP MINISTER
DEPUTY MINISTER

Truong Quoc Cuong
