

Circular on Prescribing Marketing Authorization of Drugs and Medicinal Materials¹

Authority: **The Ministry of Health of Vietnam**

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Pursuant to the Law on Pharmacy dated April 06, 2016;

Pursuant to the Law on amendments to the Law on Pharmacy dated November 21, 2024;

Pursuant to the Law on Technology Transfer dated June 19, 2017;

Pursuant to the Government's Decree No. 69/2018/ND-CP dated May 15, 2018 elaborating some articles of the Law on Foreign Trade Management;

Pursuant to the Government's Decree No. 76/2018/ND-CP dated May 15, 2018 elaborating and providing guidelines for implementation of the Law on Technology Transfer;

Pursuant to the Government's Decree No. 42/2025/ND-CP dated February 27, 2025 defining functions, tasks, powers and organizational structure of the Ministry of Health of Vietnam (MoH);

At the request of the Director of the Drug Administration of Vietnam (DAV);

The Minister of Health of Vietnam promulgates a Circular prescribing marketing authorization of drugs and medicinal materials.

Chapter I: General Provisions

Article 1 Scope

1. This Circular elaborates and provides guidelines for implementation of some Articles of the Law on Pharmacy dated April 06, 2016 and the Law on amendments to the Law on Pharmacy dated November 21, 2024 (hereinafter referred to as “the Pharmacy Law”), including:

¹ Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law



- a) Regulations on clinical data about drug safety and efficacy in the application for marketing authorization, criteria for exemption from clinical trial or certain stages thereof in Vietnam, and drugs that have to undergo stage 4 clinical trial in clause 4 Article 89 of the Pharmacy Law;
- b) Documentation requirements, procedures for issuance, renewal, approval of variations and revocation of marketing authorizations of chemical drugs, vaccines, biologicals, herbal drugs and medicinal materials for human use in Vietnam in clause 9 Article 56 and clause 2 Article 58 of the Pharmacy Law;
- c) Principles and criteria for classification of over-the-counter (OTC) drugs in clause 27 Article 2 of the Pharmacy Law;
- d) Regulations on post-authorization safety and efficacy reporting for performing pharmacovigilance activities as prescribed in clause 2 Article 78 of the Pharmacy Law;
- e) Principles for organization and operation of the Advisory Board, validating units and validators.

2. This Circular does not apply to applications for marketing authority of traditional drugs; applications for marketing authority of medicinal materials which are herbal materials or traditional medicinal materials.

Article 2 Definitions

For the purposes of this Circular, the terms used herein are construed as follows:

1. *ASEAN common technical dossier (ACTD)* means a standardized format of common technical dossier for registration of drugs of the Association of Southeast Asian Nations (ASEAN).

2. *ICH-CTD* means the Common Technical Document (CTD) developed by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.

3. *Major variations (MaV)* are variations that may affect significantly and/or directly the aspects of quality, safety and efficacy of the drug, specified in Appendix II hereof.

4. *Minor variations (MiV)* are variations with minimal or no significant impact on the aspects of quality, safety and efficacy of the drug, specified in Appendix II hereof.

5. *Applicant* means the establishment whose name appears on the application for issuance, renewal or approval of variations to marketing authorization of a drug or medicinal material.

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

7. *Medicinal material manufacturer* means the establishment that manufactures or releases the batch of material(s) of a drug product.



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8. *Certificate of Pharmaceutical Product (CPP)* means a certificate issued in the format recommended by the World Health Organization (WHO) according to WHO's certification scheme on the quality of pharmaceutical products moving in international commerce.

9. *European Medicines Agency (EMA) and Stringent Regulatory Authorities (SRAs)* are the following agencies:

A) European Medicines Agency (EMA);

B) Stringent Regulatory Authorities (SRAs): drug regulatory authorities that are considered as SRAs by WHO. SRAs include:

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

- ICH observers established before October 23, 2015, including: drug regulatory authorities of European Free Trade Association (EFTA), and representatives of Swissmedic and Health Canada;

- Regulatory authorities associated with ICH members through legally-binding, mutual recognition agreements made before October 23, 2015, including: Australia, Iceland, Liechtenstein and Norway.

10. *Product license holder or marketing authorization holder* means the establishment that holds the marketing authorization of the drug written on the Certificate of Pharmaceutical Product (CPP) issued using WHO's format.

11. *Drug processing* means manufacturing of a drug under a lawfully signed processing contract under which the processing facility takes charge of one, some or all of the stages in the manufacturing process at the request of the ordering facility and receives processing costs in return.

12. *Technology transfer* in drug manufacturing means transfer of the ownership of, or the right to use, the drug manufacturing technology, as prescribed in clause 1 Article 4 of the Law on Technology Transfer, from a sending facility to a receiving facility to perform one, some or all of the stages in the drug manufacturing process under a technology transfer contract signed by and between the parties in conformity with laws.

13. *Ordering facility* means the party that provides a part or all of ingredients, materials, manufacturing process, and technical documents proving the quality, safety, and efficacy of the drug for the processing facility to process the drug under a processing contract signed by and between the parties.

14. *Processing facility* means the party that uses a part or all of ingredients, materials, manufacturing process, and technical documents provided by the ordering facility to perform one, some or all of the stages in the manufacturing process at the request of the ordering facility, and receives processing costs under a processing contract signed by and between the parties.



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15. *Sending facility* means the party that transfers its lawfully acquired ownership of, or right to use, the drug manufacturing technology to a receiving facility for application to one, some or all of the stages in the drug manufacturing process.

16. *Receiving facility* means the party that receives the ownership of, or right to use, the drug manufacturing technology transferred from the sending facility under a technology transfer contract signed by and between the parties for application to one, some or all of the stages in the drug manufacturing process.

17. *Drug ordered for processing* means a drug which has been granted the marketing authorization in Vietnam or the product license in at least one country in the world, and one, some or all of the stages in the manufacturing process of which shall be performed at the processing facility's facility at the request of the ordering facility under a processing contract signed by and between the parties.

18. *Processed drug* means a drug one, some or all of the stages in the manufacturing process of which are performed by the processing facility at the request of the ordering facility under a processing contract signed by and between the parties.

19. *Drug before technology transfer* means a drug which has been granted the marketing authorization in Vietnam or the product license in at least one country in the world, and the ownership of, or right to use, the technology for manufacturing of which is transferred from the sending facility to the receiving facility for application to one, some or all of the stages in the manufacturing process.

20. *Drug manufactured adopting transferred technology* means a drug one, some or all of the stages in the manufacturing process of which are performed by the receiving facility adopting the technology transferred, as prescribed in clause 1 Article 4 of the Law on Technology Transfer, from the sending facility under a technology transfer contract signed by and between the parties.

Article 3 Responsibilities of applicants

Each applicant shall:

1. Assume the full legal responsibility for accuracy, legitimacy and truthfulness of all documents included in its marketing authorization application (MAA) for drugs/medicinal materials, except the cases specified in clause 1 Article 4 hereof; Cooperate with domestic and foreign authorities and manufacturers in responding to inquiries of DAV regarding the authenticity of legal documents included in its MAA.

2. Ensure quality, safety and efficacy of the drugs/medicinal materials as declared in its MAA.

3. Send a written notice to DAV within 15 days from the date on which a decision to revoke the marketing authorization or decision to recall the drug/medicinal material is issued in any country in the world if the drug/medicinal material has been granted the marketing authorization in Vietnam which has not yet expired, except cases of voluntary withdrawal of the marketing authorization for commercial reasons in the countries other than the country where



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CPP which is included in the submitted MAA is issued; the reasons for such revocation or recall must be also specified in the notice.

4. Cooperate, at the request of competent authorities, with the drug manufacturer in doing studies or providing additional information about the registered drug when there is information or evidence about the safety and efficacy of the drug during its marketing.

5. Cooperate with the drug manufacturer, importer and distributor in monitoring, supervising, collecting, consolidating and analyzing information, and sending reports to the National Centre of Drug Information and Adverse Reactions Monitoring (National DI & ADR Centre) on post-vaccination reactions and adverse reactions of the drug in accordance with Clause 5 Article 77 of the Pharmacy Law, National Pharmacovigilance Guidelines issued by MoH and relevant regulations.

6. Take responsibility for issues relating to intellectual property rights of the drugs/medicinal materials registered in Vietnam in accordance with regulations of law on intellectual property.

7. Implement the approved risk management plan included in MAA for a new chemical drug, vaccine or biological (except probiotic biological products).

8. An applicant for the marketing authorization for a processed drug shall discharge the responsibilities set forth in clauses 1, 2, 3, 4, 5, 6, 7 and 10 of this Article, and the following:

a) Send a written notice to DAV within 30 days from the date on which a competent authority gives approval of variations to technical documents of the drug ordered for processing during its marketing in case the processed drug meets the requirements laid down in clause 1 Article 9 hereof;

b) Send a written notice to DAV within 15 days from the date on which a decision to revoke the marketing authorization of the drug ordered for processing is issued in any country in the world (during the validity period of the marketing authorization of the processed drug);

c) Send a written notice to DAV within 30 days from the date on which the manufacturing of the drug ordered for processing is stopped;

d) Regarding the processed drug which meets the requirements laid down in clause 1 Article 9 hereof, within 03 months from the date on which changes in the formulation, manufacturing process, quality specifications of materials, or quality specifications of drug products, or trade name of the drug ordered for processing which is being manufactured and placed on the market in its country of origin are approved by a competent authority of its country of origin, the applicant must make changes corresponding to those changes in the drug ordered for processing.

9. An applicant for the marketing authorization for a drug manufactured adopting transferred technology shall discharge the responsibilities set forth in clauses 1, 2, 3, 4, 5, 6, 7 and 10 of this Article, and the following:

a) Send a written notice to DAV within 30 days from the date on which a competent authority gives approval of variations to technical documents of the drug before technology transfer



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during its marketing in case the drug manufactured adopting transferred technology meets the requirements laid down in clause 1 Article 9 hereof;

b) Send a written notice to DAV within 15 days from the date on which a decision to revoke the marketing authorization of the drug before technology transfer is issued in any country in the world (during the validity period of the marketing authorization of the drug manufactured adopting transferred technology);

c) Send a written notice to DAV within 30 days from the date on which the manufacturing of the drug before technology transfer is stopped;

d) Regarding the drug manufactured adopting transferred technology which meets the requirements laid down in clause 1 Article 9 hereof, within 03 months from the date on which changes in the formulation, manufacturing process, quality specifications of materials, or quality specifications of drug products, or trade name of the drug before technology transfer which is being manufactured and placed on the market in its country of origin are approved by a competent authority of its country of origin, the applicant must make changes corresponding to those changes in the drug before technology transfer.

10. Fulfill other relevant responsibilities as prescribed in relevant laws.

Article 4 Responsibilities of drug material manufacturers

1. Assume the full legal responsibility for the accuracy, legitimacy and truthfulness of all documents about the drug/medicinal material provided for the applicant to apply for the marketing authorization in Vietnam.

2. Closely cooperate with the applicant in fulfilling the responsibility in clause 3 Article 3 hereof.

3. Cooperate with the applicant in complying with competent authorities' requests for inspection or evaluation of the manufacturing site.

4. Within 15 days from the date on which a competent regulatory authority of its country of origin issues a notice that the manufacturer has its license revoked or fails to meet GMP (Good Manufacturing Practices) requirements for drugs/medicinal materials, the manufacturer shall send a written notice of such event to DAV.

5. Retain all documents on registration of the drug/medicinal material and provide them to competent regulatory authorities upon their request, including those documents specified in point e clause 7 Article 22 hereof.

6. Implement the approved risk management plan included in MAA for a new chemical drug, vaccine or biological (except probiotic biological products).

7. A manufacturer that is a processing facility shall discharge the responsibilities set forth in clauses 1, 2, 3, 4, 5, 6 and 9 of this Article, and the following:

a) Fulfill the obligations as prescribed in Article 182 of the Law on Commerce and clause 2 Article 42 of the Government's Decree No. 69/2018/ND-CP dated May 15, 2018 elaborating



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some Articles of the Law on Foreign Trade Management (hereinafter referred to as “Decree No. 69/2018/ND-CP”);

b) Regarding the processed drug which meets the requirements laid down in clause 1 Article 9 hereof, within 03 months from the date on which changes in the formulation, manufacturing process, quality specifications of materials, or quality specifications of drug products, or trade name of the drug ordered for processing which is being manufactured and placed on the market in its country of origin are approved by a competent authority of its country of origin, the manufacturer must cooperate with the applicant in making changes corresponding to those changes in the drug ordered for processing.

c) Follow procedures for applying for a processing permit to be eligible to perform the drug processing at the request of a ordering facility that is a foreign trader as prescribed in clause 4 Article 38 of the Decree No. 69/2018/ND-CP in respect of MAA for the processed drug which is imported and exported with permit.

8. A manufacturer that is a receiving facility shall discharge the responsibilities set forth in clauses 1, 2, 3, 4, 5, 6 and 9 of this Article, and the following:

a) Fulfill the obligations set out in Article 26 of the Law on Technology Transfer;

b) Regarding the drug manufactured adopting transferred technology which meets the requirements laid down in clause 1 Article 9 hereof, within 03 months from the date on which changes in the formulation, manufacturing process, quality specifications of materials, or quality specifications of drug products, or trade name of the drug before technology transfer which is being manufactured and placed on the market in its country of origin are approved by a competent authority of its country of origin, the manufacturer must cooperate with the applicant in making changes corresponding to those changes in the drug before technology transfer;

c) Carry out procedures for registration of technology transfer as prescribed in Article 31 of the Law on Technology Transfer, Article 5 of the Government’s Decree No. 76/2018/ND-CP dated May 15, 2018 elaborating some Articles of the Law on Technology Transfer.

9. Fulfill other relevant responsibilities as prescribed in relevant laws.

Article 5 Responsibilities of ordering facilities

1. Fulfill the obligations of an ordering facility as prescribed in Article 181 of the Law on Commerce and Clause 1 Article 42 of the Decree No. 69/2018/ND-CP.

2. Provide the processing facility with:

a) A part or all of materials, and technical documents, including manufacturing process, quality specifications and test methods for starting materials, semi-finished products, finished products and auxiliary materials of the ordered processing stage(s).

b) Other documents relating to application for marketing authorization of processed drug and relating to the drug processing.



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3. Assume responsibility for the accuracy, legitimacy and truthfulness of technical documents provided for the processing facility in comparison to the dossier on the drug ordered for processing approved by a competent authority.
4. Cooperate with the applicant for marketing authorization for processed drug in fulfilling the responsibility in clause 8 Article 3 hereof.
5. Fulfill other relevant responsibilities as prescribed in relevant laws.

Article 6 Responsibilities of sending facilities

1. Fulfill the obligations of a technology sending facility as prescribed in clause 2 Article 25 of the Law on Technology Transfer.
2. Provide the receiving facility with:
 - a) Technical documents, including manufacturing process, quality specifications and test methods for starting materials, semi-finished products, finished products and auxiliary materials of the stage(s) performed using transferred technology;
 - b) Other documents relating to application for marketing authorization of the drug manufactured adopting transferred technology and relating to the drug manufacturing technology transfer.
3. Assume responsibility for the accuracy, legitimacy and truthfulness of technical documents provided for the receiving facility in comparison to the dossier on the drug before technology transfer approved by a competent authority.
4. Cooperate with the applicant for marketing authorization for the drug manufactured adopting transferred technology in fulfilling the responsibility in clause 9 Article 3 hereof.
5. Fulfill other relevant responsibilities as prescribed in relevant laws.

Article 7 Drug processing contract

In addition to the contents prescribed in Article 39 of the Decree No. 69/2018/ND-CP, a drug processing contract must also include:

1. Agreements on supply of materials. Agreements on provision by the ordering facility of the following technical documents for the processing facility, including: manufacturing process, quality specifications and test methods for starting materials, semi-finished products, finished products and auxiliary materials, and other documents relating to the drug processing.
2. Rights and responsibilities of the ordering facility, the processing facility and the applicant (if any), in respect of:



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- a) in each stage of the manufacturing process, the manufacturing process, quality control, storage and transport of starting materials, semi-finished products, drug products, auxiliary materials, procedures for packaging, printing or labeling of processed drug, and responsibilities of the signatories of the certificate of analysis for each batch of drug products and the release certificate of the processed drug; and
 - b) the retention of documents and records relating to manufacturing, quality control, distribution, marketing of the drug, retention of drug samples, settlement of issues relating to quality, complaints, and recall of the drug products.
3. Responsibilities of the ordering facility, the processing facility and the applicant (if any) for the matters relating to the intellectual property rights over the processed drug.
 4. Procedures for inspection or supervision of the manufacturing site.
 5. Contract termination cases and responsibility for breach of agreements.

Article 8 Technology transfer contract

In addition to the contents prescribed in Article 23 of the Law on Technology Transfer, a technology transfer contract must also include:

1. Agreements on provision by the sending facility of the following technical documents for the receiving facility, including: manufacturing process, quality specifications and test methods for starting materials, semi-finished products, finished products and auxiliary materials, and other documents relating to the drug manufacturing technology transfer.
2. Responsibilities of the sending facility, the receiving facility and the applicant for the matters relating to the intellectual property rights over the drug manufactured adopting transferred technology.
3. Contract termination cases and responsibility for breach of agreements.

Article 9 Classification of processed drugs, drugs manufactured adopting transferred technology

Processed drugs/drugs manufactured adopting transferred technology are classified as:

1. Processed drug/drug manufactured adopting transferred technology having the same trade name, formulation, quality specifications of materials, quality specifications of drug products as, and having manufacturing process similar to that of, the drug ordered for processing/the drug before technology transfer.

In case of any changes in the abovementioned criteria (except change in the trade name) of the processed drug/the drug manufactured adopting transferred technology or any other changes in the quality of the drug, the applicant must provide the comparative tabulated summary of such changes (Form O1/TT) and relevant technical documents according to guidelines in



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Appendix II enclosed herewith in order to prove the quality equivalence between the processed drug/the drug manufactured adopting transferred technology and the drug ordered for processing/the drug before technology transfer.

2. Other processed drug/drug manufactured adopting transferred technology which does not fall in the case specified in clause 1 of this Article.

Article 10 Reporting on safety and efficacy

1. Each applicant shall submit the following reports to serve the monitoring of safety and efficacy of the drug during its marketing:

a) Periodic report, for new drugs, vaccines and biologicals (except probiotic biological products) (Form 2A/TT enclosed herewith);

b) Individual case safety report (ICSR) on adverse events (including adverse drug reactions, medication errors, suspected counterfeit or substandard medicines and therapeutic ineffectiveness or lack of efficacy) which occur in Vietnam (Form 2B/TT enclosed herewith).

2. Reporting time:

a) For periodic reports as prescribed in point a clause 1 of this Article:

After obtaining a marketing authorization, the applicant shall submit reports on a periodical basis of every 06 months within the first 02 years; from the third year to the fifth year, the applicant shall submit reports on an annual basis;

b) For ICSRs as prescribed in point b clause 1 of this Article:

The applicant shall submit ICSRs within the time limit prescribed in the National Pharmacovigilance Guidelines issued by MoH.

3. Submission methods, recipients:

Submission methods and recipients of reports shall comply with the National Pharmacovigilance Guidelines issued by MoH.

4. Handling and assessment of reports, and provision of information for state regulatory authorities and Specialized Councils of MoH to serve management of marketing authorization-related tasks:

Comply with the National Pharmacovigilance Guidelines issued by MoH.

Article 11 Language, format of documents, submission methods, inclusion of multiple drugs materials in an MAA, validation methods

1. Language of documents included in an MAA:



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All documents included in an MAA shall be written in either Vietnamese or English language. The package insert of the drug to be marketed in Vietnam shall be written in Vietnamese language.

2. Format of documents:

a) Documents included in an MAA for drug material must be prepared according to ACTD or ICH-CTD guidelines and provisions herein;

b) Regarding an MAA imposing data confidentiality requirements, the applicant shall comply with provisions of the Circular No. 05/2010/TT-BYT dated March 01, 2010 of the Minister of Health of Vietnam providing guidelines for confidentiality of test data in marketing authorization application (hereinafter referred to as “Circular No. 05/2010/TT-BYT”).

3. MAA submission methods:

a) MAAs shall be submitted to DAV in accordance with provisions of Article 16 of the Government’s Decree No. 61/2018/ND-CP dated April 23, 2018 regarding implementation of single-window system and inter-agency single-window system for handling administrative procedures, as amended in clause 1 Article 2 of the Government’s Decree No. 107/2021/ND-CP dated December 06, 2021 providing amendments to the Government’s Decree No. 61/2018/ND-CP dated April 23, 2018 regarding implementation of single-window system and inter-agency single-window system for handling administrative procedures (hereinafter referred to as “Decree No. 61/2018/ND-CP”);

b) In case MAAs are submitted via the online public service portal of MoH, applicants shall comply with provisions of the Government’s Decree No. 45/2020/ND-CP dated April 08, 2020 prescribing completion of administrative procedures in electronic environment, as amended by the Government’s Decree No. 59/2022/ND-CP dated September 05, 2022 prescribing electronic identification and authentication, the Government’s Decree No. 68/2024/ND-CP dated June 25, 2024 prescribing specialized digital signatures for public services, and the Government’s Decree No. 69/2024/ND-CP dated June 25, 2024 prescribing electronic identification and authentication.

4. Multiple drugs may be included in a single MAA if they:

a) are of the same manufacturer; and

b) have the same name; drug substances or herbal materials; strength, concentration, or weight of drug substances or herbal materials in a single dose; dosage form; administration route; formulation; quality specifications of the drug.

5. MAA validation methods:

a) An MAA shall be considered by different teams in charge of validating legal documents, quality specifications, dosage form, pharmacology, clinical data and bioequivalence, depending on constituent parts of the submitted application for issuance, renewal or approval of variations to the marketing authorization;



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b) Parts of legal documents, quality specifications, dosage form, pharmacology, clinical data and bioequivalence must be adequately validated according to ACTD or ICH-CTD guidelines and provisions herein, including name of the document to be validated and requirements to be satisfied corresponding to each matter of validation as prescribed in this Circular;

c) Validation of an MAA in the case prescribed in clause 10 Article 26 hereof is subject to the following provisions:

- Based on the documents specified in clause 10 Article 26 hereof, validation is carried out to verify the consistency of the technical documents included in the MAA submitted in Vietnam with those of the drug granted product license by a drug regulatory authority mentioned in clause 9 Article 2 hereof.

- Validations of administrative documents and technical documents in the MAA submitted in Vietnam which are found to be different from those of the drug approved by a drug regulatory authority mentioned in clause 9 Article 2 hereof shall be carried out individually.

Article 12 Validity periods, symbols of marketing authorizations, deadline for application submission

1. The validity period of a marketing authorization is 5 years from the issuance date or renewal date, except for the cases specified in clause 2 of this Article.

2. The validity period of a marketing authorization of the following drugs subject to extended monitoring of safety and efficacy is 3 years from the issuance date or renewal date:

a) New drugs, vaccines and biologicals (except probiotic biological products) which are granted the marketing authorization in Vietnam for the first time;

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

c) Any of the drugs specified in point a or b of this clause which is not actually placed on the market during the validity period of its marketing authorization;

d) A drug which is mentioned in neither of points a, b and c of this clause but is subject to an extended monitoring of safety and efficacy as advised by the Marketing Authorization Advisory Board (hereinafter referred to as “the Advisory Board”).

3. When a marketing authorization of drug or medicinal material expires after DAV has received an application for renewal thereof, it may be used until an official approval for renewal is granted or DAV issues a notification that the application for renewal is rejected or the marketing authorization is suspended in case the drug or medicinal material is found potentially unsafe for users or legal documents in the application are suspected of being forged.

4. Each approved MAA shall be granted a marketing authorization with a unique marketing authorization number whose structure is specified in Appendix V enclosed herewith.



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5. An application for renewal of the marketing authorization of a drug or medicinal material must be submitted before its expiration date. An application for renewal of the marketing authorization which is submitted after its expiration date shall be refused by DAV. In this case, the applicant is required to submit an application for issuance of a new marketing authorization.

6. An MAA which is to be validated using reference to available validation results must be submitted to DAV within 05 years from the date on which the drug is approved for the first time by a drug regulatory authority prescribed in clause 9 Article 2 hereof according to the validation report.

Article 13 Criteria for classification of original brand-name drugs and reference biologicals

1. Criteria for classification of original brand-name drugs and reference biologicals:

a) A drug which has been granted marketing authorization shall be classified as an original brand-name drug when it meets all of the following criteria:

- It is the first drug granted the marketing authorization on the basis of sufficient quality, safety and efficacy data;
- Its clinical data meets the requirements laid down in Article 18 hereof.

b) A drug which has been granted marketing authorization shall be classified as a reference biological when it meets all of the following criteria:

- It is granted a marketing authorization in Vietnam on the basis of sufficient quality, safety and efficacy data;
- Its clinical data meets the requirements laid down in Article 18 hereof and is sufficient to prove that it is developed as a biological product other than a biosimilar product from the first stage.

2. Where a drug which has been classified as an original brand-name drug or reference biological is granted a new marketing authorization due to changes in its manufacturer or manufacturing site, it shall continue to be classified as an original brand-name drug or reference biological if its trade name, formulation, qualification specifications of materials and of drug product remain unchanged, and its manufacturing process before the change is similar to that after the change.

Where there are changes in any of the criteria mentioned in this clause (except changes in the trade name) or other changes relating to the quality of the drug manufactured by the new manufacturer or in the new manufacturing site, they must be approved by the drug regulatory authority that issued the marketing authorization for that drug or the applicant must provide the comparative tabulated summary of such changes (Form O1/TT) and relevant technical documents according to the guidelines in Appendix II enclosed herewith in order to prove the quality equivalence between the drug manufactured by the new manufacturer or in the new manufacturing site and the original brand-name drug or reference biological.



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Regarding changes in the manufacturer or manufacturing site of reference biologicals, additional documents proving quality equivalence must be provided according to guidelines of US FDA, ICH, WHO, EMA, and international organizations to which Vietnam is a member, and guidelines given by the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

3. If a drug ordered for processing or drug before technology transfer, whether it has been classified as original brand-name drug or reference biological or not, has clinical data meeting the requirements laid down in point a or b clause 1 of this Article and is processed or manufactured adopting transferred technology in Vietnam, the processed drug or the drug manufactured adopting transferred technology shall be classified as original brand-name drug or reference biological if it fully meets the criteria set out in clause 2 of this Article and in point d clause 2 Article 38 hereof.

4. Cases in which drugs are classified as original brand-name drugs or reference biologicals:

a) The request for classification of original brand-name drug or reference biological is included in the submitted MAA of the drug:

The applicant shall submit a request for classification of original brand-name drug or reference biological when submitting an MAA of the drug. The MAA which is validated and approved for grant of the marketing authorization must meet the criteria set out in clause 1, 2 or 3 of this Article;

b) Request for classification of a drug which has been granted marketing authorization as an original brand-name drug or reference biological:

The applicant shall submit a request for classification of a drug which has been granted marketing authorization as an original brand-name drug or reference biological in the form of variations to the marketing authorization as prescribed in Appendix II enclosed herewith. An application for approval of variations to the marketing authorization which is validated and approved must meet the criteria set out in clause 1, 2 or 3 of this Article.

5. A drug which has been classified as an original brand-name drug or reference biological shall continue to be classified as original brand-name drug or reference biological when an application for renewal or approval of variations to its marketing authorization is put under consideration. The applicant is not required to submit request for classification of the drug as an original brand-name drug or reference biological.

Article 14 Criteria for classification of drugs having demonstrated bioequivalence

Drugs granted the marketing authorization in Vietnam shall be classified as drugs having demonstrated bioequivalence when their bioequivalence study reports on meet the requirements laid down in the Circular No. 07/2022/TT-BYT dated September 05, 2022 of the Minister of Health of Vietnam prescribing pharmaceutical products for which in vivo bioequivalence studies are required and requirements for documentation of bioequivalence study reporting during application for marketing authorization of these pharmaceutical products in Vietnam (hereinafter referred to as “Circular No. 07/2022/TT-BYT”).



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Article 15 Principles, criteria and methods for classification of OTC drugs

1. Principles for classification of OTC drugs:

- a) Ensure safety for drug users;
- b) Ensure people's timely access to drugs;
- c) Conform to the reality of use and supply of drugs in Vietnam;
- d) Be harmonized with principles and regulations on classification of OTC drugs announced by the States in the region and the world.

2. Criteria for determination of OTC drugs:

A drug shall be classified as an OTC drug if it meets all criteria below:

- a) It must have been proven to be safe and effective in preventing, alleviating, or treating diseases; have a wide margin of safety to ensure users' health; have low toxicity, do not produce toxic degradation products during storage and within the human body, do not cause reproductive toxicity, genotoxicity, or carcinogenicity, do not have any unwanted side effects that require supervision or monitoring by physicians or healthcare workers when used according to instructions in its package insert, and do not interact with commonly used medications or foods in a way that could lead to serious adverse reactions;
- b) It is indicated to be used for short-term treatment of common diseases which can be treated by patients themselves without prescription and monitoring by healthcare workers;
- c) It rarely causes dependency; does not pose risks of overdose or misuse, which will cause harm to users' health; does not hide symptom indicators of a serious disease, potentially leading to delayed diagnosis and treatment;
- d) It must have simple dosage form and route of administration that allow users to take it on their own without the need for technical assistance or instructions from physicians or healthcare workers; not require any special conditions for storage or handling before and after use;
- dd) It does not contain any of herbal ingredients on the List of toxic herbal ingredients announced by Minister of Health.

3. Methods for classification of OTC drugs

- a) Generic drugs are classified as OTC drugs according to the classification of the original brand-name drugs granted marketing authorization in Vietnam;
- b) If the original brand-name drugs granted marketing authorization in Vietnam are not available, drugs are classified as OTC drugs according to the classification of drugs which have the same active ingredients, herbal materials, strength, concentration and dosage forms as those of drugs granted marketing authorization in the countries of the drug regulatory authorities prescribed in clause 9 Article 2 hereof;



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c) Drugs are classified as OTC drugs according to the classification of the drugs which have the same active ingredients, herbal materials, strength, concentration and dosage forms and have been granted marketing authorization in Vietnam if meeting the principles and criteria set out in clauses 1 and 2 of this Article;

d) Classification of OTC drugs in other cases shall be subject to opinions given by the Advisory Council on the basis of the principles and criteria set out in clauses 1 and 2 of this Article.

Article 16 Confidentiality of information in MAAs

Applicants that wish to keep the information in their MAAs confidential shall follow the guidelines in the Circular No. 05/2010/TT-BYT and include their request (which is made using Form No. 4A/TT enclosed herewith) in their submitted MAAs.

Article 17 Verification of legal documents in applications for issuance, renewal or approval of variations to marketing authorization

1. The authenticity of CPP included in an application for issuance, renewal or approval of variations to marketing authorization must be verified in the following cases:

a) Information on the CPP is founded to have been erased or altered;

b) The manufacturer or applicant has incurred administrative penalties imposed by Vietnam's competent authorities for the violation in point q clause 2 Article 42 of the Pharmacy Law. Verification of CPP shall be required for 03 years from the issue date of the penalty imposition decision or, if the violating manufacturer or applicant is suspended from submitting applications for issuance or renewal of marketing authorization, from the end of the suspension period;

c) The manufacturer applies for marketing authorization in Vietnam for the first time, including the cases where the manufacturer only engages in one or some stages of the manufacturing process;

d) CPP is an electronic copy issued by a foreign country's competent authority but cannot be found by accessing the website or database provided by the applicant during validation;

e) The verification is made at the request of the Advisory Board.

2. The authenticity of legal documents in MAAs shall be also verified in some other cases:

a) Regarding a foreign applicant that applies for marketing authorization in Vietnam for the first time, DAV shall carry out verification of the authenticity of the license to manufacture and trade drugs at their country of origin;

b) The legal documents issued by competent authorities of foreign countries do not yet meet the requirements laid down in point b clause 1 Article 22 hereof.



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3. Regarding drugs granted the marketing authorization, DAV shall carry out verification of legal documents when it receives information relating to the licensing and/or marketing of the drug in its country of origin which needs to be verified or clarified, or any information about the failure to satisfy operating conditions by the foreign manufacturer or applicant from the following sources:

a) Written document sent to DAV, which includes adequate information about the name and address of the sender, and is accompanied with relevant supporting documents;

b) Information obtained from the mass media.

4. Verification of the authenticity of CPP and legal documents included in MAAs shall be carried out in the following forms:

a) Verification of the authenticity of legal documents concerning consular legalization:

DAV shall cooperate with the Consular Department affiliated to the Ministry of Foreign Affairs of Vietnam or Vietnamese diplomatic missions performing consular legalization tasks in foreign countries to verify the competence and information concerning the consular legalization of foreign legal documents for use in Vietnam in the cases specified in point c clause 1 and point a clause 2 of this Article;

b) Verification of the authenticity of legal documents:

DAV shall cooperate with issuing authorities to verify the information on such legal documents in the cases specified in points a, b, d and e Clause 1 and point b clause 2 of this Article;

c) The verification of authenticity of the legal documents shall be simultaneous with the validation of the MAA or upon receipt of the information as prescribed in clause 3 of this Article;

d) A request for verification of the authenticity of legal documents shall be also sent to the relevant applicant.

5. Regarding an application for issuance of marketing authorization containing the legal documents subject to verification as prescribed in clauses 1 and 2 of this Article, the drug/medicinal material shall only be granted a marketing authorization if competent authorities are satisfied with verification results as prescribed in clause 4 of this Article.

6. Regarding an application for renewal or approval of variations to the marketing authorization containing the legal documents subject to verification as prescribed in clauses 1 and 2 of this Article, it is not mandatory to obtain verification results before the grant of approval for renewal or variations.

Chapter II: Clinical Data Requirements for Assurance of Drug Safety and Efficacy, and Criteria for Exemption from Clinical Trial or Certain Stages Thereof, and Drugs that Have to Undergo Stage 4 Clinical Trial in Vietnam

Article 18 Clinical data requirements for assurance of drug safety and efficacy



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1. Any drug for which an MAA is submitted must have sufficient clinical data to prove its safety and efficacy.

2. Sufficient clinical data means data obtained from studies conducted, reported and assessed in conformity with guidelines given by MoH or other organizations accredited by Vietnam (ICH, WHO, EMA, and other international organizations of which Vietnam is a member, guidelines given by the drug regulatory authorities prescribed in clause 9 Article 2 hereof).

Article 19 Criteria for exemption from clinical trial in Vietnam

A drug is exempted from clinical trial in the following cases:

1. It is a generic drug meeting any of the following criteria:

a) It has bioequivalence data as prescribed in the Circular No. 07/2022/TT-BYT;

b) It is not subject to bioequivalence study reporting upon submission of MAA in Vietnam as prescribed in the Circular No. 07/2022/TT-BYT.

2. It is a new drug (except vaccines) meeting all criteria below:

a) It has been granted marketing authorization in at least one country in the world;

b) It is supported by adequate clinical data as prescribed in Article 18 hereof;

c) Its clinical data is sufficient for analysis and justification of the impact of ethnic factors of Asian populations on the safety and efficacy of the drug according to ICH-E5 guidelines.

3. It is an herbal drug granted the marketing authorization before January 01, 2017.

Article 20 Criteria for exemption from certain stages of clinical trial in Vietnam

1. The Minister of Health shall consider issuing decisions to grant exemption from certain stages of clinical trial in Vietnam to new drugs and vaccines on the basis of opinions given by the Advisory Board in the following cases:

a) The drug or vaccine is meant to serve urgent needs for national defense and security, epidemic prevention and control, disaster recovery and cannot be replaced by any other drug available on the market; it is meant to treat a rare or fatal disease;

b) The drug or vaccine has been granted marketing authorization by at least one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof on the basis of a reduced clinical data package as prescribed by this authority.

2. A new drug or vaccine exempted from certain stages of clinical trial in Vietnam must meet all criteria below:



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- 
- a) It has been granted marketing authorization in at least one country in the world;
 - b) Its clinical data is not yet adequate as prescribed in Article 18 hereof or its clinical data is adequate as prescribed in Article 18 hereof but does not include sufficient assessment of the impact of ethnic factors on the safety and efficacy of the drug.

Article 21 Criteria for drugs that have to undergo stage 4 clinical trial

Drugs have been granted marketing authorization but their safety and efficacy need additional evaluation as proposed by the Advisory Board.

Chapter III: Marketing authorization applications for drugs materials

Section 1 General provisions on documents in marketing authorization applications for drugs materials

Article 22 General provisions on administrative documents

1. The documents specified in clauses 3, 4, 5, 6 and 7 Article 26 hereof (hereinafter referred to as “legal documents”) included in an MAA must meet the following requirements:

a) The legal documents included in an MAA must be originals or copies as prescribed in the Government’s Decree No. 23/2015/ND-CP dated February 16, 2015 prescribing issuance of copies extracted from master registers, certified true copies of originals, signature certification and certification of contracts and transactions. The legal documents issued by foreign competent authorities must bear consular legalization in accordance with regulations of law on consular legalization, unless such consular legalization procedures are exempted in accordance with regulations of law;

b) Legal documents must bear authorized signatures, full names of signatories, issue dates and seals of competent authorities of their issuing countries, unless a legal document which does not bear all of these required information pieces is still considered valid according to the domestic legislation of the issuing country;

c) In case of an electronic legal document (which does not have to bear the authorized signature, name of the signatory or seal of the issuing authority), the applicant is required to submit one of the following documents:

- The legal document printed from the website or database of the issuing authority or from the website operated by a competent authority of the country of origin or regional authority;

- The result of searching for the legal document from the English database or website of the issuing authority or from the website operated by a competent authority of the country of origin or regional authority. This result must bear the applicant’s seal and be accompanied with a document providing information about the search link;



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d) A legal document which has validity period written thereon must be still valid on the date of receipt specified on the MAA receipt note. In case a CPP does not contain the validity period thereon, it shall be 24 months from its issue date.

2. For CPPs:

a) A CPP must contain sufficient information according to the model CPP published on WHO's website (<https://www.who.int>);

b) CPP must be issued by a competent authority of the manufacturing country or the authority competent to issue CPP of the country of one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof to certify that the drug has been granted marketing authorization and is actually placed on the market of that country;

c) In case of serving the purpose of meeting the needs for prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases, the CPP may be replaced by another document issued by a competent authority confirming that the drug has been granted marketing authorization and is being used in the country of origin and fully stating information about name and address of the manufacturer and licensing conditions;

d) Where a CPP fails to meet the requirements laid down in points a, b of this clause, it shall be subject to the decision issued by the Minister of Health on the basis of opinions given by the Advisory Board if the drug has been granted marketing authority by a competent authority of at least one country in the world and falls into one of the following cases:

- It is a drug, vaccine or biological meant to serve the needs for national defense and security, epidemic prevention and control, disaster recovery, or a state health program;

- It is a vaccine used in the national expanded immunization program for which another substitute vaccine with equivalent quantity, quality, safety, efficacy or costs is not available on the market;

- In other cases under a mutual recognition agreement between competent authorities in terms of conditions for manufacturing and marketing of drugs, vaccines and biologicals;

e) The information displayed on the CPP must be consistent with relevant information in the MAA. In case the information on the CPP is not consistent with that in the administrative documents of the MAA, the applicant shall provide an explanatory report and relevant documentary evidence.

3. For the application form and other administrative documents:

a) The application form and other relevant documents in the administrative section of the MAA must bear authorized signatures and seals. Digital signatures are permitted but signature stamps are not permitted;

b) The abovementioned documents by signed by one of the following title holders:



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- Chairperson of the Board of Members or the Board of Directors; general director; chief executive officer; director of the manufacturer or applicant;

- A person who is assigned to sign documents as defined in the company charter, written task assignment or another document proving his/her authority to sign documents;

- Persons who are authorized by the persons mentioned in paragraph 1 or 2 of this point.

4. For letters of authorization:

a) The letter of authorization to act as an applicant must be the original containing adequate information as follows:

- Name and address of the authorizing product license holder/marketing authorization holder or manufacturer;

- Name and address of the authorized applicant;

- Name, concentration, strength of drug substance, and dosage form of the drug;

- Contents of authorization.

In case the authorization involves multiple drugs, the letter of authorization shall have a list of drugs with adequate information as prescribed in paragraph 3 of this point;

b) The letter of authorization to sign the documents included in the MAA must be the original containing adequate information as follows:

- Name and address of the applicant;

- Names and titles of the authorizing person and the authorized person;

- Name, concentration, strength of drug substance, and dosage form of the drug;

- Contents of authorization;

- Validity period of the letter of authorization.

In case the authorization involves multiple drugs, the letter of authorization shall have a list of drugs with adequate information as prescribed in paragraph 3 of this point;

c) Quantity of the letter of authorization in an MAA:

- In case the applicant is not the manufacturer or the product license holder/marketing authorization holder, each submitted MAA shall include a letter of authorization to act as the applicant;

- In case the title of the person who signs the documents included in the MAA is not one of those specified in point b clause 3 of this Article, each MAA shall include a letter of authorization to sign documents in MAA.



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5. An applicant must have one of the following legal documents:

a) A Vietnamese applicant must have a certificate of satisfaction of conditions for pharmaceutical business covering one of the following business lines: manufacture, wholesaling, import and export of drugs/medicinal materials;

b) A foreign applicant must have a license to manufacture and trade drugs which is issued by a foreign competent authority and covers one of the following business lines: manufacture, wholesaling, import and export of drugs/medicinal materials, and a license to establish representative office in Vietnam.

If the applicant's name or address on the license to establish representative office in Vietnam is different from that on its legal documents issued by foreign competent authorities, documentary evidence therefor is required.

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 materials is not issued in any country, it is required to have an establishment license or business registration license which covers at least one of the following business lines: manufacture, wholesaling, export or import of drugs/medicinal materials, and is accompanied with a certification issued by a competent authority that the applicant meets relevant business conditions and is operating in the pharmaceutical field, or one of the following documents: certificate of GMP (Good Manufacturing Practices) compliance, certificate of GDP (Good Distribution Practices) compliance, certificate of GSP (Good Supply Practices) compliance or certificate of GSP (Good Storage Practices) compliance.

Regarding medicinal materials: if the country of origin does not grant pharmaceutical business licenses to medicinal material traders, other licenses which are issued according to the domestic legislation of the country of origin and cover one of the following business lines: manufacture, wholesaling, export or import of medicinal materials, shall be accepted.

6. The certificate that the medicinal material is permitted to be manufactured or marketed in the manufacturing country must have the following information: name of the medicinal material, name and address of the manufacturer, the manufacturing country, signature, seal and full name of the signatory.

7. Documents proving compliance with GMP guidelines submitted by a manufacturer of drug substances, excipients, capsule shells, or herbal materials (for manufacture of herbal drugs) may be any of the following documents:

a) Certificate of GMP compliance;

b) The manufacture license containing certification of GMP compliance;

c) For a drug substance, the CPP containing certification of GMP compliance;

d) The Certificate of suitability to the Monographs of the European Pharmacopoeia (CEP);



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e) Other legal documents which are issued by competent authorities and have the following mandatory information: name and address of the manufacturer, certification of GMP compliance, and name of the drug substance, herbal material, excipient or capsule shell;

f) For the excipients in an MAA:

In case the documents specified in points a, b, d and e of this clause cannot be provided, the manufacturer of drug products or semi-drug products shall carry out self-evaluation of GMP compliance for excipients manufacturers according to regulations in point e clause 1 Article 3, point b clause 3 Article 3 and point e clause 5 Article 20 of the Circular No. 35/2018/TT-BYT dated November 22, 2018 of the Minister of Health (as amended in points a, b, and dd clause 6 Article 1 of the Circular No. 29/2020/TT-BYT dated December 31, 2020 of MoH), include in its submitted MAA a declaration of GMP compliance (using Form No. 05/TT enclosed herewith), and take legal responsibility for such provided declaration;

g) For herbal materials in an MAA:

In case the documents specified in points a and b of this clause cannot be provided, a certificate of compliance with GACP (Good Agricultural and Collection Practices) for starting materials of herbal origin shall be submitted.

8. The samples of the label and package insert of the drug to be marketed in Vietnam shall comply with the Circular No. 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health of Vietnam prescribing labeling and package inserts of drugs and medicinal materials, as amended by the MoH's Circular No. 23/2023/TT-BYT dated November 30, 2023 providing amendments to the Circular No. 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health of Vietnam prescribing labeling and package inserts of drugs and medicinal materials, (hereinafter referred to as "Circular No. 01/2018/TT-BYT") and the following provisions:

a) The samples of label and package insert to be used in Vietnam shall bear the seal of the representative office in Vietnam, of the applicant, or the manufacturer;

b) The secondary package label of the drug/medicinal material must bear a printed barcode, QR code, DataMatrix code or another printed code, as prescribed by relevant laws, of the manufacturer to serve management, identification and tracing of origin of the drugs and medicinal materials placed on the market according to the roadmap prescribed in point h clause 1 Article 55 hereof;

c) The secondary package label of the drug product/semi-drug product must have the name of every drug substance or herbal material in the formulation, and strength, weight or concentration thereof in a smallest dose or smallest package unit of the drug product/semi-drug product;

d) Regarding the dosage form or packaging form which requires stability study after opening according to ACTD or ICH-CTD guidelines, the package insert must include information on the shelf life and storage conditions after opening;

e) The samples of the label and package insert of a biosimilar must clearly provide information on its reference biological.



Article 23 General provisions on quality documents

1. Specifications, test method, certificate of analysis and stability study documents (for both drug substances and drug product) must be original copies bearing the seal of the manufacturer; in case there are multiple establishments participating in the manufacture of the drug product, the seal of the establishment responsible for quality control of the drug or batch release shall be accepted.

In case the manufacturer uses a digital signature instead of a seal, the applicant shall append its seal to and assume legal responsibility for the accuracy, legitimacy and truthfulness of these documents.

2. The certificate of analysis of a drug/medicinal material must meet the following requirements:

a) The testing report shall be made in either Vietnamese or English language. If it is made in a language other than Vietnamese or English language, a notarized Vietnamese or English translation shall be required;

b) In case a batch of drug/medicinal material is manufactured by 02 establishments or more, the certificate of analysis made by the establishment responsible for the final manufacturing or packaging stage or for batch release shall be required;

c) A certificate of analysis shall, inter alia, include:

- Name and address of the manufacturer, number of the certificate of analysis, name and signature of the responsible person, and issuance date of the certificate of analysis. In case a certificate of analysis is made using an electronic signature, regulations of law on electronic transactions shall apply. In case a certificate of analysis does not bear the signature of the responsible person, the certificate of analysis bearing the manufacturer's seal shall be accepted. The applicant shall assume the full legal responsibility for the accuracy and legitimacy of the submitted certificate of analysis;

- Information on the sample of drug/medicinal material, including: name of the product; batch number, shelf life/expiry date or retest date (for medicinal material), applied specifications, quality indicators, quality requirements, test results, conclusion on quality of the batch.

3. Certificate of analysis, results of validation of specifications, and experimental test methods adopted by state laboratories in charge of testing drugs/medicinal materials at the request of regulatory authorities:

The certificate of analysis, results of validation of specifications, and experimental test methods must bear certification of GLP-compliant state laboratories in charge of testing drugs/medicinal materials.

Article 24 Clinical documents required for assurance of the drug safety and efficacy in MAAs

1. For new chemical drugs, vaccines and biologicals:



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a) Clinical data must be sufficient to prove safety and efficacy and meet the following requirements:

- Clinical studies on the drug, data included in the clinical documents must be in conformity with ICH guidelines, guidelines given by MoH or other organizations accredited by Vietnam (including international organizations of which Vietnam is a member, and the drug regulatory authorities prescribed in clause 9 Article 2 hereof);

- Clinical data (except biosimilar of reference biological which has been granted marketing authorization in Vietnam) must be sufficient for analysis and justification according to ICH-E5 guidelines;

- A drug with new combination of drug substances must have sufficient clinical data according to guidelines of WHO, US FDA, EMA on clinical development of fixed combination medicinal products as prescribed in Appendix I enclosed herewith;

b) If a vaccine has sufficient clinical data for evaluation of its safety and efficacy as prescribed in point a of this clause but is yet to be granted marketing authorization by a drug regulatory authority prescribed in clause 9 Article 2 hereof, it is required to have clinical data pertinent to its safety and immunogenicity in the target populations in Vietnam before granting marketing authorization;

c) Biosimilars must have sufficient clinical data according to the guidelines of MoH or WHO, US FDA, EMA for development of biosimilar products as prescribed in Appendix I enclosed herewith;

d) In case of changes in the manufacturer (including such a change in the manufacturing site) of a biological, additional documents proving quality equivalence between biological products of the former manufacturer and those of the new manufacturer shall be provided according to guidelines of US FDA, ICH, WHO, EMA, and international organizations to which Vietnam is a member, and guidelines given by the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

2. For chemical drugs which are new drugs other than original brand-name drugs:

One of the following clinical data shall be submitted:

a) Clinical data meeting the requirements laid down in point a clause 1 of this Article;

b) Clinical data of a similar drug with the same drug substances, concentration, strength, dosage form and administration route, granted marketing authorization by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof, which is used with the permission of the clinical data owner. The clinical data of the similar drug must also meet the requirements laid down in point a clause 1 of this Article;

c) Clinical data obtained from researches published in medical literatures which are scientific documents in medical sector, including clinical study or trial reports, scientific articles, medical journals, pharmaceutical journals, medical and pharmaceutical books (hereinafter referred to as "medical publications") and data on comparative bioequivalence studies involving similar drugs which have the same drug substances, concentration, strength, dosage form and administration



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route, have been granted marketing authorization by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof, and are in compliance with MoH's regulations on reference drugs in bioequivalence studies.

3. For herbal drugs which are new drugs; orally administered drugs containing herbal materials combined with drug substances which are essential oils or purified essential oil extracts (including synthetic and semi-synthetic substances); drugs containing purified active ingredients extracted from herbal materials:

It is required to have clinical data or data obtained from documents meeting one of the following requirements:

a) Clinical studies of the drug, data in clinical documents must meet the requirements laid down in Article 18 hereof or be conformable with the guidelines for preclinical and clinical studies of herbal drugs of MoH as prescribed in Appendix III enclosed herewith or of other organizations accredited by Vietnam, including WHO's Research guidelines for evaluating the safety and efficacy of herbal medicines, or of the drug regulatory authorities prescribed in clause 9 Article 2 hereof;

b) Drug/medicinal material monographs of pharmacopoeias or drug formularies of Vietnam or other countries in the world;

c) Articles on evaluation of safety and efficacy of the drug published on international journals of WOS (Web of Science) and Scopus, clinical data obtained from researches published in other medical publications;

d) Reports on evaluation of safety and efficacy in a national, ministerial or provincial research which has been accepted.

4. For chemical drugs which have the same drug substances, strength, concentration, administration route and dosage form as those of drugs granted marketing authorization by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof but do not have original brand-name drugs granted marketing authorization in Vietnam or whose strength, concentration, administration route or dosage form is different from that of original brand-name drugs granted marketing authorization in Vietnam, one of the following clinical data must be submitted:

a) Clinical data meeting the requirements laid down in point a clause 1 of this Article;

b) Clinical data collected from researches published in medical publications, accompanied with the package insert or summary of product characteristics of the drug which has the same drug substances, strength, concentration, administration route and dosage form and has been granted marketing authorization by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

5. Submission of safety and efficacy documents in MAAs for the following drugs is exempted:

a) Generic drugs;



b) Drugs which have the same drug substances, strength, concentration, administration route and dosage form as those of the drugs granted marketing authorization as prescribed in clause 4 of this Article. In this case, the drug package insert must be conformable with that of the drug granted marketing authorization as prescribed in clause 4 of this Article.;

c) Probiotic biological products with origins, bacterial strain, concentration, strength, indications and doses that are similar to biologicals licensed by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof;

d) Topical chemical drugs with direct local action which have the same drug substances, strength, concentration, dosage form and indications as those of the drugs granted marketing authorization in Vietnam for at least 30 years and included in the monographs of Vietnamese pharmacopoeia or reference pharmacopoeia or Vietnamese National Drug Formulary;

e) Topical drugs which contain drug substances being essential oils or purified essential oil extracts (including synthetic and semi-synthetic substances) and have the same drug substances, strength, concentration, and dosage form as those of a drug which has been granted marketing authorization in Vietnam for at least 10 years or which has been licensed and marketed in at least one country in the world for at least 10 years;

f) Orally administered drugs containing herbal materials combined with drug substances which are essential oils or purified essential oil extracts (including synthetic and semi-synthetic substances) or drugs containing purified active ingredients extracted from herbal materials with the same drug substances, herbal materials, strength, concentration, dosage form and indications as those of a drug granted marketing authorization in Vietnam;

g) Herbal drugs which have the same herbal materials, strength, concentration or weight of herbal materials, dosage form, indications and administration route as those of a drug granted marketing authorization by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof or a drug granted marketing authorization in Vietnam (even if it has expired).

6. MAAs for any drugs other than those specified in clauses 1, 2, 3, 4 and 5 of this Article must have sufficient clinical data to prove their safety and efficacy in conformity with the guidelines of ICH, WHO, US FDA, EMA, Ministry of Health of Vietnam or other organizations accredited by Vietnam.

7. If a clinical study has been carried out before the regulations or guidelines mentioned in point a clause 1 and point a clause 3 of this Article are adopted, the data of such study may be acceptable.

Section 2 Structure and composition of Marketing Authorization Application for drugs materials

Article 25 Structure of MAA packages

1. MAAs shall be prepared according to ACTD or ICH-CTD, and in compliance with regulations herein.



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2. Structure of MAAs for chemical drugs, vaccines and biologicals:

a) The ASEAN Common Technical Dossier (ACTD) is organized into four parts as follows:

- Part I: Administrative Document.
- Part II: Quality Document.
- Part III: Nonclinical Document.
- Part IV: Clinical Document.

b) ICH-CTD:

- Module I: Administrative Document.
- Module II: Quality, nonclinical and clinical overall and overview summaries
- Module III: Quality Document.
- Module IV: Nonclinical Document.
- Module V: Clinical Document.

3. Structure of MAAs for herbal drugs; orally administered drugs containing herbal materials combined with drug substances which are essential oils or purified essential oil extracts (including synthetic and semi-synthetic substances); drugs containing purified active ingredients extracted from herbal materials:

a) For herbal drugs which are new drugs; orally administered drugs containing herbal materials combined with drug substances which are essential oils or purified essential oil extracts (including synthetic and semi-synthetic substances); drugs containing purified active ingredients extracted from herbal materials:

- Part I: Administrative Document.
- Part II: Quality Document:

Comply with the guidelines in Appendix III enclosed herewith.

- Part III: Clinical data or data obtained from the sources prescribed in clause 3 Article 24 hereof;

b) For herbal drugs which are not new drugs:

- Part I: Administrative Document.
- Part II: Quality Document:

Comply with the guidelines in Appendix III enclosed herewith.

4. Structure of MAAs for medicinal materials:



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a) Part I: Administrative Document.

b) Part II: Quality Document:

Comply with the guidelines in Appendix IV enclosed herewith.

Article 26 Administrative Document

1. Application forms are made using Form 4A/TT, Form 4B/TT, Form 4C/TT enclosed herewith.

2. Letters of authorization in an MAA:

a) Letter of authorization to act as applicant, if the applicant is not the manufacturer;

b) Letter of authorization to sign documents in MAA (if any).

3. CPP (for imported drugs).

4. License to manufacture and trade drugs in the country of origin; license to establish representative office in Vietnam (for a foreign applicant).

5. Certificate of satisfaction of conditions for pharmaceutical business (for a Vietnamese applicant).

6. Legal documents of the manufacturer of drug substances, excipients, capsule shells or herbal materials as prescribed in clause 7 Article 22 of this Circular.

7. Certificate that the medicinal material is permitted to be manufactured or marketed in the manufacturing country (for medicinal materials manufactured in a foreign country).

8. Samples of the label of drug/medicinal material and the package insert:

a) of the drug/medicinal material to be marketed in Vietnam;

b) of the drug actually placed on the market of the manufacturing country or CPP issuing country (for imported drugs).

9. Summary of product characteristics or package insert approved at the country of origin (for new drugs, vaccines, biologicals, or drugs of which MAA is validated using reference to available validation results as requested by applicant).

10. Regarding an MAA to be validated using reference to available validation results or an MAA for a drug which is manufactured in a country where none of the drug regulatory authorities prescribed in clause 9 Article 2 hereof is located but is only supported by O1 CPP issued by the authority competent to issue CPP of the country of one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof to certify that the drug has been granted marketing authorization and is actually placed on the market of that country, the following documents must be additionally submitted:



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- a) The validation report which is made by one of the drug regulatory authority prescribed in clause 9 Article 2 hereof and meets the requirements laid down in Article 30 hereof;
- b) Comparative tabulated summary of similarities between the MAA in Vietnam and information on the drug granted marketing authorization in the country of origin, which is made using Form 09/TT enclosed herewith.

Article 27 Quality Document

1. Quality documents are prepared according to the guidelines in Part II of ACTD or the guidelines in Module 2 and Module 3 of ICH-CTD, and relevant guidelines.

Biosimilars must have sufficient documents and data to prove their quality similarity with reference biologicals according to the guidelines of WHO, US FDA, EMA.

2. If materials are supported by CEP, the documents on the drug substance may be replaced by the following documents:

- The CEP for the drug substance, accompanied with all annexes issued by the European Directorate for the Quality of Medicines & Healthcare (EDQM);
- Analytical data of the drug substance batch;
- If the quality retest date of the drug substance is not specified in the CEP, the stability study data of the drug substance shall be submitted.

3. For vaccines, antisera, derivatives of human blood and plasma, documents shall be submitted according to clause 1 of this Article and include the following:

- a) The batch release certificate issued by a competent authority of the country in which the CPP is issued or one of the drug regulatory authorities prescribed in Clause 9 Article 2 of this Circular;
- b) The certificate of analysis, specifications and test method certified by the National Institute for Control of Vaccines and Biologicals (NICVB) or state drug testing facilities in charge of testing, evaluating and monitoring vaccines and medical biological as assigned by MoH.

4. For rare drugs, drugs serving national defense and security, epidemic prevention and control, disaster recovery, and drugs serving special treatment needs:

a) Rare drugs which are used for treating rare diseases:

Existing stability study data obtained according to the guidelines of ASEAN or ICH shall be accepted;

b) For drugs serving national defense and security, epidemic prevention and control, disaster recovery:



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Stability study data existing at the application submission date shall be accepted for consideration of the expiry date of the drug according to opinions given by the Advisory Board if the time period covered by the stability study data fails to meet the minimum study period requirements laid down in the ASEAN guidelines.

After obtaining the marketing authorization, the applicant shall continue submitting stability study documents of drug product, until the minimum time period of the stability study is actually satisfied according to the ASEAN guidelines, to DAV in the form of variations to the marketing authorization as prescribed in Appendix II enclosed herewith for considering and updating the expiry date as prescribed.

If the stability study result of the drug fails to meet the study proposal included in the marketing application, the applicant shall submit a report to DAV for submission to the Advisory Board for considering the drug's expiry date.

Based on opinions given by the Advisory Board, DAV shall consider making decision on the expiry date of drug, including the batch of drugs manufactured, according to the actual stability study data;

c) For drugs serving special treatment needs:

Existing stability study data according to ASEAN or ICH guidelines shall be accepted according to the Minister of Health's decision issued on the basis of opinions given by the Advisory Board if the applicant proves that the drug cannot be stored in climatic zone IVb according to ASEAN guidelines.

5. With regard to the cases prescribed in clause 2 Article 13 hereof:

The applicant is required to submit a comparative tabulated summary (Form O1/TT enclosed herewith) of the drug before and after the change, and relevant technical documents according to the guidelines in Appendix II enclosed herewith.

Article 28 Nonclinical Document

Nonclinical documents are prepared and submitted according to the guidelines in Part III of ACTD or Module 2 and Module 4 of ICH-CTD and relevant guidelines or the guidelines in Appendix III enclosed herewith.

Article 29 Clinical Document

Clinical documents are prepared and submitted according to the guidelines in Part IV of ACTD or Module 2 and Module 5 of ICH-CTD and relevant guidelines or the guidelines in Appendix III enclosed herewith.



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Article 30. Documents on validation results given by drug regulatory authorities prescribed in clause 9 Article 2 hereof in case MAAs are validated using reference to available validation results

1. They must be official validation reports which are issued by the drug regulatory authorities prescribed in clause 9 Article 2 hereof and include details of the validation and evaluation of quality, safety and efficacy of the drug as well as the scientific and legal grounds for issuance of the marketing authorization in the country of origin.

2. Validation reports must be final reports used by the drug regulatory authorities as the basis for grant of marketing authorization for the drug product, and reports on validation and approval of changes or variations to the drug product after grant of marketing authorization.

3. A validation report which is used as reference for valuation of an MAA shall, inter alia, include the following contents:

a) Administrative information must include:

- Particulars of the drug;
- List of all approved packaging specifications;
- Pharmacological class;
- Particulars of the manufacturer/marketing authorization holder:

b) Quality information must include:

- Assessment of composition and manufacturing process;
- Assessment of quality control;
- Assessment of stability, including conclusions regarding product quality;

c) Safety and efficacy information must include:

- Summary assessment of primary nonclinical data;
- Summary assessment of primary clinical data;
- Assessment of benefits and risks;
- Basis for approved indications.

4. If validation reports issued by the drug regulatory authorities prescribed in clause 9 Article 2 hereof are made in a language other than English, their notarized English or Vietnamese translations are required.



Section 3 Specific provisions on marketing provisions on Marketing Authorization Applications for drug materials

Article 31 Marketing authorization applications for drugs prescribed in clauses 1, 2 and 6 Article 24 hereof

1. Administrative Document:

As prescribed in Article 26 hereof.

2. Quality Document:

As prescribed in Article 27 hereof.

3. Nonclinical Document:

Include the documents prescribed in clauses 1, 2, 6 and 7 Article 24 hereof and comply with provisions of Article 28 hereof.

4. Clinical Document:

Include the documents prescribed in clauses 1, 2, 6 and 7 Article 24 hereof and comply with provisions of Article 29 hereof.

5. The risk management plan, for new chemical drugs, vaccines and biologicals (except probiotic biological products) (Form O3/TT enclosed herewith).

Article 32 Marketing authorization applications for generic drugs and drugs prescribed in points b, c and d clause 5 Article 24 hereof

1. Administrative Document:

As prescribed in Article 26 hereof.

2. Quality Document:

a) The documents prescribed in Article 27 hereof;

b) Documentary evidence of the drug having demonstrated bioequivalence, for drugs containing drug substances or in dosage forms requiring bioequivalence study reporting upon submission of an MAA.

Article 33 Marketing authorization applications for drugs prescribed in clause 4 Article 24 hereof

1. Administrative Document:



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As prescribed in Article 26 hereof.

2. Quality Document:

a) The documents prescribed in Article 27 hereof;

b) Documentary evidence of the drug having demonstrated bioequivalence, for drugs containing drug substances or in dosage forms requiring bioequivalence study reporting upon submission of an MAA.

3. Clinical Document:

Include the documents prescribed in clause 4 Article 24 hereof and comply with provisions of Article 29 hereof.

4. The package insert or summary of product characteristics of the drug which has the same drug substances, strength, concentration, administration route and dosage form and has been granted marketing authorization by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof, in case of submission of clinical data collected from researches published in medical publications.

5. Where necessary, additional safety and efficacy data must be submitted according to opinions given by the Advisory Board.

Article 34 Marketing authorization applications for drugs prescribed in points e and f clause 5 Article 24 hereof

1. Administrative Document:

As prescribed in Article 26 hereof.

2. Quality Document:

As prescribed in Appendix III enclosed herewith.

Article 35 Marketing authorization applications for drugs prescribed in clause 3 Article 24 hereof

1. Administrative Document:

As prescribed in Article 26 hereof.

2. Quality Document:

As prescribed in Appendix III enclosed herewith.

3. Clinical data or data obtained from the sources prescribed in clause 3 Article 24 hereof.



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Article 36 Marketing authorization applications for drugs prescribed in point g clause 5 Article 24 hereof

1. Administrative Document:

As prescribed in Article 26 hereof.

2. Quality Document:

As prescribed in Appendix III enclosed herewith.

Article 37 Marketing authorization applications for medicinal materials

1. Administrative Document:

As prescribed in Article 26 hereof.

2. Quality Document:

As prescribed in Appendix IV enclosed herewith.

Section 4 Specific provisions on Marketing Authorization Applications for processed drugs and drugs manufactured using transferred technology in Vietnam

Article 38 Marketing authorization applications for processed drugs and drugs manufactured adopting transferred technology which are chemical drugs, vaccines and biologicals

1. Administrative Document:

a) The administrative documents of the processed drug/drug manufactured adopting transferred technology as prescribed in Article 26 hereof. The submission of legal documents of the manufacturer of drug substances, excipients, capsule shells or herbal materials shall not be required if the processing or technology transfer contract only covers the packaging stage;

b) Other documents concerning the processing or technology transfer, including:

- The drug processing contract or technology transfer contract. In case the ordering facility or the processing facility is not the applicant, the drug processing contract must bear signatures of legal representatives of the ordering facility, the applicant and the processing facility.

- Processing permit as prescribed in clause 4 Article 38 of the Decree No. 69/2018/ND-CP, in respect of an MAA for the processed drug which is imported and exported with permit;



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- Certificate of registration of technology transfer as prescribed in Article 31 of the Law on Technology Transfer, in respect of an MAA for the drug manufactured adopting transferred technology;

c) CPP of the drug ordered for processing or the drug before technology transfer if it is imported drug which is not yet granted marketing authorization in Vietnam or whose marketing authorization in Vietnam has expired at the time of MAA submission.

2. Quality Document:

a) The quality documents of the processed drug, drug manufactured adopting transferred technology, drug ordered for processing and drug before technology transfer as prescribed in Articles 31, 32, 33, 34 and 35 hereof;

b) The comparative tabulated summary (Form O1/TT enclosed herewith) of changes between the drug ordered for processing and the processed drug or between the drug before technology transfer and the drug manufactured adopting transferred technology, and relevant technical documents as prescribed in Appendix II enclosed herewith;

c) Documents proving quality equivalence between the processed vaccine/biological and the vaccine/biological ordered for processing or between the vaccine/biological manufactured adopting transferred technology and the vaccine/biological before technology transfer, in respect of vaccines and biologicals exempted from submission of nonclinical data and clinical data as prescribed in clause 3 of this Article, according to the guidelines of US FDA, SUPAC, the guidelines on changes and variations of ICH, WHO, EMA, international organizations to which Vietnam is a member, or the guidelines given by the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

d) If an MAA includes a request for classification of the processed drug/drug manufactured adopting transferred technology as an original brand-name drug or as drug having demonstrated bioequivalence, the following documents must be additionally submitted:

- Bioequivalence study report of the processed drug/drug manufactured adopting transferred technology;

The applicant may replace the bioequivalence study report of the processed drug/drug manufactured adopting transferred technology with dissolution similarity study reports between the processed drug and the drug ordered for processing or between the drug manufactured adopting transferred technology and the drug before technology transfer, if the processed drug or the drug manufactured adopting transferred technology has the same formulation, manufacturing process, specifications of materials, specifications of drug product as those of the drug ordered for processing or the drug before technology transfer according to the guidelines of US FDA SUPAC, ICH, WHO, EMA, international organizations to which Vietnam is a member, or the guidelines given by the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

In case of changes in the abovementioned contents which do not require submission of the bioequivalence study report of the drug, the applicant shall submit documents relevant to each change according to the guidelines of US FDA SUPAC, ICH, WHO, EMA, international



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organizations to which Vietnam is a member, or the guidelines given by the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

- The bioequivalence study report of the drug ordered for processing or the drug before technology transfer, if the drug ordered for processing or the drug before technology transfer is not yet declared as a drug having demonstrated bioequivalence in Vietnam and a request for declaration of bioequivalence of the processed drug or the drug manufactured adopting transferred technology is submitted.

3. Nonclinical and clinical documents:

a) For the processed drug or the drug manufactured adopting transferred technology:

The nonclinical documents as prescribed in clause 3 Article 31 hereof and the clinical documents as prescribed in clause 4 Article 31 hereof, in respect of the processed drug or the drug manufactured adopting transferred technology which is a new chemical drug, vaccine or biological.

Submission of nonclinical and clinical documents is not required in the following cases:

- The drug ordered for processing or the drug before technology transfer is a chemical drug granted a marketing authorization in Vietnam which is still valid at the time of MAA submission or whose nonclinical documents, as prescribed in clause 3 Article 31 hereof, and clinical documents, as prescribed in clause 4 Article 31 hereof, have been submitted;

- The drug ordered for processing or the drug before technology transfer is a biological granted a marketing authorization in Vietnam which is still valid at the time of MAA submission or whose nonclinical documents, as prescribed in clause 3 Article 31 hereof, and clinical documents, as prescribed in clause 4 Article 31 hereof, have been submitted, and there are sufficient documents to prove quality equivalence between the processed drug and the drug ordered for processing or between the drug manufactured adopting transferred technology and the drug before technology transfer;

- The drug ordered for processing or the drug before technology transfer is a vaccine granted a marketing authorization in Vietnam which is still valid at the time of MAA submission and there are sufficient documents to prove quality equivalence between the processed drug and the drug ordered for processing or between the drug manufactured adopting transferred technology and the drug before technology transfer;

b) For the drug ordered for processing or the drug before technology transfer:

The nonclinical documents as prescribed in clause 3 Article 31 hereof and the clinical documents as prescribed in clause 4 Article 31 hereof, in case the processed drug or the drug manufactured adopting transferred technology is a new chemical drug, vaccine or biological, or the MAA includes a request for classification of the processed drug or the drug manufactured adopting transferred technology as an original brand-name drug or reference biological if the drug ordered for processing or the drug before technology transfer is yet to be classified as an original brand-name drug or reference biological.



4. The risk management plan, for new chemical drugs, vaccines and biologicals (except probiotic biological products) (Form O3/TT enclosed herewith).

Article 39 Marketing authorization applications for processed drugs and drugs manufactured adopting transferred technology which are herbal drugs

1. Administrative Document:

a) The administrative documents of the processed drug/drug manufactured adopting transferred technology as prescribed in Article 26 hereof. The submission of legal documents of the manufacturer of herbal materials, excipients, or capsule shells shall not be required if the processing or technology transfer contract only covers the packaging stage;

b) Other documents concerning the processing or technology transfer, including:

- The drug processing contract or technology transfer contract. In case the ordering facility or the processing facility is not the applicant, the drug processing contract must bear signatures of legal representatives of the ordering facility, the applicant and the processing facility.

- The processing permit as prescribed in clause 4 Article 38 of the Decree No. 69/2018/ND-CP, in respect of an MAA for the processed drug which is imported and exported with permit;

- Certificate of registration of technology transfer as prescribed in Article 31 of the Law on Technology Transfer, in respect of an MAA for the drug manufactured adopting transferred technology;

c) CPP of the drug ordered for processing or the drug before technology transfer if it is an imported drug which is not yet granted marketing authorization in Vietnam or whose marketing authorization in Vietnam has expired at the time of MAA submission.

2. Quality Document:

a) The quality documents of the processed drug, drug manufactured adopting transferred technology, drug ordered for processing and drug before technology transfer as prescribed in Articles 35 and 36 hereof;

b) The comparative tabulated summary (Form O1/TT enclosed herewith) of changes between the drug ordered for processing and the processed drug or between the drug before technology transfer and the drug manufactured adopting transferred technology, and relevant technical documents as prescribed in Appendix II enclosed herewith.

3. Clinical Document:

a) For the processed drug or the drug manufactured adopting transferred technology:

The clinical documents as prescribed in clause 3 Article 35 hereof, if the processed drug or the drug manufactured adopting transferred technology is a new drug.



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Submission of clinical documents is not required in case the drug ordered for processing or the drug before technology transfer is a herbal drug granted a marketing authorization in Vietnam which is still valid at the time of MAA submission or whose clinical documents, as prescribed in clause 3 Article 35 hereof, have been submitted;

b) For the drug ordered for processing or the drug before technology transfer:

- The clinical documents as prescribed in clause 3 Article 35 hereof, if the processed drug or the drug manufactured adopting transferred technology is a new drug;

- The clinical documents as prescribed in Article 18 hereof, for an MAA including a request for classification of the processed drug or the drug manufactured adopting transferred technology as an original brand-name drug if the drug ordered for processing or the drug before technology transfer is yet to be classified as an original brand-name drug.

Article 40 Marketing authorization application for a drug processed adopting technology transferred from the ordering facility to the processing facility

1. The MAA includes the documents prescribed in Article 38 or 39 of this Circular.

2. The applicant must also submit:

a) The drug processing contract and the technology transfer contract;

b) The processing permit as prescribed in clause 4 Article 38 of the Decree No. 69/2018/ND-CP, in respect of an MAA for the processed drug which is imported and exported with permit, and the certificate of registration of technology transfer as prescribed in Article 31 of the Law on Technology Transfer.

Section 5 Specific provisions on applications for renewal or approval of variations to Marketing Authorizations of drugs/ medicinal materials

Article 41 Application for renewal of marketing authorization of drug/medicinal material

1. An application form for renewal of marketing authorization of drug/medicinal material which is made using Form 4B/TT enclosed herewith.

2. The unexpired CPP (for an imported drug).

3. A report on safety and efficacy of the drug during its marketing which is made using Form 2C/TT enclosed herewith.

Article 42 Application for approval of variations to marketing authorization of drug/medicinal material



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1. An application form for approval of variations to the marketing authorization of drug/medicinal material which is made using Form 4C/TT enclosed herewith and the letter of authorization to sign documents in the application (if any).

2. Documents relevant to major variations/minor variations as prescribed in Appendix II enclosed herewith.

3. Regarding changes in the technical documents of the processed drug/the drug manufactured adopting transferred technology which have been declared conformable with the criteria set out in clause 1 Article 9 hereof, the applicant shall provide evidence that changes in the drug ordered for processing/the drug before technology transfer which is being manufactured and marketed in the country of origin has been approved by a competent regulatory authority.

Chapter IV: Authority to approve and procedures for issuance, renewal and approval of variations to Marketing Authorization of drugs and medicinal materials

Article 43 Authority to approve issuance, renewal and approval of variations to marketing authorization of drugs and medicinal materials

1. DAV shall consider issuing, renewing and approving variations to marketing authorizations of drugs/medicinal materials on the basis of the application validation results and consulting opinions given by the Advisory Board in the following cases:

a) Issue marketing authorizations of drugs/medicinal materials;

b) Grant approval of renewal of marketing authorizations of drugs/medicinal materials on the basis of the application validation results and consulting opinions given by the Advisory Board in the following cases:

- The drugs prescribed in clause 2 Article 12 of this Circular;

- The drugs or medicinal materials subject to decisions on mandatory or voluntary recall due to nonconformance with quality specifications during their marketing from the latest issuance or renewal of marketing authorization;

- The drug which is reported using Form 2C/TT enclosed herewith to have new adverse events or adverse events that are known but occur at a higher frequency than the frequency stated in the approved package insert or adverse events that are known but require further evaluation;

c) Grant approval of variations to the marketing authorization as prescribed in Appendix II enclosed herewith in respect of:

Classification of prescription drugs, OTC drugs, changes in indications, dose, administration route, intended users; classification of original brand-name drugs, reference biologicals, and drugs having demonstrated bioequivalence.

2. DAV shall consider granting approval of renewal and variations to marketing authorizations of drugs/medicinal materials on the basis of the application validation results without requiring



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application validation results and consulting opinions given by the Advisory Board in the following cases:

- a) Grant approval of renewal of marketing authorizations of drugs/medicinal materials in cases other than those prescribed in point b clause 1 of this Article;
 - b) Grant approval of variations to marketing authorizations of drugs/medicinal materials in cases other than those prescribed in point c clause 1 and clause 3 of this Article, and updates to the package insert according to the relevant original brand-name drug.
3. DAV shall publish on the web portal of MoH and on its website the variations to marketing authorization of drugs/medicinal materials without requiring application validation in respect of the minor variations that only require notification.

Article 44 Submission of additional documents during validation, cases in which variation application is not required, and periods of applying existing information before approving or publishing variations

1. The applicant is required to submit additional documents within 06 months from the date on which it receives a written request from DAV. Otherwise, its submitted application will no longer be valid.

The period of time starting from the date on which DAV sends a request for additional documents to the date on which additional documents are submitted shall not be included in the calculation of the time limit prescribed in clause 6 Article 56 of the Pharmacy Law.

2. Times of submission of additional documents to an application for issuance, renewal or approval of variations to marketing authorization of drug/medicinal material:

a) Additional documents to an application for issuance, renewal or approval of variations to marketing authorization of drug/medicinal material may be submitted up to 02 times.

In case an application is considered unsatisfactory by validators after 02 times of submission of additional documents, DAV shall request the Advisory Board to refuse to issue or renew the marketing authorization or refuse to approve variations thereto, in respect of the drugs prescribed in clause 1 Article 43 hereof, or shall give written notices of refusal to renew the marketing authorization or to approve variations thereto, in respect of the drugs prescribed in clause 2 Article 43 hereof.

If an application is considered unsatisfactory by validators after 02 times of submission of additional documents as a result of a new issue found, DAV shall request the Advisory Board to allow the applicant to submit additional documents one more time in order to provide justifications for the issue, in respect of the drugs prescribed in clause 1 Article 43 hereof, or shall give a written request for submission of additional documents one more time, in respect of the drugs prescribed in clause 2 Article 43 hereof;



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b) Submission of additional documents at the request of the Advisory Board will be excluded when calculating total number of times of submission of additional documents as prescribed in point a of this clause.

3. During the validation of an application, the applicant shall not be allowed to make any variations in terms of the contents of the submitted application other than those requested by DAV, except the following documents:

a) Documents providing safety and efficacy updates to the package insert, in respect of an application for issuance of marketing authorization or approval of variations thereto;

b) Documents providing updated administrative information in terms of change of the name or address of the manufacturer without replacing the manufacturer, in respect of an application for issuance of marketing authorization or approval of variations thereto;

c) Documents providing updated administrative information in terms of change of the name or method of writing address of the manufacturer without replacing the manufacturer and changing the manufacturing site, in respect of an application for issuance of marketing authorization or approval of variations thereto;

d) Documents providing updated information on the actual marketing of the drug in Vietnam, in respect of an application for renewal of the marketing authorization.

4. Regarding an application for renewal of the marketing authorization of the drug/medicinal material prescribed in Article 41 hereof, the applicant shall only be allowed to make change of the drug product name specified in the submitted application package and the application form for renewal.

5. When considering issuing the marketing authorization for a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases, DAV must not carry out validation of technical documents and assessment of compliance with GMP requirements on the basis of recognizing licensing results given by one of the drug regulatory authorities prescribed in clause 9 Article 2 hereof.

6. The applicant or manufacturer shall themselves update the label and package insert of the drug without submitting a variation application or sending notification to DAV in the following cases:

a) The information position or information about the importer of the drug/medicinal material on the label or package insert is changed;

b) The label or package insert is provided in accordance with clause 2 Article 35 of the Circular No. 01/2018/TT-BYT;

c) The label or package insert is revised according to the Official Dispatch given by DAV on the basis of consulting opinions given by the Advisory Board;

d) Unless the sample label or package insert has to be re-submitted in cases of variations specified in Appendix II enclosed herewith, other changes in the information on the label or



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package insert shall be updated by the applicant or manufacturer after they are approved by DAV;

e) Other contents:

- Change of the information position or information about the importer of the drug/medicinal material on the label or package insert;
- Correction of spelling errors on the label or package insert;
- Change of the layout of information items on the package insert without altering the meaning of the approved information thereon;
- Change or addition of specifications on the label or package insert as approved by DAV;
- Deletion of information other than the compulsory one on the label or package insert.

7. At the latest 12 months after DAV issues an official dispatch approving or publishing variations, the application of such approved variations to the drug/medicinal material is compulsory. Within 12 months after DAV issues an official dispatch approving or publishing variations, the application of such variations shall be subject to the following provisions:

a) An imported drug/medicinal material shall continue to be imported and marketed until the end of its shelf life with its information existing before such variations are approved or announced, provided that the shipment departs from the port of the exporting country before the date on which such variations are compulsorily applied as prescribed;

b) Any drug/medicinal material manufactured in Vietnam shall continue to be manufactured and marketed until the end of its shelf life with its information existing before such variations are approved or announced.

8. At the latest 12 months after grant of an approval for renewal of the marketing authorization of the drug/medicinal material which covers the change of its name, the use of the new name of the drug/medicinal material which is approved upon grant of such approval is compulsory. Within 12 months after grant of an approval for renewal of the marketing authorization, the use of the drug name is subject to the following provisions:

a) An imported drug/medicinal material shall continue to be imported and marketed until the end of its shelf life using its name existing before grant of an approval for renewal of the marketing authorization provided that the shipment departs from the port of the exporting country before the date on which the new name which is covered in such approval is compulsorily used as prescribed;

b) Any drug/medicinal material manufactured in Vietnam shall continue to be manufactured and marketed until the end of its shelf life using its name existing before grant of an approval for renewal of the marketing authorization.

Article 45 Procedures for issuance of marketing authorizations of drugs/medicinal materials



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1. Application submission method:

Applications shall be submitted according to provisions of Article 16 of the Decree No. 61/2018/ND-CP.

2. Application receipt and processing time limit:

a) Application receipt:

Upon receipt of an adequate application, DAV shall give an application receipt note to the applicant as prescribed.

DAV shall receive the application without requesting the applicant to submit a CPP in the case prescribed in point d clause 2 Article 22 hereof and the documents prescribed in point b clause 3 Article 27 hereof at the time of application submission;

b) Time limits for processing applications counted from the date of application receipt:

- Application for issuance of marketing authorization of a drug: not exceeding 12 months;
- Application for issuance of marketing authorization of a drug which is validated using reference to available validation results: not exceeding 09 months;
- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: not exceeding 03 months;
- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: not exceeding 09 months.
- Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: not exceeding 15 days;
- Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: not exceeding 06 months;



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- Application for issuance of marketing authorization of a medicinal material: not exceeding 06 months.

3. Organization of validation:

a) Upon its receipt of an application, DAV shall review, classify and transfer the received application to qualified validators or validating units within the following time limits:

- Application for issuance of marketing authorization of a drug: 10 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a drug which is validated using reference to available validation results: 10 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: 03 working days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: 10 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: 01 working day, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: 03 working days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a medicinal material: 03 working days, in respect of initial and additional submission;

b) Upon their receipt of an application from DAV, validators and validating units shall conduct validation, prepare and send a complete validation record to DAV within the following time limits:

- Application for issuance of marketing authorization of a drug: 07 months, for initial submission, and 02 months, for additional submission;



- Application for issuance of marketing authorization of a drug which is validated using reference to available validation results: 04 months, for initial submission, and 02 months, for additional submission;
- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: 01 month, in respect of initial and additional submission;
- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: 04 months, for initial submission, and 01 month, for additional submission;
- Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: 03 working days, in respect of initial and additional submission;
- Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: 04 months, for initial submission, and 01 month, for additional submission;
- Application for issuance of marketing authorization of a medicinal material: 04 months, for initial submission, and 01 month, for additional submission.

4. Actions taken after validation:

Upon its receipt of the validation record, DAV shall, on the basis of validation opinions given by validators, validating units and regulations in force, send a written request for additional documents to the applicant, if the application is not yet satisfactory, or send the application to the Advisory Board, if it is considered satisfactory, unsatisfactory or requires additional opinions, and is to be approved, refused or given additional opinions of the Advisory Board as proposed by DAV within the following time limits:

- a) Application for issuance of marketing authorization of a drug: 02 months, for initial submission, and 01 month, for additional submission;
- b) Application for issuance of marketing authorization of a drug which is validated using reference to available validation results: 02 months, for initial submission, and 01 month, for additional submission;



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c) Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: 15 days, in respect of initial and additional submission;

d) Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: 02 months, for initial submission, and 01 month, for additional submission;

e) Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: 01 working day, in respect of initial and additional submission;

f) Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: 15 days, in respect of initial and additional submission;

g) Application for issuance of marketing authorization of a medicinal material: 15 days, in respect of initial and additional submission.

5. Meeting of the Advisory Board:

Upon its receipt of the documents from DAV, the Office of the Advisory Board shall hold a meeting within the following time limits:

a) Application for issuance of marketing authorization of a drug: 01 month, in respect of initial and additional submission;

b) Application for issuance of marketing authorization which is validated using reference to available validation results: 01 month, in respect of initial and additional submission;

c) Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: 15 days, in respect of initial and additional submission;



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d) Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: 01 month, for initial submission, and 15 days, for additional submission;

e) Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: 03 working days, in respect of initial and additional submission;

f) Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: 15 days, in respect of initial and additional submission;

g) Application for issuance of marketing authorization of a medicinal material: 15 days, in respect of initial and additional submission.

6. Actions taken after the meeting of the Advisory Board:

a) Completing the meeting minutes:

From the date of its meeting, the Office of the Advisory Board shall complete the meeting minutes and send them to DAV within the following time limits:

- Application for issuance of marketing authorization of a drug: 01 month, in respect of initial and additional submission;

- Application for issuance of marketing authorization which is validated using reference to available validation results: 01 month, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: 10 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: 01 month, for initial submission, and 15 days, for additional submission;



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- Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: 01 working day, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: 10 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a medicinal material: 10 days, in respect of initial and additional submission;

b) Upon its receipt of the minutes of the meeting of the Advisory Board, DAV shall issue a marketing authorization using Form 6A/TT enclosed herewith, for a satisfactory application, or give a written notice which is made according to the conclusions given by the Advisory Board to the applicant, for an application which is not yet satisfactory or unsatisfactory, within the following time limits:

- Application for issuance of marketing authorization of a drug: 20 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization which is validated using reference to available validation results: 20 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer has been granted a marketing authorization in Vietnam which is still valid at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing has been granted a marketing authorization in Vietnam which is still valid at the date of application submission: 15 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a processed drug/drug manufactured adopting transferred technology, in case the drug ordered for processing/drug before technology transfer is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission, or a drug processed adopting technology transferred from the ordering facility to the processing facility, in case the drug ordered for processing is yet to be granted a marketing authorization in Vietnam or has been granted a marketing authorization but it has expired at the date of application submission: 20 days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a new drug which is indicated to serve the prevention and treatment of any group A infectious disease causing an epidemic which has been declared in accordance with regulations of law on prevention and control of infectious diseases: 02 working days, in respect of initial and additional submission;

- Application for issuance of marketing authorization of a drug in case of prioritized administrative procedures prescribed in clause 5 Article 7 of the Pharmacy Law: 15 days, in respect of initial and additional submission;



- Application for issuance of marketing authorization of a medicinal material: 15 days, in respect of initial and additional submission.

Article 46 Procedures for renewal of marketing authorizations of drugs/medicinal materials

1. Application submission method:

Applications shall be submitted according to provisions of Article 16 of the Decree No. 61/2018/ND-CP.

2. Application receipt and processing time limit:

a) Application receipt:

Upon receipt of an adequate application, DAV shall give an application receipt note to the applicant as prescribed;

b) Time limit for processing an application counted from the date of application receipt: not exceeding 03 months.

3. Organization of validation:

a) Within 03 working days from its receipt of an application as prescribed in clause 2 of this Article, DAV shall review, classify and transfer the received application to validators or validating units;

b) Within 01 month from their receipt of an application from DAV, validators and validating units shall conduct validation, prepare and send a complete validation record to DAV.

4. Actions taken after validation:

a) For a renewal application prescribed in point b clause 1 Article 43 hereof:

Within 15 days from its receipt of the validation record, DAV shall, on the basis of validation opinions given by validators, validating units and regulations in force, send a written request for additional documents to the applicant, if the application is not yet satisfactory, or send the application to the Advisory Board, if it is considered satisfactory, unsatisfactory or requires additional opinions, and is to be approved, refused or given additional opinions of the Advisory Board as proposed by DAV;

b) For a renewal application prescribed in point a clause 2 Article 43 hereof, on the basis of validation opinions given by validators, validating units and regulations in force, DAV shall:

- Send a written request for additional documents to the applicant, if the application is not yet satisfactory, or send a written notice of refusal to renew the marketing authorization, if the application is considered unsatisfactory, within 10 days;

- Renew the marketing authorization using Form 6B/TT enclosed herewith, if the application is considered satisfactory, within 15 days.



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5. Meeting of the Advisory Board:

Within 15 days from its receipt of the documents from DAV, the Office of the Advisory Board shall hold a meeting of the Advisory Board.

6. Actions taken after the meeting of the Advisory Board:

a) Within 10 days from the date of its meeting, the Office of the Advisory Board shall complete the meeting minutes and send them to DAV;

b) Within 15 days from its receipt of the minutes of the meeting of the Advisory Board, DAV shall renew the marketing authorization using Form 6B/TT enclosed herewith, for a satisfactory application, or give a written notice which is made according to the conclusions given by the Advisory Board to the applicant, for an application which is not yet satisfactory or unsatisfactory.

Article 47 Procedures for approval of variations to marketing authorizations of drugs/medicinal materials

1. Application submission method:

Applications shall be submitted according to provisions of Article 16 of the Decree No. 61/2018/ND-CP.

2. Application receipt and processing time limit:

a) Application receipt:

Upon receipt of an adequate application, DAV shall give an application receipt note to the applicant as prescribed;

b) Time limits for processing applications counted from the date of application receipt:

- For a variation application prescribed in clause 3 Article 43 hereof: not exceeding 20 days;
- For a variation application prescribed in point c clause 1 or point b clause 2 Article 43 hereof: not exceeding 03 months.

3. Organization of validation:

a) Upon its receipt of the application as prescribed in clause 2 of this Article, DAV shall publish variations, for an application prescribed in clause 3 Article 43 hereof, within 20 days; review, classify and transfer the application to validators or validating units, for an application prescribed in point c clause 1 or point b clause 2 Article 43 hereof, within the following time limits:

- Regarding an application prescribed in point c clause 1 Article 43 hereof: 03 working days, for initial submission, or 02 workings days, for additional submission;



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- Regarding an application prescribed in point b clause 2 Article 43 hereof: 03 working days, for initial and additional submission;

b) Upon their receipt of an application from DAV, validators and validating units shall conduct validation, prepare and send a complete validation record to DAV within the following time limits:

- Regarding an application prescribed in point c clause 1 Article 43 hereof: 01 month, for initial submission, or 15 days, for additional submission;

- Regarding an application prescribed in point b clause 2 Article 43 hereof: 01 month, for initial and additional submission.

4. Actions taken after validation:

a) For a variation application prescribed in point c clause 1 Article 43 hereof:

Upon its receipt of the validation record, DAV shall, on the basis of validation opinions given by validators, validating units and regulations in force, send a written request for additional documents to the applicant, if the application is not yet satisfactory, or send the application to the Advisory Board, if it is considered satisfactory, unsatisfactory or requires additional opinions, and is to be approved, refused or given additional opinions of the Advisory Board as proposed by DAV, within 15 days, for initial submission, or 10 days, for additional submission;

b) For a variation application prescribed in point b clause 2 Article 43 hereof:

Upon its receipt of the validation record, DAV shall, on the basis of validation opinions given by validators, validating units and regulations in force, send a written request for additional documents to the applicant, if the application is not yet satisfactory, or grant a written approval of variations to the marketing authorization, if the application is considered satisfactory, or issue a written notice of refusal to grant approval, if the application is considered unsatisfactory, within 25 days, for initial and additional submission.

5. Meeting of the Advisory Board:

Within 15 days from its receipt of the documents from DAV, the Office of the Advisory Board shall hold a meeting of the Advisory Board.

6. Actions taken after the meeting of the Advisory Board:

a) Within 10 days from the date of its meeting, the Office of the Advisory Board shall complete the meeting minutes and send them to DAV;

b) Within 15 days, for initial submission, or 08 days, for additional submission, from its receipt of the minutes of the meeting of the Advisory Board, DAV shall grant a written approval of variations to the marketing authorization, for a satisfactory application, or give a written notice which is made according to the conclusions given by the Advisory Board to the applicant, for an application which is not yet satisfactory or unsatisfactory.



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Chapter V: Documentation requirements, procedures for withdrawal and revocation of Marketing Authorizations of drugs and medicinal materials

Article 48 Documentation requirements for withdrawal and revocation of marketing authorizations of drugs/medicinal materials

1. If a marketing authorization of drug is revoked as prescribed in points a, b clause 1 Article 58 of the Pharmacy Law, the following documents shall be required:

- a) Decision on imposition of administrative penalties issued by a competent regulatory authority;
- b) Document on the drug recall made by a competent regulatory authority.

2. If a marketing authorization of drug/medicinal material is revoked as prescribed in points d, e clause 1 Article 58 of the Pharmacy Law, the following documents shall be required:

The written conclusion drawn by a competent regulatory authority that the documents used as the basis for grant of the marketing authorization are forged, or the drug/medicinal material is manufactured at a place other than that specified in the submitted MAA.

3. If a marketing authorization of drug/medicinal material is revoked as prescribed in point c clause 1 Article 58 of the Pharmacy Law, the following documents shall be required:

The notice, issued by the competent CPP issuing authority, of revocation of the issued CPP which is used as the basis for DAV to issue the marketing authorization of the drug/medicinal material in Vietnam.

4. If a marketing authorization of drug/medicinal material is revoked as prescribed in point e clause 1 Article 58 of the Pharmacy Law, the following documents shall be required:

The notice, issued by WHO or a competent regulatory authority of Vietnam or of the country of origin of the drug/medicinal material, of warning that the drug/medicinal material is ineffective or unsafe for human use.

5. If a marketing authorization of drug/medicinal material is withdrawn as prescribed in point g clause 1 Article 58 of the Pharmacy Law, the following documents shall be required:

The written request for withdrawal of the marketing authorization of drug/medicinal material in Vietnam which is made by the manufacturer or applicant using Form 07/TT enclosed herewith.

Article 49 Procedures for revocation and withdrawal of marketing authorizations of drugs/medicinal materials

1-Within a maximum duration of 30 days from its receipt of the documents prescribed in clause 1 Article 48 hereof, DAV shall issue a decision to revoke the marketing authorization of drug.

2-Within a maximum duration of 30 days from its receipt of the documents prescribed in clause 2 Article 48 hereof, DAV shall issue a decision to revoke the marketing authorization of drug/medicinal material.



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3- Within a maximum duration of 10 days from its receipt of the documents prescribed in clause 3 or 4 Article 48 hereof, DAV shall issue a decision to revoke the marketing authorization of drug/medicinal material.

4- Within a maximum duration of 20 days from its receipt of the documents prescribed in clause 5 Article 48 hereof, DAV shall issue a decision to withdraw the marketing authorization of drug/medicinal material.

Chapter VI: Principles for organization and operation of advisory board, validating units and validators

Article 50 Organization and operation of Advisory Board

1. The Advisory Board is established by the Minister of Health of Vietnam. The Advisory Board is composed of experts whose qualifications and experience are appropriate for validating applications, questioning opinions of validators and proposals of DAV, and providing the Minister of Health with advice about the matters concerning pharmacy laws, and safety and efficacy documents of drugs/medicinal materials.

2. The Advisory Board has the responsibility to provide the Minister of Health of Vietnam with advice on issuance, renewal, and approval of variations to marketing authorizations of drugs/medicinal materials on the basis of validation conclusions given by validators and DAV's proposals, and relevant issues at the request of the Minister of Health of Vietnam. The Advisory Board shall assume responsibility before the Minister of Health of Vietnam for its advice and opinions.

3. Operational principles of the Advisory Board:

a) The Advisory Board operates following the principles of unanimity, democratic centralism, objectivity, openness and transparency. The Advisory Board shall give opinions on a scientific and lawful basis while taking account of validation conclusions given by validators, clinical reality and DAV's proposals;

b) Every meeting of the Advisory Board shall be conducted if it is attended by at least 2/3 of its qualified members (according to the regulations on organization and operation of the Advisory Board announced by MoH), including those who send their opinions in writing without directly attending the meeting;

The Chairperson of the Advisory Board or the person authorized by the Chairperson to chair the meeting shall draw the conclusion when it is approved by at least 2/3 of the participants. Dissenting opinions shall be reserved.

Opinions, including dissenting opinions, of its members and the conclusions drawn by the Advisory Board shall be included in the meeting minutes;

c) If its meeting is not held, the Chairperson of the Advisory Board shall collect written opinions from its members;



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After the deadline for sending opinions, the Chairperson of the Advisory Board or his/her authorized person shall reach conclusions upon its standing committee's receipt of opinions given by at least 2/3 of its members.

The Advisory Board shall reach conclusions on the basis of consenting opinions of at least 2/3 of its members, the consolidated report and proposal of DAV;

The conclusions of the Advisory Board shall be written in the Statement of conclusions of its Chairperson or his/her authorized person;

d) Where necessary, members of the Advisory Board are entitled to consider and validate the application, and the Chairperson of the Advisory Board may seek additional opinions from independent experts other than its members before reaching final conclusions. These experts may directly attend the meeting of the Advisory Board or give their written opinions, have the same responsibilities and rights as those of the members of the Advisory Board;

e) Conflicts of interest rule must be complied with.

4. DAV shall propose to the Minister of Health of Vietnam regulations on organization and operation of the Advisory Board, the mechanism for cooperation between the Advisory Board and validators regarding issuance, renewal and approval of variations to marketing authorizations of drugs/medicinal materials.

5. Funding for covering operating expenses of the Advisory Board shall comply with regulations of law.

6. The standing committee of the Advisory Board shall be located on the same premises as DAV.

Article 51 Organization and operation of validating units and validators

1. DAV and validating units shall establish validator teams in charge of validating legal documents, quality specifications, dosage form, pharmacology, clinical data, bioequivalence, and lists of validators of teams in charge of validating applications for issuance, renewal and approval of variations to marketing authorizations of drugs/medicinal materials. The composition of each validator team shall be suitable for the product category and registration form.

2. Operational principles of validators and validating units:

a) All validation opinions must be given on a lawful and scientific basis, and included in the validation record;

b) Validators shall assume responsibility before the DAV's Director and validating units for their validation works and opinions about applications for issuance, renewal and approval of variations to marketing authorizations of drugs/medicinal materials.

3. DAV shall, within the ambit of its assigned functions and tasks, formulate and issue regulations on organization and operation of validator teams (including those of validating



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units) in charge of validating applications for issuance, renewal and approval of variations to marketing authorizations of drugs/medicinal materials; sign contracts with validators or validating units;

DAV and validating units shall provide training courses for validators; organize assessment of the validators' knowledge and compliance with regulations of law, which is the basis for replacement or employment of validators.

4. Funding for covering validation expenses shall comply with regulations of law.

Chapter VII: Supplementary provisions

Article 52 Effect

1. This Circular comes into force from July 01, 2025.

2. The following regulations and Circulars shall cease to have effect from the effective date of this Circular:

a) Regulations on chemical drugs, biologicals and herbal drugs in the Circular No. 07/2017/TT-BYT dated May 03, 2017 of the Minister of Health prescribing list of OTC drugs;

b) Paragraph 1 point a clause 1 Article 16 and paragraph 2 point c clause 3 Article 29 of the Circular No. 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health of Vietnam prescribing labeling and package inserts of drugs and medicinal materials;

c) The Circular No. 08/2022/TT-BYT dated September 05, 2022 of the Minister of Health of Vietnam prescribing marketing authorization of drugs and medicinal materials;

d) The Circular No. 16/2023/TT-BYT dated August 15, 2023 of the Minister of Health of Vietnam prescribing marketing authorization of processed drugs and drugs manufactured adopting transferred technology in Vietnam;

e) The Circular No. 55/2024/TT-BYT dated December 31, 2024 of the Minister of Health of Vietnam providing amendments to some articles on renewal of marketing authorization of drugs and medicinal materials in the Circular No. 08/2022/TT-BYT dated September 05, 2022 of Minister of Health of Vietnam prescribing marketing authorization of drugs and medicinal materials.

3. When applying for import of medicinal materials which are excipients and capsule shells for manufacturing of domestically manufactured drugs/medicinal materials which have been granted the marketing authorization before October 20, 2022:

Before the first shipment to Vietnam, the applicant shall adequately update information about the medicinal materials which are excipients and capsule shells in its approved application on the DAV's online public service system. Within 05 working days from the date on which information is updated on the system, DAV shall complete the publishing of information on such medicinal materials which are excipients and capsule shells on its website. The applicant shall assume responsibility for the accuracy of its updated information in comparison with the



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information included in its approved application, and shall not be required to update information for the following shipment.

4. At the latest 12 months after the marketing authorization of a drug/medicinal material which has been granted before January 01, 2023 is renewed, its label and package insert must bear the marketing authorization number with the structure prescribed in Appendix V enclosed herewith. Within 12 months after grant of an approval for renewal of the marketing authorization of a drug/medicinal material, the marketing authorization number shall be written according to the following provisions:

a) A domestically manufactured drug/medicinal material shall continue to be manufactured and marketed until the end of its shelf life with its label indicating the marketing authorization number granted before such grant of approval for renewal;

b) An imported drug/medicinal material shall continue to be imported and marketed until the end of its shelf life with its label indicating the marketing authorization number granted before such grant of approval for renewal, provided that the shipment departs from the port of the exporting country before the date on which such an marketing authorization number is compulsorily written on label as prescribed in point a of this clause.

5. Re-classification of prescription drugs and OTC drugs which have been classified before the effective date of this Circular is not required during the validity periods of the marketing authorizations. A drug shall be classified as a prescription drug or OTC drug according to provisions of this Circular during processing of application for renewal of its marketing authorization. The applicant that wishes to apply for change in the category of a prescription drug or OTC drug shall comply with provisions in Appendix II enclosed herewith.

6. Classification of OTC drugs covered by applications which have been submitted to DAV before the effective date of this Circular but are yet to be processed (i.e. the marketing authorization is yet to be issued or renewed) shall comply with provisions herein.

Article 53 Transition

1. Applications submitted before the effective date of this Circular shall continue to be processed in compliance with the regulations in force at the time of application submission or the regulations herein as of the effective date of this Circular, whichever is more convenient for the applicants.

2. DAV is assigned to modify or update variations to the published information about the drugs which have been classified and declared by MoH as original brand-name drugs or reference biologicals or drugs having demonstrated bioequivalence at the request of applicants.

Article 54 Terms of reference

If any legislative documents and regulations referred to in this Circular are amended, supplemented or superseded, the new ones shall apply.



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Article 55 Implementation organization

1. DAV shall, within the ambit of its assigned functions and tasks, and pursuant to the roadmap for ASEAN harmonization of drug registration, take the responsibility to:

a) Provide guidelines for and organize the implementation of this Circular;

b) Publish the following on its website:

- The list of drugs and medicinal materials granted or having marketing authorizations renewed (including information on the drugs before technology transfer, for drugs manufactured adopting transferred technology in Vietnam, and information on the drugs ordered for processing, for drugs processed in Vietnam) within 05 days from the date on which the marketing authorization is granted or renewed, and information on classification of prescription drugs or OTC drugs and other information about marketing authorization of drugs and medicinal materials;

- The list of drugs having demonstrated bioequivalence, drugs declared as original brand-name drugs or reference biologicals within 05 days from the date on which the marketing authorization of the drug is granted, and information on variations to such a listed drug within 07 days from the date on which such variations to the marketing authorization are approved;

- The lists of processed drugs and drugs manufactured adopting transferred technology which are made using Form 8A/TT, Form 8B/TT and Form 8C/TT enclosed herewith;

c) Remove drugs from the lists of drugs having demonstrated bioequivalence, and drugs declared as original brand-name drugs or reference biologicals when these drugs no longer meet relevant classification criteria set out herein on the basis of consulting opinions given by the Advisory Board;

d) Remove drugs from the lists of processed drugs and drugs manufactured adopting transferred technology published as prescribed in paragraph 3 point b on the basis of consulting opinions given by the Advisory Board when these drugs no longer meet the requirements laid down in clause 1 Article 9 hereof;

e) Formulate, promulgate, and organize implementation of standard operating procedures (SOPs) in marketing authorization application; manuals for marketing authorization application; manuals for validation of MAAs;

f) Cooperate with the Traditional Medicine Administration of Vietnam in renewing and approving variations to the marketing authorizations of traditional drugs and herbal materials granted according to provisions of the Circular No. 44/2014/TT-BYT dated November 25, 2014 of the Minister of Health prescribing marketing authorization of drugs;

g) Where necessary, DAV shall hold meetings with applicants, manufacturers and validators to clarify the issues that arise during validation of MAAs;



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h) Formulate regulations on use of barcodes, QR codes, DataMatrix codes or other printed codes, as prescribed by relevant laws, on secondary package labels of drugs/medicinal materials of manufacturer to serve management, identification and tracing of origin of the drugs and medicinal materials placed on the market, and the roadmap for implementation thereof according to regulations adopted by the Minister of Health;

i) Within 15 days from the date of issuance or renewal, or 07 working days from the date of approval of variations to the marketing authorization, DAV shall share quality specifications with the testing system; share information on risk management plans with the National DI & ADR Centre, with respect of applications for marketing authorization of new chemical drugs, vaccines and biologicals (except probiotic biological products); publish information on materials, in respect of domestically manufactured drugs; publish the list of drugs classified as original brand-name drugs or reference biologicals, and drugs having demonstrated bioequivalence;

k) Within 03 working days from its receipt of an application for renewal of marketing authorization of drug/medicinal material, DAV shall publish information on the received application on MoH's web portal and on its website;

l) Within 03 working days from the date on which DAV gives a notification that the application for renewal is rejected or the marketing authorization is suspended in case the drug or medicinal material is found potentially unsafe for users or legal documents are suspected of being forged, DAV shall publish information thereon on MoH's web portal and on its website;

m) Publish on its website the technical documents prescribed in Appendix I enclosed herewith.

2. When writing the expiry dates on labels of their drugs/medicinal materials, manufacturers shall comply with provisions on labeling in the Circular No. 01/2018/TT-BYT and the following:

The expiry date of a drug/medicinal material on its label must not be later than the ending date of its shelf life as specified in the approved MAA and must not be sooner than its shelf life by more than 31 days.

Article 56 Responsibility for implementation

1. DAV shall assume responsibility to provide guidelines for implementation of regulations herein; play the leading role or cooperate with the MoH Inspectorate, functional Departments, Administrations, and provincial Departments of Health in conducting inspection of the implementation of regulations herein by pharmaceutical manufacturers and traders nationwide.

2. MoH's affiliated units, Vietnam Pharmaceutical Corporation (Vinapharm), and pharmaceutical manufacturers and traders are responsible for implementation of this Circular.

Difficulties that arise during the implementation of this Circular should be promptly reported to MoH (via DAV) for consideration.



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