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| **MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT**<br>**-------** | **SOCIALIST REPUBLIC OF VIETNAM**<br>**Independence - Freedom - Happiness**<br>**----------** |
| No.: 13/2016/TT-BNNPTNT | *Hanoi, June 02, 2016* |

# CIRCULAR

ON VETERINARY DRUG MANAGEMENT

*Pursuant to the Law on veterinary medicine 2015;*

*Pursuant to the Law on Product and goods quality 2007;*

*Pursuant to the Decree No. 89/2006/ND-CP dated 30/8/2006 by the Government providing for labels of goods;*

*Pursuant to the Decree No. 132/2008/ND-CP dated December 31, 2008 by the Government detailing the implementation of a number of articles of the Law on Product and goods quality;*

*Pursuant to the Decree No. 181/2013/ND-CP dated 14/11/2013 by the Government detailing the implementation of a number of articles of the Law on Advertising;*

*Pursuant to Decree No. 199/2013/ND-CP dated 26/11/2013 by the Government defining the functions, tasks, entitlements and organizational structure of the Ministry of Agriculture and Rural development;*

*Pursuant to the Decree No. 35/2016/ND-CP dated 15/5/2016 by the Government detailing a number of articles of the Law on veterinary medicine;*

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

*The Minister of Agriculture and Rural development hereby promulgates the Circular on veterinary drug management.*

## Chapter I

## GENERAL PROVISIONS

### Article 1. Scope of regulation and regulated entities

1. Scope of regulation

This Circular provides for the registration, testing/inspection, manufacture, trade, export, import, quality inspection, recalling, destruction and advertising of veterinary drug.

2. Regulated entities

This Circular applies to Vietnamese and foreign organizations and individuals related to the registration, testing, manufacture, trade, export, import, quality inspection, recalling, destruction or advertising of veterinary drugs in Vietnam.

**Article 2. Interpretation of terms**

In this Circular, these terms can be construed as follows:

1. “Manufacture of veterinary drugs” includes the forms of manufacture, processing, portioning and packaging of veterinary drugs.

2. “New drug” means a drug with a dosage formula containing new active ingredients, drugs with a new combination of active ingredients, drugs with a new dosage form, drugs with new indications or drugs with a new route of administration.

3. “New active ingredient” means an active ingredient with is registered for sale in Vietnam for the first time.

4. “Innovator drug” means drug which has a patent and a stable manufacturing process which has been issued with a License for free sale.

5. “Generic drug” means a drug that has the same formulation, dosage form, uses, indications, dosage and the withdrawal time as those of the innovator drug when the patent or the exclusive license is expired.

6. “Proprietary name” means a commercial brand named by a drug manufacturer, which is different from the original or international nonproprietary name.

7. “Drug label” means written, printed or drawn words, drawings, images or signs which are directly printed on, or stuck, pinned or securely attached to, the commercial packaging of a drug.

8. “Labeling” of a drug means the presentation of basic and necessary information on a drug on its label for user to identify, select and consume, serving as the basis for inspection and control by functional agencies.

9. “Original label” of a drug means the first label printed, stuck, pinned or securely attached to the commercial packaging of the drug after it is packed in a manufacture chain.

10. “Supplementary label” means a label displaying compulsory information translated from a foreign language into Vietnamese and supplementing compulsory information in Vietnamese as required by law, which the original label does not contain.

11. “Commercial packaging” of a drug means the packaging which contains the drug and is sold together with the drug, comprising two types:

a) Primary packaging, which means the packaging in direct contact with and directly containing the drug;

b) Secondary packaging, which means the packaging used for packing one or a number of drug units contained in primary packagings.

12. Name and address of the organization or individual responsible for a drug means the name and address of the manufacturer, exporter, importer, entrusted exporter or entrusted importer of the drug.

13. “Packing specifications” of a drug means the drug quantity in net weight, actual volume or cardinal number in a packaging unit.

14. “Batch number” means the code in numbers or letters or a combination of numbers and letters to enable recognition, and tracing back of the history of, a drug batch, covering all stages of manufacture, quality inspection and distribution of such batch.

15. “Date of manufacture” means the point of time when the manufacture, processing, bottling, packing or another form of finishing the final manufacture stage of a drug batch is completed.

16. “Expiry date” means the point of time past which a drug must not be used.

17. “Origin” of a drug means the country or territory where such drug is manufactured, or processed at the final stage, for a drug manufactured through many stages in different countries or territories.

18. “Indications” means information relating to the use, and necessary conditions for use and preservation, of a drug; warnings; and remedies for hazardous incidents, guiding users how to safely and properly use such drug.

“Package insert” means a document attached to a drug's commercial packaging, which presents use instructions and other information under regulations.

19. “State inspection of veterinary drug quality” means when a regulatory agency considers assessing the quality of a veterinary drug which is manufactured/imported or sold after applying quality control measures by an organization/individual producing/trading such veterinary drug.

20. “Conformable drug” means a drug satisfying quality standards which have been registered according to the pharmacopoeia, National Technical Regulation regarding veterinary drugs, National standards regarding veterinary drugs or intramural standards issued by the manufacturer and approved by a regulatory body.

21. “Unconformable drug” means a drug that does not fully satisfy the quality standards that have been registered with a regulatory body.

22. “Batch” means a certain amount of veterinary drugs which are consistent in quality, manufactured under a single procedure or a chain of procedures and whose label displayed the same batch codes.

23. “Import shipment” means a certain amount of veterinary drugs or materials thereof in one or a number of batches of the same type of products which are manufactured by the same manufacturer and imported by the same organization on the same consignment and are covered by the same import dossier.

## Chapter II

## REGISTRATION, TESTING, MANUFACTURE, TRADE AND IMPORT OF VETERINARY DRUG

### Section 1. REGISTRATION OF VETERINARY DRUG

### Section 3. Application for registration of veterinary drug

1. Regarding new veterinary drug being pharmaceutical products, chemicals or bioproducts, an application for registration shall include:

a) An application form for registration using the form specified in Annex I enclosed with this Circular;

b) A brief description of characteristics of the product using the form specified in Annex VIII enclosed with this Circular;

c) Models of the label of the product and the package insert;

d) The Certificate of GMP or the certificate of the ISO Quality Control System, applicable to a number of common chemicals, the certificate of sale isssued by a competent agency of the producing country, applicable to imported drugs;

dd) Manufacture process;

e) Quality standards and testing methods;

g) A report on data proving the the safety, including researches on the toxicity (acute toxicity, semichronic toxicity, chronic toxicity, cytotoxicity and the carcinogenicity);

h) A report on data proving the effect of the product, including researches on the experimental pharmacology; on the pharmacodynamics, pharmacokinetics and the bioavailability of the product;

i) Researches on residues in animals taken the drug to determine the withdrawal time;

k) Documents on the stability and the expiry of the drug;

l) Researches on dosage regimen and treatment course for specific species of animals;

m) The Certificate of analysis for the product issued by the manufacturer and the Certificate of analysis of the product issued by a designated veterinary drug testing authority;

n) The result of the inspection;

o) A written undertaking not to violate the provisions of the Law on Intellectual property using the form provided in Annex VII enclosed with this Circular;

p) Other technical information (if any).

2. Regarding pharmaceutical products, chemicals and bioproducts which are excempt from inspection specified in Article 11 of this Circular, an application for registration shall include:

a) Documents specified in points a, b, c, d, dd, e, k, m, o and p clause 1 of this Article;

b) Information about innovator drugs, generic drugs (name of the product, name of the manufacturer, the formulation, dosage form, uses, indications, contraindications, dose, withdrawal time, requirements for chosen animals, users and other technical features of the product).

3. Regarding vaccines and antibodies, the application shall include:

a) An application form for registration using the form specified in Annex II enclosed with this Circular;

b) A brief description of characteristics of the product using the form specified in Annex VIII enclosed with this Circular;

c) Models of the label of the product and the indication;

d) The GMP Certificate and/or the License for free sale issued by the competent agencies of the country of manufacture, applicable to imported products;

dd) Manufacture process;

e) Quality standards and testing methods for vaccines and antibodies;

g) Reports on data proving the safety, medical uses of the product, including researches on the antibody content and the immunity duration of vaccine/antibody;

h) Researches on residues in animals to determine the time for terminating the application of the vaccine/antibody;

i) Researches on the stability, a brief description of the manufacturing process of 3 consecutive batches and a suggestion on the expiration;

k) Methods for determining the dosage regimen and the treatment course for specific types of animals;

l) The Certificate of analysis for the product issued by the manufacturer and/or the Certificate of analysis of the product issued by a designated veterinary drug testing authority;

m) A report on the test on the effect and the safety of the product;

n) Relevant documents, including: the origin, the history and the stability of the original microorganism spieces used for producing vaccines/antibodies; documents relevant to the copyright and the application of the certificate of manufacture of vaccines/antibodies (if any);

o) Other technical information including the results of the test within the laboratody, data proving that the product has been sold in other countries in the world (if any);

p) epidemiological data proving the existence of pathogens in Vietnam (applicable to new vaccines/antibodies).

4. Regarding bioproducts used for diagnosis (Test KIT), the application shall include:

a) An application form for registration using the form specified in Annex III enclosed with this Circular;

b) A brief description of characteristics of the product using the form specified in Annex VIII enclosed with this Circular;

c) Models of the label of the product and the package insert;

d) The Certificate of GMP or the certificate of the ISO Quality Control System or other equivalent certificates, the certificate of sale issued by a competent agency of the producing country, applicable to imported drugs;

dd) The Certificate of analysis for bioproducts issued by the manufacturer and the Certificate of analysis of bioproducts issued by a designated veterinary drug testing authority of Vietnam;

e) A report on data proving the sensitivity analysis;

g) A report on data proving the specificity of the product;

h) Manufacture process;

i) Quality standards and testing methods for bioproducts;

k) Researches on the stability, a brief description of the manufacturing process of 3 consecutive batches and a suggestion on the expiration;

l) A report on the test results, including results of test of the sensitivity and specificity of the product;

m) Relevant documents, including: the origin, the history of the original microorganism spieces used for producing bioproducts; documents relevant to the copyright and the application of the certificate of manufacture of bioproducts (if any);

n) Other technical information (if any).

5. For veterinary drugs made from herbal ingredients, the application shall consist of:a) An application form for registration using the form specified in Annex I enclosed with this Circular;

b) A brief description of characteristics of the product using the form specified in Annex VIII enclosed with this Circular;

c) Models of the label of the product and the indication;

d) The GMP Certificate and/or the certificate of free sale issued by the competent agencies of the country of manufacture, applicable to imported drugs;

dd) Manufacture process;

e) Quality standards and testing methods;

g) A report on data proving the safety and the effectiveness of the product;

h) Researches on residues in animals taken the drug the determine the time for terminating the use of the drug;

i) Documents on the stability and the expiration of the drug;

k) Researches on dosage regimen and treatment course for specific species of animals;

l) The Certificate of analysis for the product issued by the manufacturer and the Certificate of analysis of the product issued by an designated veterinary drug testing authority;

m) A written undertaking not to violate the provisions of the Law on Intellectual property using the form provided in Annex VII enclosed with this Circular;

n) Other technical information (if any).

6. Regarding veterinary drugs with the certificate of free sale in Vietnam which are processed or portioned out, the application shall consist of:

a) An application form for processing/portioning drugs using the form specified in Annex I enclosed with this Circular;

b) A summary of information about the product (name, composition, dosage form, form of packaging, effect, use, expiration);

c) Models of the label of the product and the indication (the label of registration, processing and portioning);

d) The GMP Certificate or the certificate of eligibility for manufacture of the establishment carrying out the processing/portioning;

dd) The Certificate of free sale of the processing/portioning requester issued by the Department of Animal Health;

e) The contract on processing/portioning of the veterinary drugs;

g) Manufacturing process of the processing/portioning requester;

h) Quality standards and methods for testing the original materials, semi-finished products and finished products of the processing/portioning requester;

i) The Certificate of analysis of products of the establishment carrying out the processing/portioning;

7. Regarding veterinary drugs without the certificate of free sale in Vietnam to be exported, the application shall consist of:

a) An application form using the form specified in Annex XI enclosed with this Circular;

b) A brief description of characteristics of the product using the form specified in Annex VIII enclosed with this Circular;

c) Models of the label of the product and the indication;

d) The GMP Certificate of the manufacturer;

dd) Manufacture process;

e) Quality standards and testing methods;

g) The Certificate of analysis for the product issued by the manufacturer and the Certificate of analysis of the product issued by an designated veterinary drug testing authority;

h) An undertaking that the drugs manufacturing for export are not sold in Vietnam;

i) A written undertaking not to violate the provisions of the Law on Intellectual property using the form provided in Annex XII enclosed with this Circular.

**Article 4. Requirements for processing/portioning of veterinary drugs**

1. Only drugs which have an effective certificate of free sale in Vietnam or drugs for export are allowed to be processed/portioned out.

2. The establishment processing/portioning drugs shall be an establishment that has obtained the GMP certificate or the certificate of eligibility to manufacture the drug to be processed/portioned out.

**Article 5. Contract for processing/portioning of veterinary drugs**

The contract for processing/portioning drugs shall be made in writing and shall be conformable to relevant legal regulations which are applicable and shall include:

1. The agreement on the supply of materials, auxiliary materials, the provision of manufacturing process, technical standards and testing methods for the original materials/auxiliary materials, semi-finished products, finished products and other documents relevant to the processing/portioning.

2. Entitlements and responsibilities of each party pertaining to the inspection of quality of materials, auxiliary material, semi-finished products, packaging and labeling procedures and provisions for the verification of testing notes for each batch of finished products and the note for releasing products.

3. Entitlements and responsibilities of each party pertaining to the retention of records of the manufacture, quality inspection, distribution and sale of drugs, retention of drug samples, handling of issues related to quality, complaint or recalling of products.

**Article 6. Languages and format of the application**

1. Languages in the application

a) The application for registration of domestically manufactured veterinary medicine must be written in Vietnamese;

b) The application for veterinary medicine manufactured overseas must be written in Vietnamese or English. If the application is written in English, the information in the package insert and the summary of product characteristics must be written in Vietnamese.

2. Format of the application

a) The application for veterinary drug registration must be written on A4 papers and must be firmly bound. The application must have a cover and table of contents and the parts must be separate. The separation must be numbered; registration for each type of drug shall be separate;

b) Documents enclosed with the application, including the GMP certificate, the ISO certificate, the certificate of eligibility to manufacture veterinary drugs, the certificate of eligibility to import veterinary drugs, the Certificate of analysis, the certificate of free sale (CFS, CPP, MA) and/or the contract for processing/portioning veterinary drugs shall be the original or copies certified by the applicant.

**Article 7. Drug's name**

1. The Ministry of Agriculture and Rural development encourage establishments to apply for use of drug name according to international nonproprietary names (INN).

2. If the drug is not so named, the applicant may choose a trade name for it. The commercial name of the drug must satisfy the following principles:

a) Do not exaggerate drug effects;

b) Do not provide incorrect information about treatment effects and pharmacological effects of the drug;

c) Do not infringe Vietnam's native cultural tradition;

d) Do not cause conflict with protected intellectual property of other organizations and individuals;

dd) The drug names must not be identical or similar to those that are issued with registration numbers of other facilities;

e) Drugs with different active ingredients must not have the same name;

g) Drugs with the same formulation, the same manufacturing process of the same manufacturer must not have different names.

**Article 8. Appraisal of application, issuance of Certificate of free sale for veterinary drugs and time limit for response**

1. Appraisal of application, issuance of Certificate of free sale for veterinary drugs

a) The Department of Animal Health shall receive the application, conduct appraisal of it, hold a consultation with the Veterinary drug council, issue Certificate of free sale for veterinary drugs using the form specified in Annex IX enclosed with this Circular, request the Ministry of Agriculture and Rural development to recognize and add the drug to the List of veterinary drugs allowable in Vietnam.The Veterinary drug council shall be established under the establishment decision issued by the Director of Department of Animal Health. The Veterinary drug council shall meet at least every 3 months to assess the results of the appraisal of the application, the test results then request the Director of Department of Animal Health to issue the Certificate of free sale for veterinary drugs;

b) Regarding application for processing/portioning veterinary drugs with the certificate of free sale in Vietnam, the Department of Animal Health shall conduct appraisal of the application, issue the certificate using the form in Annex XIII enclosed with this Circular and request the Minister of Agriculture and Rural development to grant recognition and add such drug to the List of veterinary drugs allowed to be sold in Vietnam. Regarding application for export of veterinary drugs without the certificate of free sale in Vietnam, the Department of Animal Health shall conduct appraisal of the application, issue the certificate using the form in Annex XIV enclosed with this Circular or according to the request of the importing country.

2. Validity of the Certificate of free sale for veterinary drugs

a) The Certificate of free sale for veterinary drugs shall be valid for 05 years from the date of issue;

b) The validity of the Certificate of free sale for veterinary drugs which are processed/portioned shall be equivalent to sum of the valid period of the Contract for processing/portioning veterinary drugs and the useful period of the product which must not exceed 05 years from the date of issue.

3. Time limit for response

a) Within 10 days from the day on which the application is received, if the application is unsatisfactory, the Department of Animal Health shall notify the applicant for completion;

b) The Department of Animal Health shall conduct appraisal of the application and make response within 20 days from the day on which the satisfactory application is received, applicable to application for manufacture for export, processing/portioning, or 40 days from the day on which the satisfactory application is received, applicable to application for registration of drugs exempt from testing or bioproducts used for diagnosis, or 06 months from the day on which the satisfactory application is received, applicable to application for registration of new drugs, vaccines, antibodies or herbal medicines.

**Section 9. Application for reissuance of the Certificate of free sale for veterinary drugs**

1. For cases of modification of component, formulation, dosage form, administration, dosage regimen, indication of the veterinary drug; change of manufacturing method and process that modifies the product quality; reassessment of the quality, the effect and the safety of veterinary drugs according to regulations: An application for reissuance of the Certificate of free sale for veterinary drugs shall comprise documents specified in Article 3 of this Circular.

2. For cases of loss, omission, damage; modification, addition to drug name, name/address of applicant, name/address of manufacturer; change in packaging specifications of the product, form of the label; modification of expiration and withdrawal time, contraindications, treatment courses; changes which do not affect the quality, effect and the safety of the veterinary drugs: The application shall comprise: An application for reissuance of the Certificate of free sale for veterinary drugs using the form specified in Annex IV enclosed with this Circular; documents proving the modified contents; the former and the new label; the issued Certificate of free sale for veterinary drugs (the original or copies which are certified by the applicant) unless such documents are lost.

**Section 10. Application for extension of the Certificate of free sale for veterinary drugs**

An application for extension of the Certificate of free sale for veterinary drugs shall consist of:

1. An application form for registration using the form specified in Annex V enclosed with this Circular.

2. A copy of the effective Certificate of free sale for veterinary drugs.

3. The GMP certificate or the ISO certificate or the certificate of eligibility to manufacture veterinary drugs or the certificate of eligibility to import veterinary drugs;

the certificate of free sale issued by a regulatory body of the producing country for the importing country.

4. The Certificate of analysis for the product issued by the manufacturer or by the veterinary drug testing authority appointed in Vietnam within 12 months, applicable to medicinal products, chemicals or bioproducts; or the Certificate of analysis for the product issued by the manufacturer and the veterinary drug testing authority appoint in Vietnam within 12 months, applicable to vaccines and antibodies.

5. e) The contract on processing/portion out of the veterinary drugs, applicable to drugs which are processed/portioned out.

6. A report on the stability of the product in storage condition.

7. A report on the sale of drugs using the form in Annex VI enclosed with this Circular.

**Article 2. Applicant for permission to conduct veterinary drug test**

**Article 11. Veterinary drugs exempt from testing**

1. Veterinary drugs manufactured following the innovator drug, generic drug of pharmaceutical products, chemicals, bioproducts; imported veterinary drugs excluding vaccines and antibodies which are allowable in USA, Japan, Australia, Canada and Europe.

2. Pursuant to the eligibility to manufacture veterinary drugs of countries other than those specified in clause 1 of this Article, the Department of Animal Health shall consider requesting the Minister of Agriculture and Rural development to supplement countries whose veterinary drugs are exempt from testing.

**Article 12. Requirements for animals to be tested**

1. Its spieces, features, age and weight are conformable to the indications of the drug.

2. It is clinically strong to the vaccine/antibody.

3. It does not have an antibody corresponding the vaccine/antibody to be tested.

**Article 13. Criteria for testing veterinary drugs being medicinal products, chemicals, bioproducts (excluding vaccines/antibodies)**

1. Safety

a) For animals assigned to use the drug: whether or not the animal keep alive and growing normally;

b) For aquaculture environment: DO, pH, the purity;

c) Residues, applicable to animal products: the withdrawal time.

2. Effect, applicable to animals assigned to use the drug

a) Health conditions of animals after testing: whether or not the animal has the clinic symptoms of the disease;

b) Rate of animal recovering from the disease after the test.

3. Other technical criteria (which must be specified in the application for registration).

**Article 14. Scale and time of test of veterinary drugs being medicinal products, chemicals, bioproducts (excluding vaccines/antibodies)**

1. Scale of test

a) For terrestrial animals: domestic fowls: at least 300; swines: at least 40; bovines, goats, sheeps, horses, dogs, cats: at least 20; quantity of other animals shall be decided by the Department of Animal Health and written in the testing license;

b) For aquatic animals: the test shall be conducted in laboratorial environment for the scale of at least 3 raising ponds/cages.

2. Time of test shall be determined on the basis of the treatment courses of the drug.

**Article 15. Criteria for testing vaccines/antibodies**

1. Safety, applicable to animals assigned to use the drug according to the technical record.

2. Effect, applicable to animals assigned to use the drug.

a) The rate of animals with the content of antibodies at the protected benchmark after being injected;

b) The rate of protection.

3. Other technical criteria (which must be specified in the application for registration).

**Article 16. Scale and time of test of vaccines/antibodies**

1. Scale of test

a) Domestic fowls: at leats 300; swines: at least 40; bovines, goats, sheeps, horses, dogs, cats: at least 20; fish: 1000;

b) In special cases, the determination of quantity of animals to be tested is specified in the testing license;

c) The determination of quantity of serums taken for testing antibodies must provide a reliable result about biological statistics.

2. Time of test shall be determined for specific type of vaccines/antibodies.

**Article 17. Criteria and scale of test of bioproducts for diagnosis (Test KIT)**

1. The criteria shall be based on the standards declared by the manufacturer, comprising:

a) The sensitivity analysis;

b) The specificity.

2. Scale of test: The test shall be conducted in a laboratory, at least 30 experiments shall be performed for each type of product.

**Article 18. Application for issuance or reissuance of the License to conduct veterinary drug tests**

An application for issuance/reissuance of the License to conduct veterinary drug tests shall consist of:

1. An application form for issuance/reissuance of the license to conduct veterinary drug tests using the form provided in Annex XV or XVII enclosed with this Circular.

2. A report on the assessment of the establishment proving the eligibility to conduct the test as prescribed in clause 2 Article 45 of this Circular.

3. Technical documents for specific types of drug, including:

a) A report on specifications of the product using the form in Annex VIII enclosed with this Circular;

b) Technical information about the quality of the product;

c) Technical information about the safety and the effect of the product;

d) A certificate of analysis of the product issued by the manufacturer (the original or a copy certified by the establishment applying for registration);

dd) A certificate of analysis of the product issued by veterinary drug testing agency of Vietnam (the original or a copy certified by the establishment applying for registration);

e) The testing outline;

g) The testing contract between the applicant establishment and the testing establishment (the original or a copy certifiied by the establishment applying for registration).

**Article 19. License to conduct a test and reporting about veterinary drug test results**

1. The form of the license to conduct a veterinary drug test is provided in Annex XVI enclosed with this Circular.

2. The establishment applying for conducting a test shall send a report on the test to Department of Animal Health not later than 15 days counted from the day on which the test finishes. The report shall be in accordance with the testing outline, including contents specified in Annex XVIII enclosed with this Circular and shall be certified by the test supervising body.

**Section 3. MANUFACTURE, TRADE AND IMPORT OF VETERINARY DRUGS**

**Article 20. Application for issuance, extension or reissuance of the certificate of eligibility to manufacture veterinary drugs**

An application for issuance, extension or reissuance of the certificate of eligibility to manufacture veterinary drugs shall consist of:

1. An application form for issuance, extension or reissuance of the certificate of eligibility to manufacture veterinary drug using the form provided in Annex XIX or XXXI enclosed with this Circular.

2. A detailed description of facilities and technology for the manufacture of veterinary drug using the form specified in Annex XXI enclosed with this Circular.

3. An inspection record of the manufacture conditions of veterinary drugs and a certificate of eligibility to manufacture veterinary drugs using the form in Annexes XXIII and XXV enclosed with this Circular.

4. An application form for issuance, extension or reissuance of the GMP certificate for veterinary drugs using the form specified in Annexes XXVIII and XXXI enclosed with this Circular; an GMP inspection record for veterinary drugs and a GMP certificate using the form specified in Annexes XXIX and XXX enclosed with this Circular.

**Article 21. Application for issuance, extension or reissuance of the certificate of eligibility to trade/import veterinary drugs**

An application for issuance, extension or reissuance of the certificate of eligibility to trade/import veterinary drugs shall consist of:

1. An application form for issuance, extension or reissuance of the certificate of eligibility to trade/import veterinary drug using the form provided in Annex XX or XXXI enclosed with this Circular.

2. A detailed description of facilities and technology for the manufacture of veterinary drug using the form specified in Annex XXII enclosed with this Circular.

3. A inspection record of the conditions of trade/import of veterinary drugs using the form in Annex XXIV enclosed with this Circular and a certificate of eligibility to trade/import veterinary drugs using the form in Annex XXVI or XXVII enclosed with this Circular.

**Section 4. IMPORT OF VETERINARY DRUGS AND MATERIALS FOR THE MANUFACTURE THEREOF**

**Section 22. Application for permission to import veterinary drugs and materials for the manufacture thereof**

1. An application for permission to import veterinary drugs without the certificate of free sale which serving the prevention and fighting against emergency animal epidemic and/or serving disaster recovery shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A copy of the Certificate of Business registration or the Certificate of Enterprise registration or the investment license appropriate to the profession of the applicant;

c) A GMP certificate or an ISO certificate or other equivalent certificates, for common chemicals;

d) A certificate of free sale (CFS, CPP or MA) issued by a competent body of the country of manufacture;

dd) A Certificate of analysis (CoA) by the manufacturer;

e) The model of the product label.

2. An application for permission to import veterinary drugs for test or registration shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A copy of the Certificate of Business registration or the Certificate of Enterprise registration or the investment license of the applicant, applicable to organizations/individuals applying for issuance of the license to import veterinary drugs for the first time;

c) A GMP certificate or an ISO certificate or other equivalent certificates, for common chemicals;

d) A certificate of free sale (CFS, CPP or MA) issued by a competent body of the country of manufacture;

dd) A Certificate of analysis (CoA) by the manufacturer;

e) A summary of product characteristics (SmPC).

3. An application for permission to import veterinary drugs to be displayed at a fair, an exhibition or for scientific research shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A copy of the Certificate of Business registration or the Certificate of Enterprise registration or the investment license of the applicant, applicable to organizations/individuals applying for issuance of the license to import veterinary drugs for the first time;

c) Copies of documents proving the purposes of importing veterinary drugs;

d) A Certificate of analysis (CoA) by the manufacturer;

dd) A summary of product characteristics (SmPC);

e) The model of the product label.

4. An application for permission to import veterinary drugs used for animals which are temporarily imported or transited through Vietnam's territory; temporarily imported for re-export or outward processing under a contract which a foreign organization or individual shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A Certificate of analysis (CoA) by the manufacturer;

c) Copies of documents proving the purposes of importing veterinary drugs;

d) The model of the product label.

5. An application for permission to import veterinary drugs and materials thereof or microorganisms serving the reseach and manufacture of veterinary drugs, diagnosis or test of veterinary drug shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A copy of the Certificate of Business registration or the Certificate of Enterprise registration or the investment license of the applicant, applicable to organizations/individuals applying for issuance of the license to import veterinary drugs for the first time;

c) A Certificate of analysis (CoA) by the manufacturer;

d) A summary of product characteristics (SmPC);

dd) The model of the product label.

6. An application for permission to import veterinary drugs as aid from an international organization and other non-commercial forms of import shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A copy of the Certificate of Business registration or the Certificate of Enterprise registration or the investment license appropriate to the profession of the applicant;

c) A GMP certificate or an ISO certificate or other equivalent certificates, for common chemicals;

d) A certificate of free sale (CFS, CPP or MA) issued by a competent body of the country of manufacture;

dd) A Certificate of analysis (CoA) of the manufacturer;

e) The model of the product label.

7. An application for permission to import veterinary drug materials shall consist of:

a) An application form for permission to import veterinary drugs using the form in Annex XXXII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A GMP certificate or an ISO certificate or other equivalent certificates, for common chemicals;

c) A certificate of free sale (CFS, CPP or MA) issued by a competent body of the country of manufacture;

d) A Certificate of analysis (CoA) by the manufacturer;

dd) A copy of the certificate of eligibility to import veterinary drugs issued by the Department of Animal Health, applicable to establishment applying for permission to import veterinary drug materials for the first time;

e) A report on the quantity and purpose of antibiotic materials, the address of the establishment purchasing the antibiotic materials from the previous batch of antibiotic materials using the form in Annex XXXIV enclosed with this Circular, applicable to the application for permission to import antibiotic materials for the second time or later.

8. An application for permission to import vaccines and/or microorganisms in the List of veterinary drugs allowable in Vietnam or obtained the certificate of free sale in Vietnam shall consist of:

a) An application form for permission to import vaccines/microorganisms using the form in Annex XXXIII enclosed with this Circular. A copy in electronic file shall be sent by mail as well;

b) A copy of the certificate of eligibility to import veterinary drugs issued by the Department of Animal Health, applicable to establishment applying for permission to import vaccines/microorganisms for the first time.

9. The certificates (GMP, ISO, CFS, CPP, MA or CoA) included in the application may be the original or copies certified by the applicant.

10. The License to import veterinary drugs/veterinary drug materials shall be valid not exceeding 01 year as from the date of issue.

## Chapter III

## LABEL OF VETERINARY DRUGS

### Article 23. Types of veterinary drugs subject to labeling

1. Durgs which are domestically sold, exported or imported shall be labeled according to regulations in this Circular, except for cases specified in clause 2 of this Article.

2. If the foreign organization/individual importing drugs from Vietnam and request such drugs to be labeled according to a business contract and take responsibility for such request, then the organization/individual exporting drugs may follow such request, provided that such request does not falsify the substances of the drugs and is not contrary to laws of Vietnam and the importing country.

**Article 24. Responsibilities for labeling of veterinary drugs**

1. For veterinary drugs which are domestically manufactured for domestic sale, manufacturers shall be responsible for labeling thereof.

2. For veterinary drugs which are domestically manufactured for domestic sale, manufacturers shall be responsible for labeling thereof.

3. If the veterinary drugs having the certificate of free sale in Vietnam which are not exported and returned to be sale in Vietnam, the organization/individual selling such drugs shall carry out the labelling as prescribed in Article 26 of this Circular.

4. If the organization/individual responsible for the labelling of the drugs as prescribed in Article 10 of Decree No. 89/2006/ND-CP dated 30/8/2006 by the Government requests another organization/individual to carry out the labelling, the former organization/individual shall be still responsible for such labels.

5. For drugs imported into Vietnam which have the original labels unconformable to provisions of this Circular, the importing organization/individual shall attach supplementary labels to the products according to regulations in clause 3 Article 26 of this Circular before selling. The original labels shall be kept unchanged in this case.

6. Any organization/individual trading drugs shall comply which law provisions on intellectual property and shall take legal responsibility for the intellectual property towards information written on the label.

**Article 25. Location, size, color of letters, symbols and images on the label**

1. Location of labels of veterinary drug

Labels of veterinary drugs must be displayed (printed, stuck or attached) on their packages at a noticeable location, where the provided information can be seen easily and sufficiently with no need to disassemble the products, as prescribed in clause 1 Article 6 of Decree No. 89/2006/ND-CP.

2. Size of labels of veterinary drug

Any organization/individual responsible for labelling drugs shall itself determine the size of the label which must contain .sufficiently the information specified in Article 27 of this Cicular

3. Color of letters, symbols and images on the label

Color of letters, numberals, paintings, pictures, signs and symbols displayed on labels of drugs must be readable. For mandatory contents, letters and numerals must contrast with the background of the label as prescribed in Article 8 of Decree No. 89/2006/ND-CP.

**Article 26. Languague used on labels of drugs**

1. Compulsory contents of veterinary drug's labels must be in Vietnamese, except the case specified in Clause 4 of this Article.

2. For veterinary drugs domestically manufactured and sold, their labels, apart from complying with the provisions of Clause 1 of this Article, may contain information in another language. Contents in another language must correspond those in Vietnamese. The size of letters in another language must not be bigger than that of contents in Vietnamese.

3. If labels of veterinary drugs imported into Vietnam do not contain or do not fully contain compulsory contents in Vietnamese, they shall be kept together with with supplementary labels showing compulsory information in Vietnamese. The original labels shall be kept unchanged.

4. The following contents may be presented in other languages of Latin origin:

a) Proprietary name, generic name or international nonproprietary names of drugs;

b) International names or scientific names of ingredients or ingredient quantities of goods, in case they cannot be translated into Vietnamese or their Vietnamese translations are meaningless;

c) Names and addresses of foreign manufacturing or franchising enterprises.

5. Contents displayed on veterinary drugs' labels, including supplementary labels and package inserts, must be truthful, clear, precise and correctly reflect the substance of the goods.

**Article 27. Contents of labels of veterinary drugs**

1. A veterinary drug's label must display fully the following contents:

a) Name of the drug;

b) Composition and quantity of active ingredients (content or concentration);

c) Packing specifications;

d) Indications, route of administration and contraindications of drugs; withdrawa time (if any) to use eggs, meat or milk for each animal species to be treated;

dd) Dosage form, registration number, number of batch, date of manufacture, expiry date and the phrase "Chỉ dùng trong thú y" (for use in animal healthcare only);

e) Remarkable signs: For schedule-A toxic veterinary drugs, to add the phrase (in black): “không dùng quá liều quy dịnh” (Do not overdose); for schedule-B toxic veterinary drugs, to add the phrase (in red) “không dùng quá liều quy dịnh” (Do not overdose);

g) Name and address of organization/individual responsible for the drug;

h) Origin of the drug, except for veterinary drugs domestically manufactured and sold whose labels already display the place of manufacture;

i) Use and storage instructions

When it is impossible to present all the above information on a label, the information specified in points a, b, c, dd, e, g and h of this Clause shall be presented. Other compulsory information shall be presented in a supplementary label or the package insert. In this case, the label must indicate where such information is presented.

2. Other contents displayed on veterinary drug labels

Apart from compulsory contents specified in clause 1 Article 27 of thia Circular, a label may contain other information, for example, the quality standard code. Such information must be truthful and accurate and must not misrepresent the nature and effect of a drug as well as other information presented on the label.

3. The label of a veterinary drug material must contain the following information:

a) Name of the material;

b) Content or concentration (if any);

c) Standards of the material;

d) Net weight or volume;

dd) Number of batch, date of manufacture;

e) Expiry date, storage conditions;

g) Registration number (if any);

h) Name and address of manufacturer;

i) Origin of the material (except materials which are domestically manufactured and sold whose labels already contain addresses of manufacturers);

k) Name and address of importer (applicable to imported materials);

l) Remarkable signs.

4. The label of a veterinary drug pack must at least contain the following information:

a) Name of the drug;

b) Active ingredients, contents. For a veterinary drug containing 3 or fewer active ingredients, its label must fully indicate these active ingredients and their contents;

c) Number of batch, expiry date, registration number;

d) Name of manufacturer, which may be abbreviated, but must ensure the identity of the manufacturer.

A drug pack shall be put in a secondary packaging which has a label fully displaying the information specified in clause 1 Article 27 of this Circular.

5. Contents of labels of small-sized primary packagings.

a) The label of a veterinary drugs on a small-sized primary packaging with a special shape that cannot fully display compulsory information specified in clause 1 Article 27 of this Circular, must at least contain the following information: name if the drug; active ingredients, contents, for a drug containing 3 or fewer active ingredients, its label must fully indicate these active ingredients and their contents; volume or weight; number of batch, expiry date, registration number; name of manufacturer, which may be abbreviated, but must ensure the identity of the manufacturer;

b) Primary packagings of these veterinary drugs shall be put inside secondary packagings which have labels fully displaying the information specified in clause 1 Article 27 of this Circular.

**Article 28. Labelling of veterinary drugs**

1. Veterinary drug names

a) A veterinary drug shall be named by its manufacturer or trader. Such a name must not misrepresent the substance and effect of the drug. The letters for a drug name must be bold and prominent.

The label of a single-element proprietary drug must indicate the generic name or the international nonproprietary name of the drug right after the proprietary name;

b) A drug may be named after: the generic name; the international nonproprietary name (INN); proprietary name.

2. Composition of active ingredients, contents or concentrations

a) Composition of all active ingredients and excipients contained in a finished drug product shall be displayed according to regulations in clause 1 Article 18 of Decree No. 89/2006/ND-CP even when those materials change their forms in the manufacture process;

b) All active ingredients, contents or concentrations of the smalled dose or packing unit of every active ingredient, excluding component and contents of excipients, shall be displayed. Names of active ingredients shall be presented according to their generic names or international nonproprietary names;

c) Units of measurement

Units of quantitative measurement shall be presented on veterinary drug labels in their full or abbreviated forms. Units of active power may be used according to international practive for some special active ingredients.

3. Packing specifications

a) Packing specifications of a drug means the quantity, net weight or actual volume of a drug contained in a commercial packing;

b) Packing specifications shall be presented in natural numbers;

c) Packing indications of spme specific forms of veterinary drugs shall be presented as follows:

- For capsules: quantity of capsules, contents of active ingredients/capsules;

- For powder: weight;

- For liquid: real volumetric

- For gonadotropic drugs for animals and some other active ingredients: international unit (IU);

d) For a drug whose commercial packaging contains many packing units, the weight of each packing unit and the quantity of packing units must be presented.

4. Indication, route of administration, contraindication and withdrawa time

a) Indication for treatment of each animal species indicated on a drug label must match the effect of such drug.

b) Use instructions must conspicuously indicate the route of administration, dose and treatment duration;

c) Contraindication cases shall be specified for drugs with contraindication. For drugs without contraindication, the non-contraindication status shall be stated;

d) The indication, route of administration-contraindication for a drug may be presented in either of the following ways:

- Directly on the commercial packaging;

- In the package insert enclosed in the commercial packaging, for a drug whose label on the secondary packaging fails to display the drug's indication, route of administration and contraindication. In this case, the phrase “Chỉ dịnh, cách dùng, chống chỉ dịnh: xin dọc trong tờ hướng dẫn sử dụng” (See the package insert for indication, route of administration and contraindication) shall be printed on the label on the commercial packaging;

dd) Withdrawa time shall be specified for each animal species to be treated. In case the withdrawa time is not available, this shall be stated.

The withdrawa time must match the time indicated in the drug circulation registration dossier.

5. Dosage forms, registration numbers, batch numbers, date of manufacture, expiry date, storage conditions

a) Dosage forms of a drug as capsule, powder, injection solution, injection suspension, powder for injection, or oral solution shall be presented;

b) The registration number, which is the code of a veterinary drug granted by the Animal Health Department to certify the registration for sale of such drug in Vietnam shall be presented;

c) The batch number shall be presented as “Số lô sản xuất” or “Số lô SX”. The batch numbers structure shall be prescribed by the manufacturer;

d) The date of manufacture, expiry date and storage duration shall be specified as follows: the date of manufacture and expiry date shall be presented on the label fully or in abbreviation in upper case letters as NSX, HSD in the format [dd/mm/yyyy] of the calendar year. The numberals presenting a date must be displayed on the same line according to regulations in Article 16 of Decree no. 89/2006/ND-CP. When it is impossible to display “NSX”, “HSD” together with the numbers indicating fully the date the label must so indicate. When a label displays the date of manufacture NSX and expiry date HSD in a foreign language, the supplementary label must display the date of manufacture and expiry date or the phrase “NSX/HSD xem Mfg Date/Exp Date trên bao bì” (See Mfg Date/Exp Date for NSX/HSD).

dd) Storage conditions means climate factors to ensure the unchanging of quality of drugs. Necessary storage conditions shall be presented on the drug label. For example: Store in a dry and cool place at 30$^{o}$C or below.

6. Remarkable signs

a) For injection drugs or powder for injection, the administration shall be specified. Administrations of drugs may be abbreviated to tb (tiêm bắp - intramuscular injection), tdd (tiêm dưới da - subcutaneous injection), tm (tiêm tĩnh mạch - intravenous injection);

b) For eyedrops, the phrase “Thuốc tra mắt” (ophthalmic drugs) shall be displayed;

c) For drugs for external use, the phrase “Thuốc dùng ngoài” (For external use) shall be displayed;

d) For drugs in ampoules for oral use, the phrase “không dược tiêm” (Not for injection) shall be displayed;

dd) For some chemicals used in animal healthcare, their typical qualitative indicators shall be displayed. For inflammable, explosive, toxic or corrosive chemicals, respective warnings shall be displayed. For chemicals in pressure containers, container numbers, capacity and warnings shall be displayed;

e) Warnings (if any) shall be displayed on drug labels to ensure the safety for drug administrator;

g) Presentation of remarkable signs

Remarkable letters and signs shall be conspicuous and bold to be easily seen. If a drug has multiple remarkable signs, such remarkable signs shall be fully presented.

7. Name and address of organization/individual responsible for the drugs

a) Name and address of organization/individual responsible for the drugs must not be abbreviated;

b) Name and address of organization/individual responsible for the drug shall be presented according to regulations in Annex XXXV enclosed with this Circular;

c) A label containing the name and address of the distributor must display such name and address in the same place with the manufacturer's and of a size not bigger than the manufacturer's;

d) The name of the organization or individual responsible for a drug shall be printed fully as indicated in legal documents on its establishment. Its transaction name may be printed, but of a size not bigger than the full name;

dd) Addresses of manufacturer, packaging establishments, franchise manufactures or subcontract manufacturers including house number, street (village), commune (ward, township), district (town, provincial city) and province (central-affiliated cities) shall be displayed.

8. Origin of veterinary drugs

a) For imported drugs: The phrase “sản xuất tại” (manufactured in) or “xuất xứ” (origin) followed by the name of country or territory of manufacture shall be presented;

b) For domestically manufactured and sold drugs whose label already indicates the place of manufacture, the presentation of the drug's origin is not required;

c) The origin of a drug shall be presented on its secondary and primary packagings.

9. Use instructions

a) Veterinary drugs labeled under this Circular must have a package insert in Vietnamese. The contents of this insert may be printed on the primary packaging or intermediary label instead of a separate insert.

The size and color of letters printed on the package insert must be big and conspicuous to the naked eye.

b) Content of the package insert shall be conformable to regulations in Annex XXXVI enclosed with this Circular.

10. Presentation of supplementary labels

A supplementary label shall be attached to the secondary packaging of a veterinary drug and must not hide from view contents of the original label. Contents of a supplementary label must not cause misunderstanding about those of the original label and the labeling organization/individual shall take legal responsibility for the accuracy and truthfulness of additional contents. A supplementary label shall be presented as follows:

a) For labela with sufficient space, all compulsory contents shall be specified according to regulations in clause 1 Article 27 of this Circular;

b) If the supplementary is small and cannot fully display compulsory contents, at least the following information shall be presented: name of the drug; active ingredients, content or concentration; name of organization or individual responsible for the drug; registration number; packaging specifications; date of manufacture, number of batch; origin of the drug.

Other remaining compulsory information shall be presented in the package insert. In such case the supplementary label must contain the phrase: “Các thông tin khác dề nghị xem

trong tờ hướng dẫn sử dụng kèm theo" (See the package insert for other information) and the contents on the package insert indicated on the supplementary label shall be regarded as part of the supplementary label;

c) When the original label of a drug is presented in a Latin-originated language and contains the information below, the translation into Vietnamese and presentation on a supplementary label of such information is not required: proprietary name, generic or international non-proprietary name of the drug; international non-proprietary name or scientific name of each ingredient of the drug when it is impossible to translate into Vietnamese or such translation bear no meaning; name and address of foreign manufacturer or manufacture franchising grantor.

## Chapter IV

## TESTING OF VETERINARY DRUGS

### Article 29. Veterinary drug-testing system

1. Testing establishments affiliated to Department of Animal Health: National center of vet medicine control I and National center of vet medicine control II.

2. Drug testing service providers.

### Article 30. Operation of veterinary drug-testing establishments

1. Testing establishments affiliated to Department of Animal Health:

a) Conduct tests and assessments of drug quality nationwide;

b) Conduct tests of drug quality applying for registration;

c) Conduct appraisal of quality standards of drugs and other products at the request of the Ministry of Agriculture and Rural development;

d) Provide testing services;

dd) Other activities according to relevant law provisions.

2. Drug testing service providers

Provide services of testing drug materials and semi-finished products during the manufacture process and the finished drugs for establishments producing and trading drugs, serving the state management and control regarding drug quality.

3. A veterinary drug testing establishment must conduct the testing of veterinary drugs serving the state management only when it is appointed by a competent authority according to laws.

**Article 31. Application of methods for testing veterinary drugs**

1. The testing of drugs shall be conducted according to the assigned testing methods and conformable to the drug testing methods registered by the establishment producting/trading such drugs.

Any application of methods other than those specified in the registered standards must be conducted only under the approval by Department of Animal Health.

2. In case of suspicion of composition or quality of a drug, the testing agency affiliated to the Department of Animal Health may take measures other than those specified in the registered standards to conduct testing of the drug and produce the drug quality testing result.

**Chapter I**

**VETERINARY DRUG QUALITY INSPECTION**

**Article 32. Bases for formulation of veterinary drug quality standards and basis for veterinary drug quality test**

1. Bases for formulation of veterinary drug quality standards

a) National technical regulation regarding veterinary drugs;

b) National standards regarding veterinary drugs;

c) Standards in Vietnam's pharmacopoeia or international standards, including: European, British, American, Japanese. The application must contain all provisions of quality, quality rate and testing methods specified in such pharmacopoeia.

2. Bases for veterinary drug quality test are specified in clause 1 of this Article and intramural standards issued and applied by manufacturers.

**Article 33. State inspection regarding veterinary drug quality in manufacture**

1. Inspection authority: Department of Animal Health

2. Bases for inspection

a) There is information and/or warning that an exported veterinary drug is unconformable to conditions specified in Article 32 of the Law on Product and goods quality;

b) A product being sold on market is unconformable to applied standards or corresponding technical regulations, discovered by the inspection or supervision of product quality or through motion of a competent agency about the quality of the product.

3. Form of inspection: An inspection shall be conducted by inspectorates.

4. Contents of inspection

a) Inspection of the compliance with requirements specified in the Good medicine manufacturing practice (GMP) and other relevant law provisions;

b) Inspection of the registration of drug, the research of the stability of the product and the labeling of drug according to regulations;

c) Collection of samples: During the inspection at manufacture establishments, if any product is found unconformable to quality standards or denoting the unconformity with quality standards when it is on market, its samples shall be collected for testing of quality. Such samples shall be sent to recognized or appointed testing establishments for analyzing. Testing results shall be the legal basis for the inspection authority to handle during the inspection period.

5. Order and procedures for the inspection shall comply with regulations in clause 3 Article 29 of the Law on Product and goods quality.

6. Processing of inspection results: in accordance with regulations in Article 30 of the Law on Product and goods quality.

**Article 34. Testing of quality of imported veterinary drugs**

1. Inspecting authority: Department of Animal Health

2. Subject of inspection

a) Veterinary drugs imported into Vietnam, except for those not subject to testing specified in point b of this clause;

b) Imported veterinary drugs not subject to quality test: samples for testing, registration, samples to be displayed at a fair, exhibition or a scientific research; veterinary drugs to be used for animals temporarily imported or transited through Vietnam; veterinary drugs temporarily imported for re-export or for outward processing under a contract with a foreigner; materials used in diagnosis or testing pertaining to animal healthcare; drugs as aids from international organizations and drugs imported in other non-commercial forms.

3. Crietia

a) Testing of quatitative of for veterinary drug materials, medicinal products, chemicals, bioproducts;

b) Testing of condition of sterility or purity, safety and effect of vaccines/antibodies.

4. Contents

a) Examination of documents;

b) Inspection of the conformity of the contents of the Certificate of analysis of the imported products with the technical standards, the applied standards and applicable regulations;

c) Testing of samples of drug's label: the compulsory information to be displayed on the labels (including the supplementary labels) according to regulations in Chapter III of this Circular regarding labels of finished veterinary drugs; the conformity of the label's samples with the import dossier of the batch.

5. Collection of samples for quality analysis

The collection of samples for quality test shall comply with regulations in the Technical standard No. QCVN 01-03: 2009/BNNPTNT enclosed with the Circular No. 66/2009/TT-BNNPTNT dated 13/10/2009 by the Ministry of Agriculture and Rural development.

6. Frequency of sampling

a) For veterinary drug's materials and finished veterinary drugs (excluding vaccines/antibodies used in animal healthcare).

Collect samples of 02 batches of consecutive import shipments for quality test.

If the batches are satisfactory, the frequency of sampling shall be reduced to 1 imported batch for the 05 next imported batches.

If the batches are unsatisfactory, the next 03 consecutive imported batches shall be sampled for testing; if such 03 batches are satisfactory, samples from 01 batch of the next 05 batches shall be collected for quality test;

b) For vaccines/antibodies used in animal healthcare.

Collect samples of every batches of imported vaccines for quality test regarding the sterility or purity and safety; collect samples from 01 batch of imported drug of 05 consecutive batches of imported drugs manufactured by the same manufacturer and imported by the sample unit for quality test regarding the effect of drugs.

If the effect of the batch/es is unsatisfactory, the next 02 consecutive imported batches shall be sampled for testing; if such 02 batches are satisfactory, samples of 01 batch from the 05 consecutive batches manufactured by the same manufacturer and imported by the same unit shall be collected for testing.

Particularly regarding vaccines against Avian influenza, Foot-and-mouth disease, Porcine reproductive and respiratory syndrome (PRRS), 100% of batches of imported drugs shall be sampled for testing regarding the sterility, purity, safety and effect;

c) If the results of supervision or quality testing of imported veterinary drugs present the unsatisfaction, all the imported drug batches shall be sampled for quality testing. When samples from any 02 consecutive batches are satisfactory, the frequency of sampling shall be reduced that samples from 01 batch of the 05 next batches of imported drugs shall be collected for quality testing;

d) Samples shall be collected at the request of the Department of Animal Health.

**Article 35. Procedures for state inspection regarding quality of imported veterinary drugs**

1. An application for inspection regarding the quality of imported veterinary drugs shall consist of

a) An application form for inspection of imported veterinary drugs using the form in Annex XXXVII enclosed with this Circular (02 copies);

b) The contracts, the Packing list, Invoices, Bills of lading;

c) A written approval for the import of veterinary drug materials, vaccines, microorganisms and/or veterinary drugs issued by the Department of Animal Health or a Certificate of free sale for veterinary drugs excluding vaccines/microorganisms;

d) A Certificate of analysis (CoA) issued by the manufacturer;

dd) Samples of the label of the imported veterinary drug and the supplementary label (if any) according to regulations.

Documents enclosed with the application may be the original or copies certified by the imported establishment.

2. Procedures for application

a) Any establishment wishing to import veterinary drugs shall prepare and send an application for quality inspection by post or directly to the inspecting authority;

b) Within 01 working day, the inspeciting authority shall certify the application for completing the customs procedures or issue a written response in case the application is unsatisfactory. If the sampling is not required, the importing establishment shall follow the customs clearance procedures at the checkpoint.

If the sampling is required, the importing establishment may transport the products to the place stated in the application for testing, keep the current conditions of the product unchanged but must not carry out the manufacture, trade or use of such products and wait for the testing results according to regulations;c) Regarding veterinary drugs subject to sampling for quality testing as prescribed in clause 6 Article 34 if this Circular, within 02 working days when the satisfactory application is received, the testing authority shall conduct physical testing accoring to the form specified in Annex XXXVIII enclosed with this Circular, check the documents according to regulations in clause 4 Article 34 of this Circular and collection samples for quality testing.

Within 05 working days, applicable to veterinary drug materials, medicinal products, chemicals and bioproducts, or 14 days, applicable to vaccines and antibodies which are tested for the sterility or purity and safety; 60 days, applicable to vaccines/antibodies which are tested for the effect since samples are collected for quality testing, the testing authority shall notify the testing results using the form specified in Annex XXXIX enclosed with this Circular to the importing establishment and the customs authority to serve as the basis for following customs clearance procedures for the batch of product.

If the samples are unsatisfactory, the testing authority shall notify the importing establishment of the testing results. Within 05 working days from the date of notification, if the importing establishment does not make any complaint about the testing results, the testing authority shall propose functional agencies to handle according to regulations.

3. Any violations committed during the testing period shall be handled according to regulations in Article 36 of the Law on Product and goods quality.

**Article 36. State inspection regarding quality of veterinary drugs being sold**

1. Inspection authority

a) Department of Animal Health shall conduct inspection of quality of veterinary drugs nationwide;

b) Provincial veterinary authorities shall conduct quality inspection at veterinary drug stores under management.

2. Contents and proceduers for inspection of quality of veterinary drugs being sold shall be in accordance with regulations in Circular No. 26/2012/TT-BKHCN dated December 12, 2012 by the Ministry of Science and Technology.

**Article 37. Inspection of veterinary drug producing establishments at exporting countries**

1. Pursuant to an international treaty or an agreement regarding veterinary drug with veterinary medicine authorities of different countries, the Department of Animal Health shall decide the formulation of the inspectorate, plan and contents of on-site inspection at veterinary drug-producing establishments at exporting countries.

2. Funding for the inspection shall be provided annually by the State budget according to current regulations and other funds according to laws.

**Article 38. State inspection regarding quality of exported veterinary drugs**

1. Inspection authority: Department of Animal Health

2. Subject and contents of inspection

a) Veterinary drugs shall be tested before exporting according to the application of the exporting establishment and at the request of the registration authority;

b) Exported veterinary drugs which are unsatisfactory and sent back shall be tested according to regulations in clauses 4, 5 and 6 Article 33 of this Circular.

3. Bases for inspection: applied standards; regulations of the importing country, the contract or the international treaty or the mutual recognition arrangement on conformity assessment results signed with another country/region.

4. Application for inspection of quality of exported products on request shall consist of:

a) An application form for inspection of quality of exported veterinary drugs using the form in Annex XL enclosed with this Circular;

b) Applied standards, criteria to be tested;

c) The certificate of analysis of the product issued by an appointed veterinary drug testing agency for the criteria to be tested (the original or a copy certified by the enterprise).

5. Procedure for inspection of quality of exported products

a) The applicant shall send an application for exported product quality inspection directly or by post to the Department of Animal Health;

b) Within 05 working days from the day on which the satisfactory application is received, the Department of Animal Health shall appraise the application and notify the results using the form on Annex XLI enclosed with this Circular.

## Chapter VI

## PROCEDURES FOR RECALLING AND RESTRUCTION OF VETERINARY DRUGS

### Article 39. Procedures for recalling of veterinary drugs

1. Any competent agency discovering a veterinary drug subject to recalling according to regulations in clause 1 Article 105 and clause 1 Article 106 of the Law on veterinary medicine shall immediately affix seal and request a competent authority to issue a decision to recall such veterinary drug.

2. The recalling of veterinary drug which is not conformable as prescribed in the corresponding technical regulations, the registered and declared applied standards shall be conducted as follows:

a) Regarding veterinary drug samples collected at the producing/exporting/importing establishment (hereinafter referred to as establishment)

Within 10 days, applicable to pharmaceutical products, chemicals or bioproducts, or 60 days, applicable to vaccines/antibodies, from the date of sampling, the Department of Animal Health shall notify the establishment of the results of testing of the veterinary drug sample and request the establishment to immediately recall the unconformable veterinary drug batch itselt. Within 05 working days form the day on which the notification from the Department of Animal Health is received, the establishment may make a complaint with the Department of Animal Health about the results of the test of the veterinary drug sample. Past this time limit, if the establishment does not make any complaint, the Department of Animal Health shall issue a decision to nationwide recall the unconformable veterinary drug batch/es.

In case of complaint, the Department of Animal Health shall collect samples of veterinary drugs for re-test. If the result of the re-test still shows the unconformity, the Department of Animal Health shall issue a decision to nationwide recall the unconformable veterinary drug batch/es. If the result of the re-test shows the conformity, veterinary drugs from the tested batch/es shall continue to be sold;

b) Regarding samples of veterinary drugs collected at trading establishments in provinces or central-affiliated cities:

Within 10 days, applicable to pharmaceutical products, chemicals or bioproducts, or 60 days, applicable to vaccines/antibodies, from the date of sampling, the sampling authority shall notify the establishment trading, producing or importing such veterinary drug of the testing result and immediately seal the unconformable veterinary drug batch/es. Within 05 working days from the date on which the notification is received, the establishment may make a complaint with the sampling authority of the testing result. Past this time limit, if the establishment does not make any complaint or the result of the re-test shows

the unconformity, the sampling authority shall issue a decision to recall products in the province/city and notify the Department of Animal Health and the establishment producing or importing such batch/es of veterinary drugs.

When receiving the notification of the unconformable veterinary drug batch/es from the sampling authority, the Department of Animal Health shall collect samples at the producing/importing establishment for re-test. If the re-test result shows the unconformity, the veterinary drug batch/es at the producing/importing establishment shall be sealed. Within 05 working days from the date on which the notification is received, the establishment may make a complaint with the Department of Animal Health of the testing result. Past this time limit, if there is no complaint made, the Department of Animal Health shall issue a decision to nationwide recall the drug batch/es.

3. The producing/importing/trading establishment whose veterinary drug products are recalled shall conduct the recalling itself according to the decision to recall issued by the competent authority. After recalling drugs, the establishment shall report the recalling result to the authority issuing the recalling decision.

4. Regaridng veterinary drugs subject to nationwide recalling, the Department of Animal Health shall issue a decision to recall and post a notification of the recalling on its web portal within 24 hours. Provincial veterinary authorities shall supervise the recalling activities within their management.

5. Regaridng veterinary drugs subject to provincial recalling, provincial veterinary authorities shall issue decisions to recall and post notifications of the recalling on their web portal within 24 hours and shall take responsibility for supervising the recalling activities within their management.

**Article 40. Treatment of recalled veterinary drugs**

1. Veterinary drugs with the certificate of free sale in Vietnam whose labels are unconformable to laws or which are not conformable to the registered quality standards, the establishments in charge of such drugs shall carry out the recalling and treatment as follows:

a) The recalling or destruction shall be imposed on veterinary drugs violating drug quality of level 1, including: the active ingredient is unconformable to the registration; the drug is quality is changed about form (such as being curdy, turbid, transformed color, deposited sediments, bedded, transformed shape); the drug does not contain or contain fully main active ingredients stated on the label; the vaccine fails to fullfil any of the 3 conditions: sterility or purity, safety and effectiveness; the drug is urgently recalled according to the decision of a foreign authority for imported drugs;

b) The recalling, recycling and re-release shall be imposed on veterinary drugs violating drug quality of level 2, including: the drug fails to fullfil any of the registered criteria for quality standards (organoleptic conditions; physical or chemical conditions; bacterial

contamination level, the sterility level; the content of drug is ±10% exceeding the acceptable amount written on the label or the content of probiotics is 90% less than the amount written on the label, applicable to drugs containing probiotics; the net weight or the real volumetric exceeds the limit prescribed by the current pharmacopoeia);

c) Recall and remedy the incorrect labels, applicable to veterinary drugs with labels unconformable to laws on labels;

d) If a veterinary drug specified in point b of this clause cannot be recycled and re-released, it shall be destroyed.

3. The veterinary drug establishment whose products are subject to destroyed must carry out the destruction according to regulations regarding hazardous waste management in laws on environmental protection and must pay all the cost for such destruction.

4. Competent agencies shall be responsible for issuing decisions to destroy veterinary drugs and decisions to establish the veterinary drug-destroying council. The council shall comprise a presiding agency, representatives of veterinary authorities, representatives of resources and environment agencies.

## Chapter VII

## ADVERTISING VETERINARY DRUGS

### Article 41. Veterinary drug advertisment contents

1. An advertisement of a veterinary drug shall include the following information, except cases specified in clause 2 of this Article:

a) Commercial name, formulation of drug;

b) Uses and indications of use and storage of veterinary drugs;

c) Name, address of organization/individual registering or distributing drugs.

2. Advertisements for veterinary drugs which are displayed on boards, plates, panels, shelves, other objects, objects which are overhead, underwater, mobile objects, electronic equipment, terminal devices and other telecommunication devices, means of transport, advertisement transmittors are not required to displayed fully the compulsory information.

3. Veterinary drug advertisement contents shall by certified by a competent authority specified in Article 42 of this Circular.

### Article 42. Competence in issuing a certificate of veterinary drug advertisment contents

1. The Department of Animal Health shall issue the Certificate of advertisement content verification for press, web portals, electronic equipment, terminal devices and other telecommunication devices, printed products, audio and video recordings and other technological devices of the Central government which are nationwide published.

2. Provincial veterinary authorities shall issue the Certificate of advertisement content verification for advertisements displayed via:

a) Newspapers and magazines, web portals, electronic equipment, terminal devices and other telecommunication devices, printed products, audio and video recordings and other technological devices of local areas;

b) Advertising boards, banners, signboards, light box, advertising screens;

c) Means of transport;

d) Fairs, seminars, conferences, events, exhibitions, cultural and sport programs;

dd) Advertisement transmittors, advertisement objects;

e) Other means of advertising as prescribed in laws.

**Article 43. Procedures for issuance of the certificate of advertisment content verification for veterinary drugs**

1. Submission of application

a) An application shall be sent directly or by post to a competent agency as prescribed in Article 42 of this Circular;

b) Quantity of application: 01.

2. An application for the certificate of veterinary drug advertisement content shall consist of

a) An application form for verification of veterinary drug using the form in Annex XLII enclosed with this Circular;

b) A copy of the certificate of registration of veterinary drug;

c) The advertisements (content, form of advertising presented with images, sound, voice, letters, symbols, colors, light and the like);

d) A list of speakers containing information about their qualifications or academic ranks, applicable to advertisements showed at fairs, seminars, conferences, events, exhibitions, cultural/sport programs (which bears a seal of the enterprise).

3. Appraisal of application and issuance of the certificate of advertisment content verification for veterinary drugs

a) Within 05 working days from the day on which the application for certificate of veterinary drug advertisement contents, if the application is unsatisfactory, a competent agency specified in Article 42 of this Circular shall notify the applicant for completion;

b) Within 10 days from the day on which the satisfactory application is received, a competent agency specified in Article 42 of this Circular shall issue the Certificate of advertisement content verification for veterinary drugs using the form provided in Annex XLIII enclosed with this Circular. If the application is refused, the competent agency shall make a written response containing the explanation.

## Chapter VIII

## RESPONSIBILITIES OF RELEVANT PARTIES

### Article 44. Department of Animal Health

1. Direct and provide guidance pertaining to profession on the management of veterinary drugs; conduct tests of the quality of veterinary drugs at producing, exporting, importing or trading establishments.

2. Conduct appraisal of the application, conduct assessment and grant recognition for establishments eligible to manufacture or import veterinary drugs.

3. Conduct appraisal of the application, issue the license for testing veterinary drugs.

4. Conduct appraisal of application, issue the Certificate of free sale for veterinary drugs.

5. Conduct inspection/test of veterinary drugs, conduct inspection of the implementation of responsibilities and powers of agencies affiliated to the Department of Animal Health and provincial veterinary authorities in the management of veterinary drugs. Formulate annual plan for quality inspection of veterinary drugs which are being sold.

6. Every year, formulate and send a plan on management and supervision of antibiotics materials which are imported for producing veterinary drugs to the Ministry of Agriculture and Rural development for approval.

7. Receive and conduct appraisal of veterinary drug advertisement contents within the management as prescribed in clause 1 Article 42 of this Circular; issue the Certificate of advertisement content verification.

### Article 45. Agencies affiliated to the Department of Animal Health

1. Conduct quality inspection of veterinary drugs which are imported and are being sold.

2. Assess the conditions of the veterinary drug-testing establishments according to regulations in Article 88 of the Law on veterinary medicine and Article 20 of Decree No. 35/2016/ND-CP dated May 15, 2016 at the request of the Department of Animal Health.

3. Supervise the test of veterinary drugs according to the license for testing veterinary drugs; verify the reports of results of veterinary drug testing.

**Article 46. Provincial veterinary authorities**

1. Conduct quality inspection of veterinary drugs within management according to regulations.

2. Provide training, disseminate law provisions on manufacture, trade and use of veterinary drugs for relevant organizations and individuals.

3. Supervise the testing of veterinary drugs (excluding vaccines/antibodies) according to the license for testing veterinary drugs; verify the reports of results of veterinary drug testing.

4. Conduct appraisal of the application for registratioon, conduct assessment and grant recognition for establishments eligible to trade veterinary drugs.

5. Receive and conduct appraisal of veterinary drug advertisement contents within the management as prescribed in clause 2 Article 42 of this Circular; issue the Certificate of advertisement content verification.

6. Every 6 months, report the situation of trade, quality inspection and use, the results of inspection and the handling of violations pertaining to veterinary drugs under the management to the Department of Animal Health and report annually or irregularly at the request of of the Department of Animal Health.

**Article 47. Applicant for permission to conduct veterinary drug testing**

1. Formulate the testing outline;

2. Conclude a contract for veterinary drug testing with a testing establishment and fully comply with such contract.

**Article 48. Applicant for registration of veterinary drug**

1. Take responsibility to law and consumers for the quality of veterinary drugs it manufactured, traded or distributed.

2. Facilitate the inspection of competent agencies.

3. Report the situation of manufacture and trade of veterinary drugs to the authority on request.

4. Notify the authority in charge of animal healthcare of the dissolution or non-manufacture of the registered products, as the case may be.

5. Be the transferee of reseach findings, testing results, product's propriety according to laws on intellectual property and other relevant legal documents.

**Article 49. Establishments producing, trading, importing veterinary drugs**

1. Any manufacture establishment shall fulfill conditions specified in Article 90, clause 2 Article 91 of the Law on veterinary medicine and Articles 12 and 13 of Decree No. 35/2016/ND-CP dated May 15, 2016.

2. Any trading establishment shall fulfill conditions specified in Article 92, clause 2 Article 93 of the Law on veterinary medicine and Articles 17 of Decree No. 35/2016/ND-CP dated May 15, 2016.

3. Any importing establishment shall

a) Fulfill conditions specified in Article 94, clause 2 Article 95 of the Law on veterinary medicine and Articles 18 of Decree No. 35/2016/ND-CP dated May 15, 2016.

b) Only sell veterinary drug materials to establishments eligible to trade veterinary drug materials, establishments eligible to manufacture veterinary drugs; must not sell veterinary drug materials to veterinary drug stores, common people or farming/aquaculture establishments.

## Chapter IX

## ORGANIZATION OF IMPLEMENTATION

**Article 50. Implementary clause**

1. This Circular comes into effect from July 19, 2016.

2. This Circular annuls the following provisions:

a) Regulations about testing of veterinary drugs provided for in Decision No. 18/2002/QD-BTS dated 03/6/2002;

b) Articles 1 and 2 of Circular No. 47/2010/TT-BNNPTNT dated 03/8/2010 by the Ministry of Agriculture and Rural development;

c) Article 1 of Circular No. 20/2011/TT-BNNPTNT dated 06/4/2011 by the Ministry of Agriculture and Rural development;

d) Articles 19, 20 and 21 of Circular No. 04/2015/TT-BNNPTNT dated 12/02/2015 by the Ministry of Agriculture and Rural development;

dd) Article 2 of Circular No. 10/2016/TT-BNNPTNT dated 01/6/2016 by the Ministry of Agriculture and Rural development.

3. This Circular replaces the following documents:

a) Circular No. 02/2009/TT-BNN dated 14/01/2009 by the Ministry of Agriculture and Rural development;

b) Circular No. 03/2009/TT-BNN dated 14/01/2009 by the Ministry of Agriculture and Rural development;

c) Decision No. 71/2007/QD-BNN dated 06/8/2007 by the Ministry of Agriculture and Rural development;

d) Decision No. 98/2007/QD-BNN dated 03/12/2007 by the Ministry of Agriculture and Rural development;

dd) Decision No. 72/2007/QD-BNN dated 06/8/2007 by the Ministry of Agriculture and Rural development;

e) Decision No. 100/2007/QD-BNN dated 03/12/2007 by the Ministry of Agriculture and Rural development.

g) Decision No. 10/2006/QD-BNN dated 10/02/2006 by the Ministry of Agriculture and Rural development;

h) Decision No. 99/2007/QD-BNN dated 03/12/2007 by the Ministry of Agriculture and Rural development;

i) Circular No. 51/2009/TT-BNNPTNT dated 21/8/2009 by the Ministry of Agriculture and Rural development;

k) Circular No. 07/2012/TT-BNNPTNT dated 13/02/2012 by the Ministry of Agriculture and Rural development;

l) Circular No. 08/2012/TT-BNNPTNT dated 13/02/2012 by the Ministry of Agriculture and Rural development;

m) Circular No. 33/2011/TT-BNNPTNT dated 06/5/2011 by the Ministry of Agriculture and Rural development.

**Article 51. Transitional provisions**

1. Any application for testing, processing or selling veterinary drugs which is submited before the effective date of this Circular shall be processed according to regulations in Decision No. 10/2006/QD-BNN dated 10/02/2006 by the Ministry of Agriculture and Rural development, Decision No. 71/2007/QD-BNN dated 06/8/2007 by the Ministry of Agriculture and Rural development, Circular No. 08/2012/TT-BNNPTNT dated 13/02/2012 by the Ministry of Agriculture and Rural development and amendments thereof.

2. The management of bioproducts, microorganisms, chemicals and/or minerals used in aquaculture as prescribed in Circular No. 23/2015/TT-BNNPTNT dated 22/6/2015 by the Ministry of Agriculture and Rural development shall be carried out as follows:

a) For applications submitted before 01/7/2016, comply with regulations in Circular No. 23/2015/TT-BNNPTNT dated 22/6/2015 by the Ministry of Agriculture and Rural development;

b) Products which are permitted to be sold shall continue to be sold until the expiry date on the license for sale or continue to be sold for 05 years as from the date of license (applicable to license without expiry date). The application for reissuance or extension shall comply with regulations in points c or d clause 2 of this Article.

c) For antiseptics and products used for pasteurizing or disinfecting which have active ingredients specified in Annex XLIV enclosed with this Circular, comply with regulations in this Circular since this Circular comes into effect;

d) For products other than those specified in point c of this clause which are used for disintegrating organic substance, producing natural food, stabilizing raising environment or adding minerals, comply with regulations on management of animal feed since this Circular takes effect.

3. For products specified in part C Annex IC enclosed with Circular No. 10/2016/TT-BNNPTNT dated 01/6/2016 by the Ministry of Agriculture and Rural development promulgating a List of veterinary drugs permitted to be marketed and banned from use in Vietnam, and announcement of HS codes of imported veterinary drugs permitted to be marketed in Vietnam:

a) For antiseptics and products used for pasteurizing or disinfecting which have active ingredients specified in Annex XLIV enclosed with this Circular, continue to comply with regulations in the Law on veterinary medicine and this Circular.

b) Products other than those specified in point a of this clause may be sold until the expiry date written on the certificate of permission for sale, then regulations in point d clause 2 of this Article shall be applicable.

4. If an establishment producing or trading products containing active ingredients prescribed in Annex XLIV enclosed with this Circular has not obtained the certificate of eligibility to product or trade veterinary drugs or the GMP certificate, within 12 months from the day on which this Circular comes into effect, such establishment shall apply for the certificate of eligibility to manufacture/trade veterinary drugs according to regulations in the Law on veterinary medicine and this Circular.

**Article 52. Organization of implementation**

Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Agriculture and Rural development for consideration and solution./.

**P.P. THE MINISTER**
**THE DEPUTY MINISTER**

**Vu Van Tam**

## ANNEX VIII

SUMMARY OF PRODUCT CHARACTERISTICS
*(Enclosed with the Circular No. 13/2016/TT-BNNPTNT dated June 02, 2016 by the Minister of Agriculture and Rural development)*

## SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of product

2. Dosage form of product

3. Administration route

4. Composition, contents of active ingredients and excipients in the formula of the product

5. Pharmacodynamic and pharmacokinetic characteristics of the product

6. Indications

7. Dosage, usage and administration route

8. Warning

a) Notes;

b) Interaction with other drugs, other types of interaction;

c) Side effects when using according to the instructions and dosage regimen of the product;

d) Side effects upon overdose and handling measures (if any);

dd) Information about the use of the product for pregnant animals, milch animals and livestock raised for eggs;

e) Contraindications

9. Warning provided for drug users for prevention of and treatment for animal diseases

10. Time to stop using drugs

11. Information about drug usage

a) Expiry date (before and/or after the first time of opening of the product);

b) Storage conditions;

c) Characteristics and capacity of the product's package;

d) Guidance on the reduction of unused parts of the product.

12. Name and address of the manufacturer.

**[REPRESENTATIVE OF ORGANIZATION/INDIVIDUAL]**
*(Signature, full name and seal)*

*protected under Clause 2, Article 14 of the Law on Intellectual Property.Your comments are always welcomed*