

**THE GOVERNMENT**

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No. 35/2016/ND-CP

**THE SOCIALIST REPUBLIC OF VIETNAM**

**Independence - Freedom - Happiness**

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*Hanoi, May 15, 2016*

## **DECREE**

### **ON GUIDELINES FOR THE LAW OF VETERINARY MEDICINE**

*Pursuant to the Law on Government organization dated June 19, 2015;*

*Pursuant to the Law on veterinary medicine dated June 19, 2015;*

*Pursuant to the Law on investment dated November 26, 2014;*

*At the request of the Minister of Agriculture and Rural development; the Government promulgates a Decree on guidelines for the Law on veterinary medicine.*

#### **Chapter I**

### **GENERAL PROVISIONS**

#### **Article 1. Scope**

This Decree provides guidelines for the Law on veterinary medicine, in particular:

1. System of veterinary authorities and policies applied to veterinary staff of communes, wards or district-level towns (hereinafter referred to as communes).
2. Funding for prevention and fighting against animal diseases.
3. Suspension of export/import; ban on export/import of animals and animal products.
4. Requirements for manufacturing, trade, import, testing and valuation of veterinary drugs; regulations on Good manufacturing practice (GMP) for veterinary drugs.
5. Requirements for veterinary practice.

#### **Article 2. Regulated entities**

This Decree applies to domestic agencies, organizations, and individuals and foreign organizations and individuals in relation to veterinary activities in Vietnam.

### **Article 3. Interpretation of terms**

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

1. Good Manufacturing Practice (GMP) means rules, regulations and guidelines on requirements for drug manufacturing to assure that the drug products meets quality standards.
2. GMP-WHO means Good Manufacturing Practice issued by the World Health Organization (WHO), including Good Manufacturing Practice – GMP, Good Laboratory Practice – GLP, And Good Store Practice – GSP.
3. GMP-ASEAN means Good Manufacturing Practice issued by Association of Southeast Asian Nations (ASEAN).

## **Chapter II**

### **SPECIFIC PROVISIONS**

#### **Section 1. SYSTEM OF VETERINARY AUTHORITIES AND POLICIES APPLIED TO VETERINARY STAFF OF COMMUNES**

##### **Article 4. System of veterinary authorities**

1. In central government:

Department of Animal Health affiliated to the Ministry of Agriculture and Rural Development shall advise and assist the Minister of Agriculture and Rural development to carry out state management in the field of prevention, treatment and fighting against animal epidemics; quarantine of animals and animal products; animal slaughtering control, preparation or processing of animals and animal products; inspection of veterinary hygiene; management of veterinary drugs; and nationwide veterinary practice.

2. In local government:

a) Veterinary divisions affiliated to the Service of Agriculture and Rural development of provinces or central-affiliated cities (hereinafter referred to as veterinary authorities of provinces) shall assist Director of the Service to advise the People's Committee of province to implement state management and conduct law enforcement in the fields of prevention, treatment and fighting against animal diseases; quarantine of animals and animal products; animal slaughtering control, preparation or processing of animals and animal products; inspection of veterinary hygiene; management of veterinary drugs; and veterinary practice in the central-affiliated cities and provinces (hereinafter referred to as provinces) and subject to the professional direction of Department of Animal Health.

b) Veterinary stations affiliated to districts, district-level towns, provincial-affiliated cities and equivalent administrative divisions ( hereinafter referred to as veterinary authorities of districts)

shall carry out their assigned duties in the districts and cooperate with Committee division of Agriculture and Rural development or Committee division of Economic to assist People's Committees of districts to implement state management in the fields of prevention, treatment and fighting against animal diseases; quarantine of animals and animal products; animal slaughtering control, preparation or processing of animals and animal products; inspection of veterinary hygiene; management of veterinary drugs; and veterinary practice in the districts.

#### **Article 5. Policies applied to veterinary staff of communes**

1. Based on the requirements for veterinary activities in every province and the capacity of its resource balance, each People's Committee of province shall request the People's Council at the same administrative level to consider appointing veterinary staff in communes (hereinafter referred to as veterinary staff of communes) as prescribed in Clause 2 Article 6 of the Law on veterinary medicine.
2. Veterinary staff of communes shall be entitled to allowances and health insurance as prescribed in Clause 3 Article 1 of Decree No. 29/2013/ND-CP dated April 8, 2013 of the Government on amendments to Decree No. 92/2009/ND-CP dated October 22, 2009 of the Government on positions, quantity and policies applied to officials and civil servants in communes and part-time staff of communes and be entitled to insurance as prescribed in the Law on Social insurance 2014.
3. Veterinary staff of communes shall be provided with training as prescribed in Clause 1 Article 15 of Decree No. 92/2009/ND-CP dated October 22, 2009 of the Government on positions, quantity and policies applied to officials and civil servants in communes and part-time staff of communes.

### **Section 2. FUNDING FOR PREVENTATION AND FIGHTING AGAINST ANIMAL DISEASES**

#### **Article 6. Funding for prevention and fighting against animal diseases**

1. The funding source for prevention and fighting against animal diseases shall be allocated as prescribed in Clause 2 Article 23 of the Law on veterinary medicine.
2. Using the funding for prevention and fighting against animal diseases:
  - a) Government budget:

Central budget shall be allocated to Ministries, central bodies as prescribed in the Law on State budget.

Local budget shall be allocated to funding for prevention and fighting against animal diseases in provinces. In the event that the funding for prevention and fighting against animal diseases exceeds the local budget balance of a province, the People's Committee of province shall send a report in writing to the Ministry of Agriculture and Rural development and the Ministry of

Finance that submit the report to the Prime Minister for decision as prescribed in Point d Clause 3 Article 27 of the Law on veterinary medicine.

b) Funding of owners of domestic animals, owners of animal-raising establishments

Expenditures on prevention and fighting against epidemic diseases other than supportive budget from government budget, finance of domestic and foreign organizations and individuals.

c) Contribution and finance of domestic and foreign organizations and individuals shall comply with regulations of the Law on State budget and guiding documents of the Law on State budget and relevant regulations.

3. Expenditures from government budget:

a) Propagation, raising public awareness, training, conducting prevention and fighting against animal epidemics;

b) Procurement of devices, equipment, veterinary drugs (vaccines and antiseptic drugs) and expenses paid for participants of prevention and fighting against animal epidemics;

a) Supervisory activities, taking samples, analysis; monitoring and alerting farming environment; risk assessment of animal diseases;

a) Forecast or warning of animal epidemics; investigation and study of animal diseases;

dd) Subsidies on the establishment of animal epidemic-free zones;

e) Subsidies on damage from animal epidemics or due to compulsory handling measures upon the request of competent authorities and handling expenses;

g) Subsidies on remediation of breeding and aquaculture environment;

4. Level of subsidies from government budget:

a) Level of subsidies on damage from animal epidemics or compulsory handling measures upon the requests of competent authorities shall comply with regulations in force.

Regarding expenses which are not paid by subsidies prescribed in any regulation, the Ministry of Finance shall take charge and cooperate with the Ministry of Agriculture and Rural Development in requesting the Prime Minister for decision as prescribed in Point b Clause 2 of Article 27 and Clause 3 of Article 30 of the Law on veterinary medicine; the People's Committee of province shall request the People's Council of province to divide the level of subsidies in conformity with the budget balance of the province.

b) Level of subsidies on remediation of breeding and aquaculture environment

Based on the capacity of budget balance, guidelines of the Ministry of Agriculture and Rural Development and actual need in provinces, People's Committees of provinces shall request People's Councils of provinces to decide level of subsidies in conformity with the budget balance of the provinces.

### **Section 3. SUSPENSION OF EXPORT/IMPORT; BAN ON EXPORT/IMPORT OF ANIMALS AND ANIMAL PRODUCTS**

#### **Article 7. Suspension of export/import of animals and animal products**

1. Suspension of export of animals and animal products in any of the following cases:

- a) Animals and animal products posing risks of carrying subjects of quarantine of animals and animal products or subjects of veterinary hygiene inspection as prescribed by an importing country and having not implemented thorough veterinary hygiene treatment;
- b) Exported animals and animal products violating regulations of an importing country or receiving warning from an importing country but failing to thoroughly eliminate the violation reasons and posing risks of losing a Vietnamese export market.

2. Suspension of import of animals and animal products in any of the following cases:

- a) Animals and animal products from a country/region having animal epidemics included in the List of animal diseases subject to outbreak declaration of Vietnam or the List of diseases capable of transmitting between animals and humans or new pathogens of infectious diseases;
- b) Animals and animal products from a country/region discovered being infected with subjects of quarantine of animals and animal products or subjects of veterinary hygiene inspection of Vietnam
- c) Animals and animal products from a country/region that pose risks of carrying subjects of quarantine of animals and animal products or subjects of veterinary hygiene inspection of Vietnam that have not undergone through handling measures.

#### **Article 8. Requirements for continuation of export/import of animals and animal products**

1. Requirements for continuation of export/ of animals and animal products:

- a) Animals and animal products that do not pose risks of carrying subjects of quarantine of animals and animal products or subjects of veterinary hygiene inspection and have undergone thorough veterinary hygiene treatment as prescribed by an importing country;
- b) Animals and animal products violating against requirements of the importing country that have undergone inspection and supervision and it is certified that they no longer violate such requirements owing to effective remedial measures.

2. Requirements for continuation of import of animals and animal products:

a) Animals and animal products suspended from import prescribed in Point a Clause 2 Article 7 of this Decree shall be permitted to be imported to Vietnam if the competent authority of the exporting country certifies that it succeeds to control the epidemic disease and new pathogens of infectious disease as well as adopt assurance measures that no longer pose risks of spreading the disease at the request of Vietnam;

b) Animals and animal products prescribed in Point b Clause 2 Article 7 of this Decree are permitted to be imported to Vietnam if the competent authority of the exporting country sends a report determining reasons for infecting with the subject of quarantine of animals and animal products or the subject of veterinary hygiene inspection as well as adopt thorough remedial measures;

c) animals and animal products prescribed in Point c Clause 2 Article 7 of this Decree shall be permitted to be imported to Vietnam if the competent authority of the exporting country inspects and certifies that it succeeds to minimize the risks to lower level.

**Article 9. Bans on export/import of animals and animal products**

1. A ban shall apply to the export of animals and animal products that are infected with a subject of quarantine of animals and animal products or a subject of veterinary hygiene inspection and have not undergone any handling measure or have undergone handling measures which do not comply with regulations of an importing country.

2. A ban on import of animals and animal products shall apply to any of the following cases:

a) Animals and animal products from a country/region being infected included in the List of animal diseases subject to outbreak declaration of Vietnam or the List of diseases capable of transmitting between animals and humans or new pathogens of infectious diseases; likely to cause the spread of the disease to domestic animals, badly damaging people's health;

b) Animals and animal products to be imported subject to suspension of import have not undergone handling measures or have undergone remedial measures which do not comply with regulations of Vietnam.

**Article 10. Suspension of or ban on export/import of animals and animal products subject to quarantine**

1. Pursuant to Article 7 and Article 9 of this Decree, Department of Animal Health shall provide specific species of animals and types of animal products subject to suspension of or ban on export/import and reasons for suspension of or ban on export/import from/to a country/region; and send a report to the Minister of Agriculture and Rural development.

2. The Minister of Agriculture and Rural development shall, according to the report of the Department of Animal Health, consider deciding the suspension of or ban on export/import of animals and animal products.

3. A decision on suspension of or ban on export/import of animals and animal products must contain:

a) Names of animals and animal products (including botanical names);

b) Names of countries or regions from which animals and animal products are exported to Vietnam or to which animals and animal products are imported from Vietnam;

c) Reasons for suspension of or ban on export/import (including legal and scientific bases).

4. The suspension of or ban on export/import of animals and animal products shall come into force from the effective date of the decision. Such decision must be disclosed on the means of mass media and communicated to relevant agencies of Vietnam, competent authorities of the exporting country/region.

#### **Article 11. Regulations on continuation of export/import of animals and animal products**

1. Pursuant to Article 8 of this Decree, Department of Animal Health shall inspect and certify the effective implementation of handling measures and send a report to the Minister of Agriculture and Rural development.

2. The Minister of Agriculture and Rural development shall, according to the report of Department of Animal Health, consider issuing a decision on continuation of the export/import of animals and animal products. Such decision must be disclosed on the means of mass media and communicated to relevant agencies of Vietnam, competent authorities of the exporting/importing country/region.

#### **Section 4. REQUIREMENTS FOR MANUFACTURING, TRADE, IMPORT, ANALYSIS AND TESTING OF VETERINARY DRUGS**

##### **Article 12. General requirements for manufacturing of veterinary drugs**

Organizations or individuals manufacturing veterinary drugs (hereinafter referred to as veterinary drugs manufacturers) must comply with Article 90 of the Law on veterinary medicine; law on fire safety and firefighting; law on environment protection; law on occupational safety and hygiene and satisfy the following requirements:

1. Location:

a) Separating from the residential areas, public establishments, hospitals, veterinary infirmaries, establishments providing diagnosis of animals, and other sources of pollution;

- b) Not being contaminated by outside environment;
- c) Not affecting surround environment.

## 2. Workshops:

- a) The workshops are designed appropriate to the scale and manufactured drugs, to avoid flooding, moisture and intrusion of insects and other animals; their locations separate from the external source of infection;
- b) The workshops use materials with a solid structure, accordingly, to ensure the safety of labor and production;
- c) Foundation is tall, floor surface is smooth, non-cracking, non-slip, not absorbed or stagnated, easy to clean, sterilize or disinfect;
- d) Walls and ceilings are made of durable, solid and easy-to-clean materials;
- dd) There is a suitable lighting system;
- e) There is a supply and treatment system of clean water for manufacturing; there is a system of drainage and waste treatment that satisfies the requirements pertaining to veterinary hygiene and complies with regulations of law on environment protection;
- g) There is a system of fire alarm, firefighting and escape routes for people as prescribed.

## 3. Warehouses containing materials, auxiliary materials and finished products must have area that is appropriate to manufacturing scale and they also satisfy the following conditions:

- a) There are distinct warehouses for storage of materials, auxiliary materials and finished products;
- b) There are outside warehouses for storage of solvents and flammable materials;
- c) They may avoid flooding, moisture permeability and the intrusion of insects and other animals;
- d) The foundation is tall, not absorbed or stagnated;
- dd) There are suitable lighting systems;
- e) There are systems of fire alarm, firefighting and escape routes for people as prescribed in law on fire safety and firefighting;
- g) There are shelves of materials, auxiliary materials, packages, and finished products; there are also equipment and devices for storage requirements.



4. Equipment and instruments must be arranged or installed in conformity with the sale and manufactured drugs with operation manual; there are plans for maintenance; and there is a hygiene process that ensure the hygiene and avoid contamination or cross-contamination between products.

5. Quality inspection of veterinary drugs:

a) The quality inspection areas must be separated from the manufacturing areas and areas conducting biological or microbiological tests; and are arranged suitably to avoid cross-contamination;

b) Samples and titrants must be stored in a separate area that satisfy the storage requirements;

c) There are adequate appropriate equipment.

### **Article 13. Requirements for manufacturers of veterinary drugs in form of medicinal products or vaccines**

Apart from the conditions prescribed in Article 12 of this Decree, each manufacturer of veterinary drugs in form of medicinal products or vaccines must apply standards of GMP – ASEAN or GMP – WHO or a GMP at least equivalent to GMP – ASEAN.

### **Article 14. Procedures for issuance of GMP Certificates for veterinary drugs**

1. An application for issuance of a GMP Certificate for veterinary drugs (hereinafter referred to as GMP Certificate), including:

a) An application form for GMP inspection;

b) A Certificate of Enterprise registration;

c) A chart of organization and personnel of the manufacturer;

d) Programs, training materials and evaluation of training results pertaining to GMP at the manufacturer;

dd) A list of manufacturing, storing and quality-inspecting equipment;

e) A list of standard operating procedures;

g) A list of products being manufactured or to be manufactured;

h) A report on environmental impact assessment approved by an environment authority;

i) A minutes of GMP self-inspection;

k) Any new manufacturer applying for GMP inspection shall also submit manufacturing practice certificates of the employees in charge of technical matters and veterinary testing laboratory.

Each application for GMP inspection must have covers and index; its content must be sorted according to the order of the index with separation between parts.

## 2. Time limit for inspection:

a) Within 10 days from the date on which an application is received, Department of Animal Health shall assess the application, and then require amendments to the unsatisfactory application;

b) Within 30 days from the day on which a satisfactory application is received, Department of Animal Health shall establish a GMP Inspectorate, and inform the inspection schedule for the manufacturer and undertake an inspection visit;

c) Within 10 days from the end date of the inspection, Department of Animal Health shall issue a GMP Certificate to a satisfactory manufacturer or provide explanation in writing to an unsatisfactory manufacturer.

## 3. The process of inspection:

a) Upon an GMP inspection visit, the manufacturer must provide diagrams, charts and brief data on its operation and the application works of GMP;

b) When a GMP inspection is performed, the entire operation in the manufacturer must being carried out;

c) The GMP Inspectorate shall inspect whether the entire operation of the manufacturer of veterinary drugs conforms to GMP, its registration dossiers and applicable specialized regulations.

## 4. Handling inspection results:

a) According to an inspection record, the Chief inspector shall request the Director of Department of Animal Health to issue a GMP Certificate of eligibility for GMP requirements;

b) Regarding a manufacturer satisfying GMP requirements along with some shortcomings which are remediable in a short time, the Inspectorate shall request it to remedy those shortcomings. Within 2 months from the date of inspection, such manufacturer shall remedy the shortcomings and send a written report to the Department of Animal Health. The Chief inspector shall consider requesting the Director of Department of Animal Health to issue a GMP Certificate to the satisfactory manufacturer;

c) Regarding to a manufacturer failing to satisfy GMP requirements, it must remedy its shortcomings. The manufacturer shall, upon the self-inspection revealing the satisfaction of GMP requirements, re-file an application for registration as prescribed.

5. The validity period of a GMP Certificate is 5 years. At least 3 months prior to the expiry date of a GMP Certificate, the holder wishing to continue its manufacturing of veterinary drugs shall apply for Certificate renewal. Any manufacturer holding a GMP Certificate is not required to apply for a Certificate of eligibility for manufacturing of veterinary drugs.

#### **Article 15. Procedures for GMP Certificate renewal**

1. An application for GMP Certificate renewal includes:

- a) An application form for GMP re-inspection;
- b) A report on operation and changes of the manufacturer in 5-year application of GMP;
- c) A report on remedy for shortcomings in the previous inspection;
- d) A report on training at the manufacturer;
- dd) A list of existing equipment at the manufacturer;
- e) A list of products being manufactured;
- g) A list of standard operating procedures;
- h) A report on environmental impact assessment approved by an environment authority;
- i) A minutes of self-inspection and evaluation of the manufacturer in the latest self-inspection (within 3 months) in terms of GMP application.

2. Time limit for processing, process of inspection, handling of inspection results and validity of GMP Certificates shall comply with Clause 2, Clause 3, Clause 4 and Clause 5 Article 14 of this Decree.

#### **Article 16. Procedures for re-issuance or revocation of GMP Certificate**

1. Applications and procedures for re-issuance of GMP Certificates in case of losses, errors or destruction or changes of information about applicants shall comply with the following regulations:

- a) An application for re-issuance of GMP Certificate includes: an application form for re-issuance, supporting documents of changed contents in case of changes of information about the applicant, and the issued GMP Certificate, unless otherwise it is lost;

b) The applicant shall file an application for re-issuance of GMP Certificate to Department of Animal Health; within 5 working days from the day on which the satisfactory application is received, the Department of Animal Health shall whether re-issue a GMP Certificate or refuse such application and provide explanation in writing.

2. The Department of Animal Health shall revoke a GMP Certificate of a manufacturer of veterinary drugs in any of the following cases:

a) The GMP Certificate is erased or modified;

b) The manufacturer incurs administrative penalties for at least three times a year or incurs administrative penalties for 3 constant times for the same violation in the field of veterinary drug manufacturing;

c) The manufacturer no longer performs the manufacturing of veterinary drugs;

d) The manufacturer commits another violation that is regulated to have the Certificate of eligibility for manufacturing of veterinary drugs revoked.

The Minister of Agriculture and Rural development shall provide guidance on application for renewal, revocation, changes or amendments to GMP Certificate.

#### **Article 17. Requirements for trading in veterinary drugs**

Each veterinary drugs trader must comply with Article 92 of the Law on veterinary medicine and satisfy the following requirements

1. Having fixed business location and signboard(s).
2. Having cabinets, shelves and racks containing suitable drugs.
3. Having equipment for the purpose of drug storage as prescribed.
4. Having books and invoices for tracking sale and purchase of products.
5. Traders of vaccines and/or biological preparations must have refrigerators, freezers or cold storage for storage in conformity with the storage condition indicated on labels of products; and also have thermometers for checking the storage condition. They must also have standby generators, utilities and vehicles for distribution of vaccines.

#### **Article 18. Requirements for import of veterinary drugs**

Veterinary drugs importers must comply with Article 94 of the Law on veterinary medicine, Article 17 of this Decree and satisfy the following requirements:

1. Having warehouses satisfactory with requirements prescribed in Clause 3 Article 12 of this Decree.
2. Having appropriate equipment such as air ventilation, air conditioners, thermometers, hygrometers to ensure the storage condition.
3. Having a system of books and standard operating procedures to ensure the storage, control and monitoring of export and import of veterinary drugs.
4. Importers of vaccines and/or biological preparations must have separate warehouses, standby generators, equipment and vehicles to ensure the storage condition indicated in the products' labels during the transportation and distribution.

#### **Article 19. Requirements for establishments performing testing of veterinary drugs**

Each establishment performing testing of veterinary drugs must comply with Clause 3 Article 101 of the Law on veterinary medicine and satisfy the following requirements:

1. Location separates from residential areas and public works.
2. Facilities conform to biosafety, remain guaranteed condition for testing of microorganisms indicators; and have clean rooms for analysis of physical and chemical indicators.
3. There are machinery and instruments used for sampling, analysis, calibration and accurate data processing. The analysis equipment must satisfy requirements for testing methods, quality inspection as required by applicable standards and regulations.
4. There are places for keeping laboratory animals and places for testing of virulence separately from vaccines and microorganisms; regarding testing of vaccines carrying highly pathogens, it is required to have places for keeping of animals biosafety.
5. There is a system of treatment of waste and wastewater that ensure the veterinary hygiene and environment hygiene; there is a separate area for treating testing animals for testing of vaccines and microorganisms.
6. There is equipment specialized for keeping microorganisms species for testing.

#### **Article 20. Requirements for establishments performing evaluation of veterinary drugs**

Each establishment performing evaluation of veterinary drugs must comply with Article 88 of the Law on veterinary medicine and satisfy the following requirements:

1. Animal husbandry and aquaculture areas must satisfy the following requirements:
  - a) Having locations appropriate to land-use planning of local government or a competent authority;

b) Having fences or walls surrounding to prevent humans and animals from entering the areas;

c) Having clean water source;

d) Having adequate areas of barns, ponds, aquariums for arranging animals for the evaluation results;

dd) Having sufficient kinds and quantity of animals for the purpose of evaluation; having separate areas for raising testing animals, having a system of treatment of waste, sewage, dead animals and specimens conformable with veterinary hygiene and environment hygiene;

e) Having areas of manufacturing, processing and warehouses of animal feed isolated from the area of harmful chemicals and having measures against insects and pests;

g) Having separate barns, ponds and/or aquariums with food containers which are designed to meet the storage requirements.

2. There are actual faculties to perform evaluation of veterinary drugs and there is an agreement on rental of the facilities; they must also satisfy the requirements prescribed in Article 19 of this Decree.

## **Section 5. REQUIREMENTS FOR VETERINARY PRACTICE**

### **Section 21. Requirements for veterinary practice**

Entities practicing veterinary medicine must meet requirements prescribed in Article 108 of the Law on veterinary medicine and satisfy the following professional requirements:

1. Each person practicing diagnosis, treatment and/or surgery of animals, consultation on activities related to veterinary medicine is required to obtain at least an associate's degree in veterinary medicine, or husbandry and veterinary medicine or an associate's degree in aquaculture, or fish pathology for aquatic veterinary practice. Each person practicing inoculation of animals is required to obtain a certificate of graduation from a technical training course granted by a competent authority of province.

2. Each person in charge of technical matters in a facility provide surgery, treatment and/or diagnosis of animals/animal diseases is required to obtain at least a bachelor's degree in veterinary medicine, or husbandry and veterinary medicine or aquaculture, or fish pathology for aquatic veterinary practice.

3. Each trader of veterinary drugs is required to obtain at least an associate's degree in veterinary medicine, or husbandry and veterinary medicine or an associate's degree in aquaculture, or fish pathology for aquatic veterinary practice.

4. Each person in charge of technical matters in a facility of evaluation, import and/or export of veterinary drugs is required as follows:

a) With regard to a facility of evaluation, import and/or veterinary drugs pertaining to terrestrial animals, the person must obtain at least a bachelor's degree or in veterinary medicine, husbandry and veterinary medicine or pharmacy, or obtain a bachelor's degree in pharmaceutical chemistry, chemistry or biology;

b) With regard to a facility of evaluation, import and/or veterinary drugs pertaining to aquatic animals, the person must obtain at least a bachelor's degree or in aquaculture, fish pathology or pharmacy, or obtain a bachelor's degree in pharmaceutical chemistry, chemistry or biology;

5. Each person in charge of technical matters in a facility of manufacturing and/or testing of veterinary drugs is required as follows:

a) With regard to a facility of manufacturing and/or testing of drugs being medicinal products used in veterinary medicine pertaining to terrestrial animals, the person must obtain at least a bachelor's degree or in veterinary medicine, pharmacy, or pharmaceutical chemistry. With regard to such products used in veterinary medicine pertaining to aquatic animals, the person must obtain at least a bachelor's degree in aquaculture, fish pathology, pharmacy or pharmaceutical chemistry;

b) With regard to a facility of manufacturing and/or testing of drugs being vaccines, biological preparations, microorganisms or chemicals used in veterinary medicine pertaining to terrestrial animals, the person must obtain at least a bachelor's degree or in veterinary medicine, husbandry and veterinary medicine ,pharmacy, or obtain a bachelor's degree in pharmaceutical chemistry, chemistry or biology. With regard to such products used in veterinary medicine pertaining to aquatic animals, the person must obtain at least a bachelor's degree in aquaculture, fish pathology, biology, pharmacy or obtain a bachelor's degree in pharmaceutical chemistry or chemistry.

## **Article 22. Veterinary practice certificates**

1. Veterinary practice certificates shall be granted to entities satisfying practice requirements prescribed in Article 108 of the Law on veterinary medicine of this Decree and having satisfactory application prescribed in Clause 2 and Clause 5 Article 109 of the Law on veterinary medicine.

2. Each veterinary practice certificate shall contain:

a) Full name, date of birth;

b) Address;

c) Qualification;

d) Form of veterinary practice;

dd) Location.

An Appendix of form of veterinary practice certificate and application form for issuance of veterinary practice certificate shall be issued together with this Decree.

3. The use of veterinary practice certificate shall comply with the regulations below:

a) Veterinary practice certificates pertaining to inoculation, diagnosis, treatment and surgery of animals and/or consultation of activities related to veterinary medicines shall be used nationwide. The issuing authority of veterinary practice certificate shall leave the item “location” blank;

b) Veterinary practice certificates of persons in charge of technical matters in facilities providing surgery, treatment, diagnosis and/or testing of animals services, or traders of veterinary drugs shall be used within the scope of provinces and central-affiliated cities;

c) Veterinary practice certificates of persons in charge of technical matters in facilities of manufacturing, testing, evaluation, export and/or import of veterinary drugs shall be used nationwide.

### **Chapter III**

#### **IMPLEMENTATION**

##### **Article 23. Effect**

1. This Decree comes into force from July 1, 2016.

2. This Decree replaces the Government's Decree No. 33/2005/ND-CP dated March 15, 2005 on guidelines for the Ordinance on Veterinary Medicine; the Government's Decree No. 119/2008/ND-CP dated November 28th 2008 on amendments to the Government's Decree No. 33/2005/ND-CP dated March 15 2005, Article 4 of the Government’s Decree No. 98/2011/ND-CP dated October 26, 2011 of the Government on amendments to Decrees on agriculture.

##### **Article 24. Implementation**

Ministers, Heads of ministerial-level agencies, Heads of Governmental agencies, the Presidents of People’s Committees of provinces and central-affiliated cities and relevant agencies shall implement this Decree./.

**ON BEHALF OF THE GOVERNMENT  
PRIME MINISTER**

**Nguyen Xuan Phuc**



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*Unofficial translated by LPVN*