Unofficial translation

MINISTRY OF AGRICULTURE AND ENVIRONMENT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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Date: 22/12/2025

CIRCULAR

Amending and Supplementing certain Articles of Circulars on the Management of Veterinary Drugs

Pursuant to the Decree No. 35/2025/NĐ-CP dated February 25, 2025 of the Government on the functions, tasks, authority and organizational structure of the Ministry of Agriculture and Environment;

Pursuant to the Veterinary Law dated 19 June, 2015;

Pursuant to the Law on Amendments and Supplements to Certain Provisions of 15 Laws in the Field of Agriculture and Environment dated 11 December 2025;

Upon the proposal of the Director General of the Department of Animal Health and Production;

The Minister of Agriculture and Environment hereby issues this Circular on amending and supplementing certain articles of Circulars on the management of veterinary drugs.

Article 1. Amendments to Circular No. 13/2016/TT-BNNPTNT dated June 2, 2016 by the Minister of Agriculture and Rural Development on Management of Veterinary Medicines amended and supplemented at Circular No. 18/2018/TT-BNNPTNT dated November 15, 2018; Circular No. 13/2022/TT-BNNPTNT dated September 28, 2022; Circular No. 09/2024/TT-BNNPTNT dated June 28, 2024; Circular No. 09/2025/TT-BNNMT dated June 19, 2025

1. Amendments and supplements to Point (d) of Clause (1), Point (d) of Clause (3), Point (d) of Clause (4) and Point (d) of Clause (5) of Article 3 as follows:

a) Amendments and supplements to Point (d) of Clause (1) as follows:

"d) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines. ISO quality management system certificate for imported chemical compounds and biological products (excluding vaccines, antibodies, diagnostic kits);

d1) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

b) Amendments and supplements to Point (d) of Clause (3) as follows:

"d) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines;

d1) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

c) Amendments and supplements to Point (d) of Clause (4) as follows:

"d) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines or ISO quality management system certificate;

d1) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

d) Amendments and supplements to Point (d) of Clause (5) as follows:

"d) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines or ISO quality management system certificate;

d1) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

2. Amendments to Clause (1) and Point (b) of Clause (3) of Article 8 as follows:

a) Amendments to Clause (1) as follows:

"1. Registration, Review and Issuance of Veterinary Medicine Circulation Certificates... a) The Department of Animal Health and Production shall receive application dossiers for circulation registration, conduct technical review, convene meetings of the Specialized Scientific Council for Veterinary Medicines, and issue veterinary medicine circulation certificates in the form specified in Appendix IX issued with Circular No. 13/2016/TT-BNNPTNT. The Director General of the Department of Animal Health and Production shall decide on the members and evaluation content of the Specialized Scientific Council for Veterinary Medicines. The Specialized Scientific Council for Veterinary Medicines shall meet at least once every three months to evaluate dossier review results, test results, trial results and recommend that the Director General of the Department of Animal Health and Production issue veterinary medicine circulation certificates;

b) For veterinary medicines already holding circulation certificates in Vietnam registering for contract manufacturing, component packaging or redistribution, the Department of Animal health and Production shall review the registration dossier and issue veterinary medicine circulation certificates for contract manufacturing, component packaging or redistribution in the form specified in Appendix XIII issued with Circular No. 13/2016/TT-BNNPTNT. For veterinary medicines not holding circulation certificates in Vietnam manufactured for export, the Department of Animal Health and Production shall review the registration dossier and issue veterinary medicine circulation certificates for export only in the form specified in Appendix XIV issued with Circular No. 13/2016/TT-BNNPTNT or as required by the importing country."

b) Amendments to Point (b) of Clause (3) as follows:

"b) The Department of Animal Health and Production shall be responsible for reviewing dossiers and providing results within the following timeframes: 10 (ten) days from the date of receiving a valid dossier for registration of production for export, contract manufacturing or component packaging; 30 (thirty) days from the date of receiving a valid dossier for registration of medicines exempted from trials or biological products for diagnosis; 04 (four) months from the date of receiving a valid dossier for registration of new medicines, vaccines, antibodies or herbal-based medicines."

3. Amendments and supplements to Clause (2) of Article 9 as follows:

"2. Contains errors; Changes to: product name; name and location of the registered facility; name and location of the manufacturing facility; product packaging specifications; medicine label format; expiration date and discontinuation period; treatment contraindications; treatment regimens; changes that do not affect the quality, efficacy or safety of veterinary medicines.

Dossier includes: Application for reissuance of veterinary medicine circulation certificate in the form specified in Appendix IV issued with Circular No. 13/2016/TT-BNNPTNT; documents related to the content changes; old and new label samples; statement of non-violation of intellectual property law provisions in the form specified in Appendix VII issued with Circular No. 13/2016/TT-BNNPTNT for cases of product name changes.

Within 10 (ten) days from the date of receiving a valid dossier, the Department of Animal health and Production shall review the dossier and reissue the veterinary medicine circulation certificate if the dossier meets requirements. In case of non-reissuance, a written response shall be provided stating the reasons. "

4. Amendments and supplements to Article 10 as follows:

"**Article 10. Extension of veterinary medicine circulation certificate**

1. Registration dossier for extension of veterinary medicine circulation certificate

a) Application for extension of circulation certificate in the form specified in Appendix V issued with Circular No. 13/2016/TT-BNNPTNT;

b) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines. ISO quality management system certificate for imported chemical compounds and biological products (excluding vaccines, antibodies, diagnostic kits) and Certificate of Adequate Conditions for Manufacturing Veterinary Medicines for domestically manufactured medicines or Certificate of Adequate Conditions for Importing Veterinary Medicines for imported medicines;

b1) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;

c) Product quality analysis report from the manufacturing facility or from the veterinary medicine testing agency designated in Vietnam issued within 12 (twelve) months prior to dossier submission for pharmaceuticals, chemical compounds and biological products; product quality analysis report from both the manufacturing facility and the veterinary medicine testing agency designated in Vietnam issued within 12 (twelve) months prior to dossier submission for vaccines and antibodies.

d) Contract for contract manufacturing, component packaging or redistribution of veterinary medicines between the contracting party and the contract manufacturing party for medicines manufactured under contract.

đ) Product stability monitoring report under storage conditions.

e) Report on veterinary medicine circulation in the form specified in Appendix VI issued with Circular No. 13/2016/TT-BNNPTNT.

2. Within 14 (fourteen) days from the date of receiving a valid dossier, the Department of Animal health and Production shall review the dossier and extend the veterinary medicine circulation certificate if the dossier meets requirements. In case of non-extension, a written response shall be provided stating the reasons."

5. Amendments and supplements to Article 18 as follows:

"Article 18. Registration for issuance and reissuance of veterinary medicine trial license

1. Application for issuance and reissuance of veterinary medicine trial license in the form specified in Appendix XV issued with Circular No. 13/2016/TT-BNNPTNT.

2. Report on evaluation results of trial facility adequacy according to the provisions in Clause 2, Article 45 of this Circular.

3. Technical documentation for each type of trial medicine includes:

a) Summary of product characteristics in the form specified in Appendix VIII issued with Circular No. 13/2016/TT-BNNPTNT;

b) Technical information on product quality;

c) Technical information on product safety and efficacy;

d) Product quality analysis report from the manufacturer (original or certified copy affixed with the registered facility's stamp);

đ) Product quality analysis report from the veterinary medicine testing agency designated in Vietnam (original or certified copy affixed with the registered facility's stamp);

e) Trial protocol;

g) Trial contract between the registered party and the trial facility (original or certified copy affixed with the registered facility's stamp).

4. Procedures for issuance of veterinary medicine trial license... a) The organization or individual shall register for issuance of veterinary medicine trial license with the Department of Animal health and Production;

b) Within 17 (seventeen) days from the date of receiving a valid dossier, the Department of Animal health and Production shall review the dossier and issue the veterinary medicine trial license if the dossier meets requirements. In case of non-issuance, a written response shall be provided stating the reasons.

5. Reissuance of veterinary medicine trial license (In cases of errors or changes to medicine name or information of the organization or individual registering the trial)

Dossier includes: Application for reissuance in the form specified in Appendix XVII issued with Circular No. 13/2016/TT-BNNPTNT;

The organization or individual shall register for reissuance of veterinary medicine trial license with the Department of Animal health and Production;

within 5 (five) working days from the date of receiving a valid dossier, the Department of Animal health and Production shall review the dossier and reissue the veterinary medicine trial license if the dossier meets requirements. In case of non-reissuance, a written response shall be provided stating the reasons."

6. Amendments and supplements to Points (c), (d) of Clause (1); Points (c), (d) of Clause (2); Points (c), (d) of Clause (6); Points (b), (c) of Clause (7); Clause (9) and supplements to Clause (11) of Article 22 as follows:

a) Amendments and supplements to Points (c), (d) of Clause (1) as follows:

"c) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines. ISO quality management system certificate for herbal-based veterinary medicines, chemical compounds and biological products (excluding vaccines, antibodies, diagnostic kits);

d) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

b) Amendments and supplements to Points (c), (d) of Clause (2) as follows:

"c) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines. ISO quality management system certificate for herbal-based veterinary medicines, chemical compounds and biological products (excluding vaccines, antibodies, diagnostic kits);

d) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

c) Amendments and supplements to Points (c), (d) of Clause (6) as follows:

"c) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards for imported veterinary medicines. ISO quality management system certificate for herbal-based veterinary medicines, chemical compounds and biological products (excluding vaccines, antibodies, diagnostic kits);

d) Certificate or document from the competent authority of the manufacturing or exporting country confirming that the product is permitted to circulate or be used in that country; Certificate or document from the competent state authority of another country confirming that the product is permitted to circulate or be used in that country for products not yet granted circulation or use permits in the manufacturing country;"

d) Amendments and supplements to Points (b), (c) of Clause (7) as follows:

"b) GMP certificate or document from the competent state authority of the manufacturing country confirming that the manufacturing facility applies GMP standards or ISO quality management system certificate for chemical compounds and biological products;

c) Certificate or document from the competent authority of the manufacturing country confirming that the imported raw material is permitted to circulate or be used in the manufacturing country;"

đ) Amendments and supplements to Clause (9) as follows:

"9. Certificates and documents from the competent authorities of the manufacturing or exporting country, CoA attached in the registration dossier may be submitted as originals or certified copies affixed with the registered organization's stamp."

e) Supplements to Clause (11) as follows:

"11. Within 5 (five) working days from the date of receiving a valid dossier, the Department of Animal health and Production shall consider issuing an import license. In case of non-issuance, a written response shall be provided stating the reasons."

Article 2. Amendments to Circular No. 10/2018/TT-BNNPTNT dated August 14, 2018 by the Minister of Agriculture and Rural Development on National Technical Standards for Veterinary Medicines - General Requirements amended by Circular No. 09/2025/TT-BNNMT dated June 19, 2025:

1. Amendments and supplements to Section 5 of QCVN 01-187: 2018/BNNPTNT (National Technical Standard for Veterinary Medicines -

General Requirements): Responsibilities of Organizations and Individuals in the National Technical Standard for Veterinary Medicines - General Requirements as follows:

"5.1. Organizations and individuals specified in Section 1.2 of this Standard shall comply with all provisions of this Standard.

5.2. The Department of Animal health and Production and the agency designated by the Provincial People's Committee to implement this Standard shall conduct inspections in accordance with the allocation and delegation of authority by the Ministry of Agriculture and Environment."

Article 3. Repeal of Clauses (1), (2), (3), (4) of Article 20 and Article 21 of Circular No. 13/2016/TT-BNNPTNT dated June 2, 2016 by the Minister of Agriculture and Rural Development on Management of Veterinary Medicines amended and supplemented at Circular No. 18/2018/TT-BNNPTNT dated November 15, 2018; Circular No. 13/2022/TT-BNNPTNT dated September 28, 2022; Circular No. 09/2024/TT-BNNPTNT dated June 28, 2024

Article 4. Effective date and transitional provisions

1. This Circular shall take effect from [date] 2026.

2. Transitional Provisions

Administrative procedures whose dossiers have been received by the competent agency before the effective date of this Circular shall continue to be processed in accordance with the regulations of the legal normative documents in effect at the time of dossier receipt.

Recipients:
- Prime Minister and Deputy Prime Ministers;
- National Assembly Ethnic Council; National Assembly Committees;
- Supreme People's Court;
- Supreme People's Procuracy;
- Central Committee of the Vietnam Fatherland Front;
- National Assembly Office;
- Government Office;
- Ministries, ministerial-level agencies, and government agencies;
- Deputy Ministers, Ministry of Agriculture and Environment;
- Provincial and Municipal People's Committees;
- Inspection Agency for Legal Documents and Administrative Penalty Management (Ministry of Justice);

MINISTER

Tran Duc Thang

- Government Gazette; Government Information Portal;
- Agriculture and Rural Development Departments of Provinces and Cities;
- Agencies and units under the Ministry of Agriculture and Environment;
- Ministry of Agriculture and Environment Information Portal;
- File: Archives, Documents.