MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

THE SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

No. 12/2020/TT-BNNPTNT

Hanoi, November 09, 2020

CIRCULAR

PROVIDING FOR MANAGEMENT OF VETERINARY DRUGS CONTAINING NARCOTIC SUBSTANCES AND PRECURSORS; VETERINARY PRESCRIBING; AMENDMENTS TO CIRCULAR NO. 18/2018/TT-BNNPTNT

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

Pursuant to the Law on Veterinary Medicine dated June 19, 2015:

Pursuant to the Law on Animal Husbandry dated November 19, 2018;

Pursuant to the Government's Decree No. 80/2001/ND-CP dated November 05, 2001 on guidelines for control of lawful activities pertaining to narcotics in Vietnam;

Pursuant to the Government's Decree No. 58/2003/ND-CP dated May 29, 2003 on control of import, export and transit of narcotic substances, precursors, addictive drugs, and psychotropic drugs;

Pursuant to the Government's Decree No. 73/2018/ND-CP dated May 15, 2018 on List of narcotic substances and precursors;

Pursuant to the Government's Decree No. 13/2020/ND-CP dated January 21, 2020 on elaboration of the Law on Animal Husbandry;

Pursuant to the Government's Decree No. 60/2020/ND-CP dated May 29, 2020 amending list of narcotic substances and precursors enclosed with the Government's Decree No. 73/2018/ND-CP dated May 15, 2018 on list of narcotic substances and precursors;

At the request of the Director of the Department of Animal Health,

The Minister of Agriculture and Rural Development hereby promulgates a Circular providing for management of veterinary drugs containing narcotic substances and precursors; veterinary prescribing; amendments to Circular No. 18/2018/TT-BNNPTNT.

Chapter I

GENERAL

Article 1. Scope

This Circular provides for:

- 1. Import, export, transit through Vietnam, production, trading in, use, delivery, transport and storage of veterinary drugs containing narcotic substances and precursors; veterinary prescribing within the territory of Vietnam.
- 2. List of antibiotics specified in Clause 4 Article 12 of the Government's Decree No. 13/2020/ND-CP dated January 21, 2020 on elaboration of the Law on Animal Husbandry (hereinafter referred to as "13/2020/ND-CP").
- 3. Amendments to the Circular No. 18/2018/TT-BNNPTNT dated November 15, 2018 of the Minister of Agriculture and Rural Development 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 (hereinafter referred to as "the Circular No. 18/2018/TT-BNNPTNT").

Article 2. Regulated entities

This Circular applies to:

- 1. Domestic and foreign organizations and individuals related to import, export, transit through Vietnam, production, trading in, use, delivery, transport and storage of veterinary drugs containing narcotic substances and precursors; veterinary practice, veterinary prescribing and use of veterinary prescriptions within the territory of Vietnam.
- 2. Organizations and individuals producing and importing veterinary drugs within the territory of Vietnam.

Article 3. Definitions

For the purposes of this Circular, the terms below shall be construed as follows:

- 1. "veterinary drugs and veterinary drug materials containing narcotic substances and precursors" (hereinafter referred to as "narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials") mean those specified in List III and List IV enclosed with the Decree No. 73/2018/ND-CP and the Decree No. 60/2020/ND-CP.
- 2. "use of antibiotic-containing veterinary drugs for animal disease prevention" means the use of antibiotic-containing veterinary drugs in terrestrial animals in the juvenile period as prescribed in Clause 1 Article 12 of the Decree No. 13/2020/ND-CP, which are at risk of catching diseases and show no clinical signs of diseases.
- 3. "use of antibiotic-containing veterinary drugs for provision of preventive treatment for animals" means the use of antibiotic-containing veterinary drugs in a group of animals at risk of catching a disease when one or more animals in the group is diagnosed with a disease or suspected of catching a disease or for the purposes of preventing or treating infections before and after surgery for animals.
- 4. "use of veterinary drugs for animal disease prevention" means the use of veterinary drugs in animals showing clinical signs of disease or diagnosed with a disease.

Chapter II

MANAGEMENT OF NARCOTIC SUBSTANCE- AND PRECURSOR-CONTAINING VETERINARY DRUGS

Article 4. Import of narcotic substance- and precursor-containing veterinary drugs; narcotic substance-containing veterinary drug materials

- 1. Organizations and individuals entitled to apply for the license to import narcotic substance- and precursor-containing veterinary drugs include:
- a) Organizations and individuals that have the certificate of eligibility to import veterinary drugs or certificate of eligibility to produce veterinary drugs as prescribed by the law on veterinary medicine;
- b) Organizations and individuals that apply for import of narcotic substance- and precursor-containing veterinary drugs for the first time for the purposes of participation in exhibitions or fairs, scientific search, precious and rare animal disease prevention and treatment and have the business registration certificate or enterprise registration certificate or investment license or establishment decision issued by a competent authority.
- 2. Applications and procedures for importing narcotic substance- and precursor-containing veterinary drugs that have the certificate of free sale in Vietnam, narcotic substance-containing veterinary drug materials are as follows:
- a) An application includes: an application form for import of narcotic substance- and precursor-containing veterinary drugs, which is made using the form in the Appendix I hereof and the documents specified in Point a Clause 1 Article 6 of the Government's Decree No. 58/2003/ND-CP dated May 29, 2003 on control of import, export and transit of narcotic substances, precursors, addictive drugs, and psychotropic drugs (hereinafter referred to as "the 58/2003/ND-CP"); the foreign documents must be translated into Vietnamese and certified the translation. The applicant shall submit 01 application, whether in person or by post or online (through the national single-window system or online public service);
- b) The import procedures are specified in Clause 3 Article 6 of the Decree No. 58/2003/ND-CP.
- 3. Applications and procedures for importing narcotic substance- and precursor-containing veterinary drugs that are yet to have the certificate of free sale in Vietnam are as follows:
- a) An application includes the documents specified in Point a Clause 2 of this Article; the documents in Points b, c, d, dd and e Clause 1 Article 22 of the Circular No. 13/2016/TT-BNNPTNT dated June 02, 2016 of the Minister of Agriculture and Rural Development (hereinafter referred to as "the Circular No. 13/2016/TT-BNNPTNT") in the case of import for emergency animal disease prevention and control or disaster recovery; the documents in Points c, d, dd and e Clause 3 Article 22 of the Circular No. 13/2016/TT-BNNPTNT in the case of import for participation in an exhibition or fair, scientific research or rare and precious animal disease prevention and treatment. The applicant shall submit 01 application, whether in person or by post or online (through the national single-window system or online public service);
- b) The import procedures are specified in Point b Clause 2 of this Article.
- 4. Regulations on import of narcotic substance-containing veterinary drugs materials:
- a) The permission for import of narcotic substance-containing veterinary drug materials is only granted to a producer that imports veterinary drugs to serve its production activities;
- b) If veterinary drugs materials are not used up, the importer is permitted to transfer them to the producer that complies with the regulation set out in Clause 1 Article 7 hereof and a written notification shall be sent to the Department of Animal Health before the transfer;

- c) An application for import of narcotic substance-containing veterinary drugs includes the documents mentioned in Point a Clause 2 of this Article and Points b, c and d Clause 7 Article 22 of the Circular No. 13/2016/TT-BNNPTNT. The applicant shall submit 01 application, whether in person or by post or online (through the national single-window system or online public service);
- b) The import procedures are specified in Point b Clause 2 of this Article.
- 5. The Department of Animal Health has the power to issue licenses to import narcotic substance- and precursor-containing veterinary drugs, and narcotic substance-containing veterinary drug materials.
- 6. The license to import narcotic substance- and precursor-containing veterinary drugs or narcotic-containing veterinary drug materials is issued for each import and valid for 12 months from the date of issue.
- 7. The importer shall physically or electronically archive records on import of narcotic substance- and precursor-containing veterinary drugs or narcotic-containing veterinary drug materials, including:
- a) A delivery, receipt and inventory logbook, which is prepared using the form in the Appendix III hereof;
- b) A delivery note, which is prepared using the form in the Appendix IV hereof;
- c) Documents concerning import, sale and transfer of narcotic substance- and precursor-containing veterinary drugs or narcotic-containing veterinary drug materials.

Article 5. Export of narcotic substance- and precursor-containing veterinary drugs

- 1. Narcotic substance- and precursor-containing veterinary drugs for export must have the certificate of free sale in Vietnam.
- 2. Applications and procedures for exporting narcotic substance- and precursor-containing veterinary drugs are as follows:
- a) An application includes an application form for export of narcotic substance- and precursor-containing veterinary drugs, which is made using the form in the Appendix I hereof and the documents mentioned in Point a Clause 1 Article 6 of the Decree No. 58/2003/ND-CP. The foreign documents must be translated into Vietnamese and certified the translation. The applicant shall submit 01 application, whether in person or by post or online (through the national single-window system or online public service);
- b) The export procedures are specified in Clause 3 Article 6 of the Decree No. 58/2003/ND-CP.
- 3. The Department of Animal Health has the power to issue the license to export substance- and precursor-containing veterinary drugs.
- 4. The license to export substance- and precursor-containing veterinary drugs is issued for each import and valid for 12 months from the date of issue.
- 5. The exporter shall physically or electronically archive records on export of substance- and precursor-containing veterinary drugs, including:
- a) The documents specified in Points a and b Clause 7 Article 4 hereof;
- b) Documents concerning export and sale of substance- and precursor-containing veterinary drugs.

Article 6. Transit of substance- and precursor-containing veterinary drugs and veterinary drug materials through Vietnam

Applications and procedures for licensing transit of substance- and precursor-containing veterinary drugs and veterinary drug materials through Vietnam are specified in Articles 12 and 13 of the Decree No. 58/2003/ND-CP.

Article 7. Production and registration of sale of narcotic substance- and precursor-containing veterinary drugs

- 1. Domestic production of substance- and precursor-containing veterinary drugs shall be only carried out by producers having an effective certificate of eligibility to produce veterinary drugs issued by the Department of Animal Health.
- 2. Procedures for registering sale of substance- and precursor-containing veterinary drugs are specified Articles 3 and 8 of the Decree No. 13/2016/TT-BNNPTNT.
- 3. The manufacturer shall physically or electronically archive substance- and precursor-containing veterinary drug production records, including:
- a) A processing and production logbook, which is prepared using the form in the Appendix V hereof;
- b) The documents specified in Points a and b Clause 7 Article 4 hereof;

c) Documents concerning sale of narcotic substance- and precursor-containing veterinary drugs; substance- and precursor-containing veterinary drug materials.

Article 8. Trading in narcotic substance- and precursor-containing veterinary drugs licensed for free sale in Vietnam

- 1. Every trader of narcotic substance- and precursor-containing veterinary drugs must obtain the certificate of eligibility to trade veterinary drugs as prescribed by the law on veterinary medicine.
- 2. The trader of veterinary drugs is only allowed to sell narcotic substance- and precursor-containing veterinary drugs to users that have the prescription as prescribed in this Circular and other traders that have the certificate of eligibility to trade veterinary drugs issued by the provincial veterinary authority.
- 3. The trader shall physically or electronically archive records on trading in narcotic substance- and precursor-containing veterinary drugs, including:
- a) The documents specified in Points a and b Clause 7 Article 4 hereof;
- b) Contracts, invoices and documents concerning sale of substance- and precursor-containing veterinary drugs;
- c) Prescriptions for substance- and precursor-containing veterinary drugs archived by the trader after the sale; record on receipt of substance- and precursor-containing veterinary drugs, which is prepared using the form in the Appendix VI hereof.

Article 9. Use of substance- and precursor-containing veterinary drugs for animal disease treatment

- 1. A person having the veterinary practice certificate covering animal diagnosis, examination, surgery and testing is permitted to use substance- and precursor-containing veterinary drugs to treat animal diseases by prescription; the substance- and precursor-containing veterinary drugs that are not used or are underused must be returned to the veterinary drug selling establishment within 10 days.
- 2. The veterinary drug selling establishment shall receive and make a record on receipt of the substance- and precursor-containing veterinary drugs that are not used or are underused from the user specified in Clause 1 of this Article using the form in the Appendix VI hereof. The record shall be made into 02 copies (01 archived at the veterinary drug selling establishment, 01 issued to the user).

Article 10. Storage of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials

- 1. Importers and producers must store narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials in separate warehouses and cabinets that should be marked with signs and firmly locked, and separate them from other veterinary drugs, veterinary drug materials, animal feeds, aquaculture feeds and raw materials for production of animal feeds and aquaculture feeds, and other products.
- 2. Traders must separately store narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials in lockable cabinets marked with signs.
- 3. Users must separately store narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials and avoid loss during use.

Article 11. Delivery and transport of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials

- 1. The delivery of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials shall comply with Clauses 2 and 3 Article 6 of the Decree No. 80/2001/ND-CP.
- 2. The transport of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials shall comply with Clause Article 8 of the Decree No. 80/2001/ND-CP.

Article 12. Period of archiving of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials

- 1. Establishments importing, exporting, producing, trading and using of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials shall physically or electronically archive relevant documents for at least 02 (two) years from the expiry of the narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials; prescriptions for substance- and precursor-containing veterinary drugs shall be archived as prescribed in Article 22 hereof.
- 2. As the archiving period expires, heads of the establishments specified in Clause 1 of this Article shall establish a council to destroy documents, make a destruction record and archive it.

Chapter III

VETERINARY PRESCRIBING

- 1. All veterinary drugs must be prescribed prior to use, except the veterinary drugs specified in Article 1 hereof.
- 2. The prescribing of veterinary drugs must be based on the examination or diagnosis or testing result, except for the cases in Clause 1 Article 19 hereof; ensure appropriateness, safety, efficiency and suitability for the degree of the disease.
- 3. The prescriber is only allowed to prescribe the veterinary drugs licensed for sale and use in Vietnam.

Article 14. Types of veterinary drugs not subject to prescription

Types of veterinary drugs that are not subject to prescription must be used following the manufacturer's instructions, including:

- 1. Veterinary drugs containing active ingredients belonging to the group of anticoccidial drugs, including Decoquinate, Diclazuril, Halofuginone hydrobromide, Lasalocid A sodium, Maduramicin ammonium alpha, Monensin sodium, Narasin, Nicarbazin, Robenidine hydrochloride, Salinomycin sodium and Semduramicin sodium.
- 2. Veterinary drugs containing antiseptics, disinfects and decontaminants, which are used in animal husbandry and aquaculture.
- 3. Vaccines and antibodies used in veterinary medicine.
- 4. Hormones used in aquaculture.
- 5. Veterinary drugs intended for strengthening resistance and supporting disease treatment.
- 6. Herbal medicines and materials used in veterinary medicine.

Article 15. Lists of antibiotic active ingredients used for terrestrial animal disease prevention

- 1. List of veterinary active ingredients belonging to group of critically important antibiotics, which is provided in Appendix VIII hereof.
- 2. List of veterinary active ingredients belonging to group of highly important antibiotics, which is provided in Appendix IX hereof.
- 3. List of veterinary active ingredients belonging to group of important antibiotics, which is provided in Appendix X hereof.
- 4. The period of use of antibiotic-containing veterinary drugs specified in Clauses 1, 2 and 3 of this Article for animal disease prevention in the juvenile period shall comply with Clause 3 Article 12 of the Decree No. 13/2020/ND-CP.

Article 16. Types of veterinary drugs directly used for treatment by holders of the practice certificate covering animal diagnosis, examination, surgery and testing

- 1. Injectable analgesics, except for nonsteroidal anti-inflammatory drugs.
- Inhalational or injectable anesthetics.
- 3. Analgesics (opioid or opiates), anti-epileptic drugs, barbiturates, benzodiazepines and antipsychotics.
- 4. Selenium injection.
- 5. Injectable medicines acting on sympathetic and parasympathetic nervous systems.
- 6. Hormones used for injection, including adrenal glands; adrenal steroids; sex hormones containing anabolic steroids.
- 7. Veterinary drugs used for intravenous injection.

Article 17. Veterinary prescribers

The following individuals are allowed to prescribe veterinary drugs:

- 1. Holders of the veterinary practice certificate covering animal diagnosis, examination, surgery and testing.
- 2. Veterinarians or persons who obtain a bachelor's degree in veterinary medicine, animal husbandry veterinary medicine and have the veterinary practice certificate covering animal diagnosis, examination, surgery and testing when prescribing narcotic substance- and precursor-containing veterinary drugs.

Article 18. Veterinary prescribing

1. Contents of a prescription must be written in a sufficient, clear and accurate manner according to the form in the Appendix VII hereof.

- 2. Veterinary drugs shall be prescribed as follows:
- a) Regarding active ingredient-single veterinary drugs

Assign international nonproprietary names (INN aka generic name). E.g. If a drug contains 500mg of active ingredient Amoxicillin, its name shall be written out as Amoxicilline 500mg.

Assign international nonproprietary names and trade names. E.g. If a drug contains 500mg of active ingredient Amoxicillin and is known under the trade name A, its name shall be written out as Amoxicilline (A) 500mg.

- b) Regarding veterinary drugs containing multiple active ingredients: assign trade names and names of main active ingredients.
- 3. It is required to write names, strength or content of active ingredients, weight, quantity or volume, dose, route of administration, time of administration if necessary) and dosing interval of each type of drug.
- 4. A 0 (zero) number shall be put in front of the one-digit number indicating the quantity of drug (less than 10).
- 5. The prescriber shall put his/her signature next to the corrections made to the prescription.
- 6. The blank from the bottom left of prescription contents to the top right of the prescriber's signature must be crossed out; the prescriber must sign and write his/her full name (or affix his/her signature stamp).
- 7. Contraindications and warnings shall be specified.
- 8. The prescription is valid for one-time use only and must be marked to show it has been dispensed..

Article 19. Prescribing of veterinary drugs in production of animal feeds

- 1. Prescribing of antibiotic-containing veterinary drugs for animal disease prevention shall be carried out as follows:
- a) The prescribing of antibiotic-containing veterinary drugs for animal disease prevention only applies to young animals. The determination of whether an animal is in the juvenile period shall comply with Clause 1 Article 12 of the Decree No. 13/2020/ND-CP;
- b) The prescribing shall comply with Clause 3 Article 13, Article 17 and Article 18 hereof and ensure appropriateness, safety and efficiency. The prescription shall be made up using the Form No. 2 in the Appendix VII hereof.
- 2. The prescribing of veterinary drugs for providing treatment and preventive treatment for animals shall comply with Articles 13, 17 and 18 hereof. The prescription shall be made up using the Form No. 1 in the Appendix VII hereof.

Article 20. Prescribing of narcotic substance- and precursor-containing veterinary drugs

- 1. A prescription for narcotic substance- and precursor-containing veterinary drugs shall be made into 03 copies: 01 archived at the examination, diagnosis, surgery and testing establishment; 01 archived at the animal raising establishment; 01 archived at the veterinary drug supplying and selling establishment. If the prescription is made up and the veterinary drugs are sold by the examination, diagnosis, surgery and testing establishment itself, the prescription shall be made into 02 copies: 01 archived by the prescriber; 01 archived at the animal raising establishment.
- 2. The quantity of drugs in a prescription shall not exceed a 07 (seven)-day supply or shall follow the manufacturer's instructions and comply with Articles 13, 17 and 18 hereof.
- 3. The establishment or individual in charge of examination, diagnosis, surgery and testing shall compile and send a list of sample signatures of prescribers for narcotic substance- and precursor-containing veterinary drugs to the provincial veterinary authority.

Article 21. Prescribing of veterinary drugs applying information technology

- 1. The prescription shall be made up by computer aid or electronic device and stored on software of the examination, diagnosis, surgery and testing establishment. Prescriptions for narcotic substance-and precursor-containing veterinary drugs must be printed out and delivered to animal owners, and also kept by veterinary drug supplying and selling establishment.
- 2. Every examination, diagnosis, surgery and testing establishment must ensure that prescriptions are archived for management and data retrieval when necessary.

Article 22. Archiving of veterinary prescriptions

1. Every organization and individual practicing in examination, diagnosis, surgery and testing, animal feed producer, veterinary drug wholesaler, livestock production establishment and aquaculture establishment must archive prescriptions for at least 02 (two) years from the prescribing date.

- 2. A prescription may be archived adopting one of the following methods:
- a) Archiving its original or copy;
- b) Storing the prescription on the software in a manner that facilitates retrieval. Information includes: name and address of the animal disease diagnostic and treatment facility; full name of the prescriber; name and address of the animal feed producer that uses the prescription; full name and address of the animal/animal species owner; name, content, quantity, dose and route of administration of drugs.

Chapter IV

IMPLEMENTATION

Article 23. Responsibilities of specialized agencies

- 1. The Department of Animal Health shall:
- a) organize, provide guidance on, supervise, assess and inspect the implementation of this Circular;
- b) organize dissemination of information about import, export, transit, production, trading in, use, delivery, transport and storage of narcotic substance- and precursor-containing veterinary drugs and veterinary drug materials; veterinary prescribing and reasonable and effective use of veterinary drugs;
- c) organize inspection of prescribing of veterinary drugs containing antibiotics used in animal feeds;
- d) provide guidance on professional training in veterinary prescribing to holders of veterinary practice certificates;
- d) submit to the Ministry of Agriculture and Rural Development amended Lists of veterinary active ingredients belonging to group of critically important, highly important and important antibiotics provided in the Appendices VIII, IX and X hereof.
- 2. The Department of Livestock Production shall:
- a) provide guidance, supervise and inspect animal establishments producing animal feeds containing veterinary drugs;
- b) organize training and dissemination of information about veterinary prescribing and reasonable and effective use of animal feeds containing veterinary drugs.
- 3. The Directorate of Fisheries shall:
- a) organize dissemination of information about use of veterinary drugs to aquaculture establishments;
- b) cooperate with the Department of Animal Health in inspect the use of veterinary drugs by aquaculture establishments.
- 4. Every provincial Department of Agriculture and Rural Development shall direct competent units to:
- a) organize, provide guidance on, supervise and inspect the implementation of this Circular in areas under their management;
- b) manage lists and sample signatures of prescribers making up prescriptions of narcotic- and precursor-containing veterinary drugs;
- c) provide training and disseminate information about management of narcotic- and precursorcontaining veterinary drugs during their trading, use, delivery, transport and storage; veterinary prescribing in areas under their management;
- d) inspect the trading in, use, storage, delivery and transport of narcotic- and precursor-containing veterinary drugs as prescribed in this Circular in areas under their management;
- dd) on the 25th of every month, submit a report on trading in, use and delivery of narcotic- and precursor-containing veterinary drugs to the Department of Animal Health and Sub-department of Animal Health in areas under their management according to the form in the Appendix II hereof;
- e) provide professional training in veterinary prescribing to holders of veterinary practice certificates;
- g) build a roadmap for management of database of prescriptions in areas under their management.

Article 24. Responsibilities of relevant organizations and individuals

- 1. Producers and importers of narcotic- and precursor-containing veterinary drugs shall:
- a) only sell narcotic- and precursor-containing veterinary drugs to traders that have the certificate of eligibility to trade veterinary drugs as prescribed, facilities licensed to practice animal diagnosis, examination, surgery and testing;
- b) archive documents as prescribed in this Circular; on the 25th of the last month of each quarter and December 20 ever year or upon request, submit a report on production and use of narcotic- and

precursor-containing veterinary drugs to the Department of Animal Health and Sub-department of Animal Health in areas under their management according to the form in the Appendix II hereof.

- 2. Traders of veterinary drugs shall:
- a) only sell veterinary drugs to other traders of veterinary drugs that have been issued with the certificate of eligibility to trade veterinary drugs and to users with prescriptions as prescribed in this Circular;
- b) receive narcotic- and precursor-containing veterinary drugs that are yet to be used or expired from animal owners or their representatives as prescribed in Clause 2 Article 9 hereof;
- c) archive prescriptions as prescribed in Article 22 hereof;
- d) archive documents as prescribed in this Circular; on the 20th of every month or upon request, submit to the provincial veterinary authority a report on quantity and purposes of veterinary drugs imported or sold, address of the veterinary drug purchaser, quantity of narcotic- and precursor-containing veterinary drugs recalled according to the form in the Appendix II hereof.
- 3. Animal diagnosis, examination, surgery and testing facilities shall:
- a) supply and sell veterinary drugs when a prescription prescribed in this Circular is presented;
- b) receive narcotic- and precursor-containing veterinary drugs returned by animal owners or their representatives;
- c) archive prescriptions as prescribed in Article 22 hereof;
- d) on the 20th of every month or upon request, submit to the local veterinary authority a report on quantity, purposes, address of the purchaser of narcotic- and precursor-containing veterinary drugs according to the form in the Appendix II hereof.
- 4. Veterinary prescribers shall:
- a) decide and take responsibility for dose, instructions for use and shelf life of prescribed veterinary drugs;
- b) provide instructions on use of drugs to animal owners or their representatives;
- c) join professional training courses on veterinary prescribing organized by the competent training institution or veterinary authority.
- 5. Producers of animal feeds containing veterinary drugs shall:
- a) only mix animal feeds with veterinary drugs subject to prescription if having prescriptions made up as prescribed in this Circular;
- b) archive prescriptions as prescribed in Article 22 hereof;
- 6. Users of veterinary drugs shall:
- a) use veterinary drugs according to the prescription; return unused or underused narcotic- and precursor-containing veterinary drugs as prescribed in this Circular;
- b) document the use of narcotic-, precursor- and antibiotic-containing veterinary drugs in animals;
- c) promptly notify prescribers and nearest veterinary authority if animals show unusual symptoms after using drugs;
- d) archive prescriptions as prescribed in Article 22 hereof.
- 7. Organizations and individuals providing counseling or technical assistance in veterinary medicine, animal husbandry, aquaculture, processing, preliminary processing and storage of animals and animal products shall use veterinary drugs as prescribed in this Circular.
- 8. Institutions providing training in animal husbandry, veterinary medicine, aquaculture and aquatic animal pathology shall train students and learners in regulations on veterinary prescribing.

Article 25. Roadmap for veterinary prescribing

- 1. Regulations on prescribing of narcotic- and precursor-containing veterinary drugs shall apply from the effective date of this Circular.
- 2. Regulations on prescribing of veterinary drugs that do not contain narcotics and precursors for provision of treatment and preventive treatment for terrestrial animal diseases shall apply:
- a) large-scale farming from the effective date of this Circular;
- b) medium-scale farming from January 01, 2022;
- c) small-scale farming from January 01, 2023;
- d) family farming from January 01, 2025.

The livestock production scale shall be determined as prescribed in Article 21 of the Decree No. 13/2020/ND-CP.

- 3. Regulations on prescribing of veterinary drugs that do not contain narcotics and precursors for disease treatment in aquaculture shall apply to:
- a) establishments carrying out intensive aquaculture of key aquatic species from the effective date of this Circular;
- b) establishments carrying out intensive aquaculture of non-key aquatic species and semi-intensive aquaculture establishments from January 01, 2023;
- c) other types of aquaculture from January 01, 2025;
- d) If an importing country or goods owner sets forth veterinary prescribing regulations other than those specified in this Circular, the regulations set forth by such importing country or goods owner shall prevail.
- 4. Regulations on veterinary prescribing in production of animal feeds shall apply from the effective date of this Circular.
- 5. Livestock production establishments and aquaculture establishments are encouraged to comply with prescribing regulations before the compulsory dates of application specified Clauses 2 and 3 of this Article.

Article 26. Amendments to Circular No. 18/2018/TT-BNNPTNT

Clause 21 of the Circular No. 18/2018/TT-BNNPTNT is amended as follows:

"5. Conformity of veterinary drugs shall be declared as prescribed by law from February 1, 2024".

Article 27. Transitional clauses

Animal feeds containing veterinary drugs subject to prescription, which are produced and imported before the effective date of this Circular, may be sold and used until their expiry date written on the package.

Article 28. Implementation clause

- 1. This Circular comes into force from December 25, 2020.
- 2. The Department of Animal Health, Department of Livestock Production, Directorate of Fisheries, provincial Departments of Agriculture and Rural Development and relevant organizations and individuals are responsible for the implementation of this Circular.
- 3. Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Agriculture and Rural Development (the Department of Animal Health) for consideration and resolution./.

PP. THE MINISTER
THE DEPUTY MINISTER

Phung Duc Tien

