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MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	**SOCIALIST REPUBLIC OF VIETNAM**
--------	**Independence – Freedom - Happiness**

No. 18/2018/TT-BNNPTNT	*Hanoi, November 15, 2018*

CIRCULAR

ON AMENDING AND REPEALING SOME ARTICLES OF THE CIRCULAR NO. 13/2016/TT-BNNPTNT DATED JUNE 02, 2016 OF THE MINISTER OF AGRICULTURE AND RURAL DEVELOPMENT ON VETERINARY DRUG MANAGEMENT

Pursuant to the Decree No. 15/2017/ND-CP dated February 17, 2017 of the Government on defining functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;

Pursuant to the Veterinary Law in 2015;

Pursuant to the Government's Decree No. 35/2016/ND-CP dated May 15, 2016 on guidelines for some articles of the Veterinary Law;

Pursuant to the Government's Decree No. 43/2017/ND-CP dated April 14, 2017 on good labels;

Pursuant to the Government's Decree No. 74/2018/ND-CP dated May 15, 2018 on amendments to some articles of the Government's Decree No. 132/2008/ND-CP dated December 31, 2008 on detailing the implementation of some articles of the Law on quality of products and goods;

Pursuant to the Government's Decree No. 132/2018/ND-CP dated September 17, 2018 on amendments to some articles of the Decree on investment and business requirements in the agriculture sector;

Pursuant to the Government's Decree No. 154/2018/ND-CP dated November 09, 2018 on amending and repealing some regulations on investment and business conditions in sectors under the management of the Ministry of Science and Technology and some regulations on specialized inspections;

At the request of the Head of the Veterinary Department,

Minister of Agriculture and Rural Development hereby promulgates the Circular on amending and repealing some articles of the Circular No. 13/2016/TT-BNNPTNT dated June 02, 2016 of the Minister of Agriculture and Rural Development on veterinary drug management.

Article 1. Amending and repealing some articles of the Circular No. 13/2016/TT-BNNPTNT dated February 02, 2016 of the Minister of Agriculture and Rural Development on veterinary drug management

1. Add the phrase “and method for evaluating the conformity with the veterinary drugs” to the title of Article 20; and add clause 5 to Article 20 as follows:

“5. Evaluation of the compatibility of veterinary drugs domestically produced shall be carried out in accordance with the formula 2 or formula 5 specified in Circular No. 28/2012/TT-BKHCN dated December 12, 2012 of the Minister of Science and Technology on declaration of standard conformity and declaration of technical regulation conformity and method for evaluating the conformity with standards and technical regulations (hereinafter referred to as "Circular No. 28/2012/TT-BKHCN). In case where the veterinary drug production facility has the Good Manufacturing Practice Certificate issued by the Veterinary Department and is still effective or the Certificate of Eligibility to Manufacture Veterinary Drugs issued by the aforesaid Department and is still effective, the manufacturing process shall not be re-evaluated."

2. Add clause 4 to Article 21 as follows:

“4. Upon importing drugs and medicinal ingredients for preparing veterinary drugs for manufacturing and business demands, if the veterinary drug manufacturing establishment has been issued with the GMP Certificate or the Certificate of Eligibility to Manufacture Veterinary Drug issued by the Veterinary Department and is still effective, such establishment is not required to complete the procedures for issuing the Certificate of Eligibility to Import Veterinary Drugs if such drugs of the same types have been licensed to be produced."

3. The title of clause 3, Article 22 is amended as follows:

“3. Application dossier on veterinary drug import for exhibition, fair, scientific research, prevention and treatment of rare animal diseases, shall consist of:"

4. Change the phrase "Summarization of the product characteristics” to “Summarization of product characteristics using the form specified in Appendix VIII hereto" specified in clause 2e, clause 3dd, clause 5d of the Article 22.

5. Title of clause 7, Article 22 is amended as follows:

“7. Application dossier for importing medicinal ingredients to prepare veterinary drugs (except the application dossier for importing medicinal ingredients which are solvents and excipients, including the documents specified in points a, d and dd of this clause), shall consist of:

6. Change the phrase “Article 10 of the Government’s Decree No. 89/2006/ND-CP dated August 30, 2006 on good labels (hereinafter referred to as “the Government’s Decree No. 89/2006/ND-CP)” to “Article 9 of the Government’s Decree No. 43/2017/ND-CP on good labels (hereinafter referred to as Decree No. 43/2017/ND-CP)" in clause 4, Article 24; change the phrase “clause 1, Article 6 of the Government’s Decree No. 89/2006/ND-CP” to "Article 4 of the Decree No.

43/2017/ND-CP” in clause 1, Article 25; change the phrase “Article 8 of the Decree No. 89/2006/ND-CP” to “Article 6 of the Decree No. 43/2017/ND-CP” in clause 3, Article 25; change the phrase “clause 1, Article 18 of the Decree No. 89/2006/ND-CP” to “Article clause 1, Article 16 of the Decree No. 43/2017/ND-CP” in clause 2a, Article 28; change the phrase “Article 16 of the Decree No. 89/2006/ND-CP) to “Article 14 of the Decree No. 43/2017/ND-CP” in clause 5d, Article 28.

7. Clause 1a, Article 30 is amended as follows:

“a. Conduct tests and assessments of quality of drugs produced, exported, imported and sold nationwide."

8. Add clause 4 to Article 30 as follows:

“4. The veterinary drug testing establishment shall:

a. For the medicinal ingredients of veterinary drugs, pharmaceutical products, chemicals and biological products of which the sensory, physical and chemical properties are evaluated, return the results of the veterinary drug quality or the results of compatibility evaluation within 05 working days; within 14 days for the medicinal ingredients of veterinary drugs, pharmaceutical products, chemicals and biological products of which the bacterial contamination and sterilization are tested; 21 days for the vaccines and antibodies of which the bacterial contamination is tested or the purity or safety is inspected; 60 days for the vaccines and antibodies of which the effectiveness is inspected after receiving the drug sample;

b. Store the samples of the batch of veterinary drugs of which the quality is tested under the preservation conditions specified on the labels until the veterinary drugs expire.”

9. Article 31 is amended as follows:

“Article 31. Application of the methods for testing veterinary drugs

1. The testing of drugs shall be conducted according to the registered or assigned testing methods as regulated by laws.

2. For the veterinary drugs of which the testing methods are not registered or assigned or are only temporarily assigned, the quality evaluation shall be carried out based on the quality testing results of the competent agency of the importing country or of the laboratory recognized by the evaluation organization signing the Mutual Recognition Agreement (MRA) within the Asia Pacific Laboratory Accreditation Cooperation (APLAC); International Laboratory Accreditation Cooperation (ILAC) or the reference laboratory of the World Organization for Animal Health (OIE).”

10. Add clause 1d to Article 32 as follows:

“d. ASEAN standards for veterinary vaccines; guidelines for diagnosis and testing of veterinary vaccines of the OIE, and international standards for veterinary vaccines of which Vietnam is a signatory."

11. Article 34 is amended as follows:

“Article 34. State testing of quality of imported veterinary drugs

1. Inspecting agency: Veterinary Department

2. Subject of inspection: veterinary drugs imported to Vietnam must be tested for their quality, except the cases specified in clause 3 of this Article.

3. Cases where imported veterinary drugs are not subject to quality test:

a. Veterinary drugs imported as samples for testing and registration;

b. Veterinary drugs imported to cure animals temporarily imported for re-export or transited through Vietnam;

c. Veterinary drugs imported as medicinal ingredients used for diagnosis and testing pertaining to animal healthcare

d. Medicinal ingredients used for preparing veterinary drugs;

dd. Cases which are not subject to quality testing during the import process are specified in clause 3, Article 1 of the Government’s Decree No. 74/2018/ND-CP dated May 15, 2018 on amendments to the Government’s Decree No. 132/2008/ND-CP dated December 31, 2008 on providing guidelines for the implementation of some articles of the Law on Quality of Products and Goods (hereinafter referred to as Decree No. 74/2018/ND-CP);

e. Cases specified in clause 2, Article 4 of the Government’s Decree No. 154/2018/ND-CP dated November 09, 2018 on amending, supplementing and repealing some regulations on investment and business conditions in sectors under management of the Minister of Science and Technology and some regulations on specialized inspections (hereinafter referred to as "Decree No. 154/2018/ND-CP).

4. Dossier, procedures and contents of the state inspection of the quality of imported veterinary drugs:

a. Implement the regulations specified in clause 3, Article 1 of the Decree No. 74/2018/ND-CP; clause 1, clause 3, Article 4 of the Decree No. 154/2018/ND-CP;

b. Quality certificate is the Certificate that shows the result of the conformity with the national technical regulation and application standards; quality certificate issued by the importing country is the Certificate of Analysis (CoA) of the manufacturer’s veterinary drug quality or issued by

the competent agency of the exporting country. If a recognized or appointed conformity-certifying organization is not available or the product does not have a declaration of conformity, the quality certificate of the import shipment will be the quality inspection result provided by an appointed laboratory; recognize the manufacturer's quality inspection result if an appointed test method is not available, or recognize the inspection quality in accordance with Clause 2, Article 31 of this Circular;

c. For application dossier for quality testing of batches of imported vaccines and veterinary antibodies, the importer shall provide the quality certificate within 60 days from the date of registration.

5. The conformity of the imported veterinary drugs shall be evaluated by using the second method specified in the Circular No. 28/2012/TT-BKHCN. The conformity evaluation is not required to include the process evaluation if:

a. The veterinary drug manufacturing establishment has obtained an unexpired GMP Certificate issued by the competent agency of the importing country;

b. The veterinary drug manufacturing establishment has obtained the ISO Certificate or another equivalent Certificate related to some common chemicals.

6. The handling of violations during the inspection process shall be carried out in accordance with the regulations specified in Article 36 of the Law on Product and Goods Quality."

12. Repeal Article 35.

13. Clause 2, Article 36 is amended as follows:

"2. Contents and procedures for testing the quality of veterinary drugs sold in the market shall comply with the regulations specified in Circular No. 26/2012/TT-BKHCN dated December 12, 2012 of the Minister of Science and Technology on inspection of quality of goods sold in the market and Circular No. 12/2017/TT-BKHCN dated September 28, 2017 of the Minister of Science and Technology on amendments to some articles of the Circular No. 26/2012/TT-BKHCN dated December 12, 2012 of the Minister of Science and Technology on state inspection of the quality of goods sold in the market."

14. Clause 2, Article 45 is amended as follows:

"2. Evaluate the conditions of the veterinary drug testing establishment specified in Article 88 of the Veterinary Law, Article 20 of the Decree No. 35/2016/ND-CP dated May 15, 2016 as requested by the Veterinary Department and clause 5, Article 2 of the Government's Decree No. 123/2018/ND-CP dated September 17, 2018 on amendments to some regulations on investment and business requirements in agriculture sector (hereinafter referred to as Decree No. 123/2018/ND-CP)".

15. Article 49 is amended as follows:

“Article 49. Establishments producing, trading and importing veterinary drugs

1. The manufacturing establishment shall satisfy the requirements specified in Article 90, clause 2 of Article 91 of the Veterinary Law, Articles 12 and 13 of the Decree No. 35/2016/ND-CP dated May 15, 2016 and clause 1, Article 2 of the Decree No. 123/2018/ND-CP.

2. The trading establishment shall satisfy the requirements specified in Article 92, clause 2, Article 93 of the Veterinary Law, Article 17 of the Decree No. 35/2016/ND-CP dated May 15, 2016 and clause 2, Article 2 of the Decree No. 123/2018/ND-CP.

3. Importing establishment

a. Satisfy the requirements specified in Article 94, clause 2, Article 95 of the Veterinary Law, Article 18 of the Decree No. 35/2016/ND-CP dated May 15, 2016 and clause 3, Article 2 of the Decree No. 123/2018/ND-CP;

b. Only sell medicinal ingredients of veterinary drugs to the establishments eligible for trading such ingredients and establishments eligible for producing veterinary drugs. Do not sell the ingredients thereof to the veterinary drug agencies or stores, citizens or aquaculture establishments for use."

16. Add the sentence “Quantity of drugs imported for reference (if any)” to the sentence “Testing criteria:” specified in Appendix XVI veterinary drug testing license.

17. Add the sentence “Pursuant to the Circular No. 18/2018/TT-BNNPTNT dated November 15, 2018 of the Minister of Agriculture and Rural Development on amending, supplementing and repealing some articles of the Circular No. 13/2016/TT-BNNPTNT dated June 02, 2016 on veterinary drug management" to the pursuant parts specified in Appendices I, II, III, IV, V, VII, X, XI, XII, XVII, XIX, XX, XXVIII, XXXI.

18. Repeal the Appendices XXXVII, XXXVIII, XXXIX.

19. Part II. Evaluation criteria group of the “inspection record of the eligibility to manufacture veterinary drugs” specified in Appendix XXIII is amended as follows:

a. Group section 1.1 and 1.2 into 01 section “There must be a safe distance between the production area and the residential areas, public works, hospitals, veterinary policlinics, animal health diagnostic establishment and polluted areas;”

b. Modify section 16.3 to "Appropriate ventilation and vacuum equipment."

20. Repeal the phrase “fire control and prevention” in section 1.16.2 of the part “Guidelines for inspecting the conditions of veterinary drug manufacturing establishment" specified in Appendix XXIII.

21. Add clauses 5, 6 and 7 to Article 51 as follows:

“5. Veterinary drugs which have been issued the sale license before this Circular comes into force but have not been announced as satisfactory may continue to be sold and the inspection of and procedures for announcing the drugs as satisfactory shall be carried out in accordance with the law within 02 years from the effective date of this Circular.

6. Application dossiers for sale registration of veterinary drugs which have been submitted to the Veterinary Department before this Circular comes into force shall continue to be appraised and issued the sale license by such Department and shall be inspected and announced as satisfactory in accordance with clause 5 of this Article.

7. For the imported veterinary drugs of which the application for quality inspection has been submitted to the inspecting agency before this Circular comes into force, their quality shall continue to be inspected in accordance with the regulations specified in Circular No. 13/2016/TT-BNNPTNT dated June 02, 2016 of the Minister of Agriculture and Rural Development."

Article 2. Entry into force

This Circular shall come into force from February 14, 2019.

Article 3. Implementation responsibilities

1. Chief of the Ministry Office, Minister of Veterinary Department, Heads of related units, organizations and individuals shall implement this Circular.

2. During the implementation process, if any problems arise or amendments must be made, agencies, organizations and individuals shall timely provide feedback to the Ministry of Agriculture and Rural Development (Veterinary Department) for solution./.

PP. MINISTER
DEPUTY MINISTER

Phung Duc Tien