

## **Circular No. 03/2009/TT-BNN of January 14, 2009, on labeling veterinary drugs**

*Pursuant to the April 29, 2004 Animal Health Ordinance; and the Government's Decree No. 33/2005/ND-CP of March 15, 2005, detailing a number of articles of the Animal Health Ordinance;*

*Pursuant to the Government's Decree No. 01/2008/ND-CP of January 3, 2008, defining the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;*

*Pursuant to the Government's Decree No. 89/2006/ND-CP of August 30, 2006, prescribing contents, presentation and state management of labels of domestically circulated goods and exported and imported goods (below referred to as Decree No. 89/2006/ND-CP);*

*Pursuant to the Science and Technology Ministry's Circular No. 09/2007/TT-BKHCN of April 6, 2007, guiding a number of articles of the Government's Decree No. 89/2006/ND-CP of August 30, 2006, on goods labeling;*

*The Ministry of Agriculture and Rural Development prescribes the labeling of veterinary drugs, veterinary pharmaceutical materials, biological preparations, microorganisms and chemicals used in animal health, including aquatic veterinary drugs, (below referred to as veterinary drugs) as follows:*

### **I. GENERAL PROVISIONS**

#### **1. Scope of regulation**

a/ This Circular prescribes contents and presentation of labels of exported, imported or domestically circulated veterinary drugs.

b/ The following cases are not governed by this Circular:

- Veterinary drugs temporarily imported for re-export or for display at fairs or exhibitions and re-export later; transited goods or goods transported to/from border gates; non-trade imported veterinary drugs, donated drugs, veterinary drugs under research at research and manufacture establishments;

- Veterinary drugs imported for test or examination;

- Veterinary drugs imported for urgent control of epidemics or in other special cases;

- Veterinary drugs being presents or gifts or personal effects of people on entry or exit.

#### **2. Subjects of application**

Domestic and overseas organizations and individuals engaged in manufacture, franchised manufacture, subcontracted manufacture, division and re-packing (below referred to as manufacture), trading in, import and export of

veterinary drugs shall comply with this Circular, the intellectual property law and other relevant legal documents.

### 3. Interpretation of terms

In this Circular, the terms below are construed as follows:

*a/ Veterinary drug* means a substance or compound originated from animals, plants, microorganisms, minerals or chemicals used for prevention, diagnosis or treatment of animal diseases or rehabilitation, adjustment or improvement of functions of bodily organs of animals, which includes pharmaceuticals, chemicals, vaccines, hormones, some other biological preparations and some microorganisms used in animal health.

*b/ Proprietary name* means a commercial brand named by a drug manufacturer, which is different from the original or international non-proprietary name.

*c/ 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 to display necessary and essential information as a basis for users' selection and proper use and for examination and control by functional agencies.

*d/ Labeling of a drug* means the presentation of basic and necessary information on a drug on its label for users' information, selection, consumption and use; for goods promotion by manufacturers and traders; and for examination and control by functional agencies.

*e/ 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 production chain.

*f/ 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.

*g/ Commercial packaging of a drug* means the packaging which contains the drug and is circulated together with the drug, comprising two types:

- *Direct packaging*, which means the packaging in direct contact with and directly containing the drug;

- *Outer packaging*, which means the packaging used for packing one or a number of drug units contained in direct packagings.

*h/ 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.

*i/ Packing specifications of a drug* means the drug quantity in net weight, actual volume or cardinal number.

*j/ Manufacture lot 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 lot, covering all stages of manufacture, quality control and distribution of such lot.

*k/ 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 lot is completed.

*l/ Expiry date* means the point of time past which a drug may not be used.

*m/ 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.

*n/ Use and storage instructions* 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.

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

#### 4. Veterinary drugs subject to labeling

a/ Domestically circulated, exported and imported veterinary drugs shall be labeled under this Circular, except the case specified at Point b of this Clause.

b/ When a foreign importer of a Vietnamese drug requests the drug exporter to label such drug under their purchase and sale contract and takes responsibility for its request, the drug exporter may do so, provided that such labeling does not misrepresent the nature of the drug and contravene the laws of Vietnam and the importing country.

#### 5. Veterinary drug label positions

The label of a veterinary drug shall be placed (printed, stuck, pinned or attached) on the commercial packaging of the drug at a position from which all of its compulsory contents can be easily noticed without having to disassemble the drug under Clause 1, Article 6 of Decree No. 89/2006/ND-CP.

#### 6. Veterinary drug label sizes

Organizations and individuals responsible for drug labeling may decide on label sizes, but shall ensure the full presentation of compulsory contents under Part II of this Circular.

#### 7. Colors of letters, signs and images shown on veterinary drug labels

The color of letters, numerals, drawings, images, signs and symbols shown on a veterinary drug label must be conspicuous. For compulsory contents, the color of letters and numerals must contrast the label’s background color as prescribed in Article 8 of Decree No. 89/2006/ND-CP.

#### 8. Language presented on veterinary drug labels

a/ Compulsory contents of a veterinary drug label shall be presented in Vietnamese, except the cases specified at Point d of this Clause.

b/ Contents of the label of a domestically manufactured and circulated veterinary drug may, apart from complying with Point a of this Clause, be concurrently presented in other languages. Contents in other languages must match those in Vietnamese. Sizes of letters for contents in other languages must not be bigger than those in Vietnamese.

c/ An imported veterinary drug whose original label does not contain or not fully contain compulsory contents in Vietnamese must have a supplementary label displaying compulsory contents in Vietnamese together with its original label.

d/ The following information may be presented in other languages of Latin origin:

- Proprietary name, original name or international non-proprietary name of a drug;

- International non-proprietary names or scientific names of ingredients, quantitative ingredients of a drug when it is impossible to translate these names into Vietnamese or such translation bears no meaning;

- Name and address of the foreign manufacturer or grantor of manufacture franchising.

e/ Information presented on a veterinary drug label, including its supplementary label, and the “use instructions” insert must be truthful, conspicuous and accurate and true to the drug’s nature.

#### 9. Veterinary drugs labeling responsibilities

a/ Manufacturers of Vietnamese veterinary drugs for domestic sale shall label their drugs.

b/ Manufacturers of Vietnamese veterinary drugs for export and exporters shall label such

drugs.

c/ When a for-export veterinary drug cannot be exported and is circulated domestically, the distributor of such drug shall label it under Clause 8, Part I of this Circular.

d/ When an organization or individual responsible for labeling a veterinary drug under Article 10 of Decree No. 89/2006/ND-CP requests another organization or individual to label such drug, the former shall still take responsibility for the label of its drug.

e/ The importer of a drug whose original label fails to comply with this Circular shall make a supplementary label under Point c, Clause 8, Part I of this Circular before circulating the drug together with the original label.

f/ Drug manufacturers and traders shall comply with the intellectual property law and take responsibility before law for intellectual property-related matters concerning drug label contents.

## II. CONTENTS AND PRESENTATION OF VETERINARY DRUG LABELS

### *Section A. CONTENTS OF VETERINARY DRUG LABELS*

#### 1. Compulsory contents on veterinary drug labels

A veterinary drug label must fully contain the following information:

- a/ Name of the drug;
- b/ Composition and quantity of active ingredients (content or strength);
- c/ Packing specifications;
- d/ Indication, route of administration, contraindication; withdrawal/withholding time (if any) to use eggs, meat or milk for each animal species to be treated;

e/ Preparation form, circulation registration number, manufacture lot number, date of manufacture, expiry date, the phrase "For use in animal health only";

#### f/ Remarkable signs

- For schedule-A toxic veterinary drugs, to add the phrase (in black) "Overdose is not allowed."

- For schedule-B toxic veterinary drugs, to add the phrase (in red) "Overdose is not allowed."

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

#### h/ Origin of the drug;

(Except domestically manufactured and circulated drugs 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 at Points a, b, c, e, f, g and h of this Clause shall be presented. Other compulsory information shall be presented in a supplementary label or "use instructions" insert. In this case, the label must indicate where such information is presented.

#### 2. Other contents presented on veterinary drug labels

Apart from compulsory contents under Clause 1, Section A, Part II of this 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. Information presented on labels of veterinary pharmaceutical materials

The label of a veterinary pharmaceutical material must contain the following information:

- a/ Name of the material;
- b/ Content or strength (if any);

- c/ Standards of the material;
- d/ Net weight or volume;
- e/ Manufacture lot number, date of manufacture;
- f/ Expiry date, storage conditions;
- g/ Circulation registration number (if any);
- h/ Name and address of manufacturer;
- i/ Origin of the material (except domestically manufactured and circulated materials whose labels already contain addresses of manufacturers).
- j/ Name and address of importer (for imported materials);
- k/ Remarkable signs.

#### 4. Contents of labels of veterinary drug packs

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 drug containing 3 or fewer active ingredients, its label must fully indicate these active ingredients and their contents;
- c/ Manufacture lot number, expiry date, circulation 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 an outer packaging which has a label fully displaying the information specified in Clause 1, Section A, Part II of this Circular.

#### 5. Contents of labels of small-sized direct packagings

- a/ The label of a veterinary drugs on a small-sized direct packaging with a special shape that cannot fully display compulsory information under Clause 1, Section A, Part II of this Circular, must at least contain the following information:
  - Name of veterinary drug;

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

- Volume or weight;
- Manufacture lot number, expiry date, circulation registration number;
- Name of manufacturer, which may be abbreviated, but must ensure the identity of the manufacturer.

b/ Direct packagings of these veterinary drugs shall be put inside outer packagings which have labels fully displaying the information specified in Clause 1, Section A, Part II of this Circular.

### *Section B. LABELING 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 nature 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 original or international non-proprietary name of the drug right after the proprietary name.

b/ A drug may be named after:

- Original name;
- International non-proprietary name (INN);
- Proprietary name.

#### 2. Composition of active ingredients, contents or strength

a/ To display the composition of all active ingredients and adjuvants contained in a drug product under Clause 1, Article 18 of Decree No. 89/2006/ND-CP even when those materials change their forms in the manufacture process.

b/ To present all active ingredients and their contents or strength for the smallest dose or packing unit. To present names of active ingredients according to their original or international non-proprietary names.

c/ To present the quantity of ingredients whose names are displayed on a veterinary drug label for the purpose of drawing attention.

d/ Particularly for aquatic veterinary drugs, apart from the above information, to present the formulation on composition.

e/ Units of measurement

To present units of quantitative measurement on veterinary drug labels in their full or abbreviated forms. For example, gram or g, milliliter or ml.

- Units of weight measurement: kilogram (kg), gram (g), milligram (mg). To present weights of under 1 kg in g (for example: 500 g instead of 0.5 kg); and of under 1 g in mg (for example: 500 mg instead of 0.5 g).

- Units of volume measurement: liter (l), milliliter (ml). To present volumes of under 1 liter in ml (for example: 500 ml instead of 0.5 l).

- Units of active power may be used according to international practice 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 packaging.

b/ Packing specifications shall be presented in natural numbers.

c/ Packing indications of some specific forms of veterinary drugs shall be presented as follows:

- For capsules: To display the number of capsules, contents of active ingredients/capsule;
- For powder: To display the net weight;
- For liquid: To display the actual volume;
- For gonadotropic drugs for fish breeding and

some other active ingredients: To use international unit (IU).

d/ For a drug whose commercial packaging contains many packing units, to display the weight of each packing unit and the number of packing units.

4. Indication, route of administration, contraindication and withdrawal/withholding time (if any)

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 a drug with contraindication.

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 "use instructions" insert enclosed in the commercial packaging, for a drug whose label on the outer packaging fails to display the drug's indication, route of administration and contraindication. In this case, the phrase "see use instructions insert for indication, route of administration and contraindication" shall be printed on the label on the outer packaging.

e/ Withdrawal/withholding time (if any): To specify the withdrawal/withholding time for each animal species to be treated.

The withdrawal/withholding time must match the time indicated in the drug circulation registration dossier.

5. Preparation forms, circulation registration numbers, manufacture lot numbers, dates of manufacture, expiry date, storage conditions

a/ To present preparation forms of a drug as capsule, powder, injection solution, injection

suspension, powder for injection, or oral solution.

b/ To present the circulation registration number, which is the code of a veterinary drug granted by the Animal Health Department to certify the circulation registration of such drug in Vietnam, as SDK: XX-XXXX-XX.

c/ To present the manufacture lot number as so lo san xuat or so lo SX (manufacture lot number): XXXX. The manufacture lot number's structure is prescribed by the manufacturer.

d/ To present the date, month and year of manufacture, expiry date and storage duration specifically as follows:

- The date of manufacture and expiry date shall be presented on the label fully or in abbreviation in capital letters as NSX (date of manufacture), HSD (expiry date) in the order of date, month and year of the calendar year. The date, month and year shall be presented in two-digit numerals. The year may be presented in four-digit numerals. The date, month and year indicating a point of time shall be presented in the same line.

- The date, month and year of manufacture and expiry date under Article 16 of Decree No. 89/2006/ND-CP shall be presented as follows:

For example: The date of manufacture is April 2, 2006, the expiry date is October 2, 2008, they can be presented on the label in one of the following ways:

+ NSX: 020406 – HSD: 021008; or  
+ NSX: 02 04 06 – HSD: 02 10 08; or  
+ NSX: 02042006 – HSD: 02102008; or  
+ NSX: 02 04 2006 – HSD: 02 10 2008; or  
+ NSX: 02/04/06 – HSD: 02/10/08; or  
+ NSX: 020406 – HSD: 30 months; or  
+ NSX: 020406 – HSD: 30 months from NSX.

- When it is impossible to display NSX, HSD together with the numbers indicating the date,

month and year, the label must so indicate.

For example: If the date of manufacture and expiry date 020406 021008 are displayed at the bottom of the packaging, the label must display the phrase: see NSX, HSD at bottom.

- When a label displays the date of manufacture NSX and expiry date HSD in a foreign language, it must so indicate.

For example, if the date of manufacture and expiry date MFG 020406 EXP 021008 are displayed at the bottom of the packaging, the label must display the phrase: See MFG, EXP at bottom for NSX and HSD.

- When a label displays the date of manufacture and expiry date in a foreign language, the supplementary label must display the date of manufacture and expiry date or the phrase "see Mfg Date, Exp Date for NSX, HSD" (which are abbreviations for date of manufacture and expiry date).

e/ Storage conditions means climate factors to ensure the quality of drugs. Necessary storage conditions shall be presented on a drug label. For example: Store in a dry and cool place at 30°C or below.

#### 6. Remarkable signs

a/ For injection drugs or power for injection, to indicate injection methods, which may be abbreviated to tb (intramuscular injection), tdd (subcutaneous injection) and ttm (intravenous injection).

b/ For eyewater, to display the phrase "Eyewater".

c/ For drugs for external use, to display the phrase "For external use".

d/ For drugs in ampoules for oral use, to display the phrase "Not for injection."

e/ For some chemicals used in animal health, to display their typical qualitative indicators. For inflammable, explosive, toxic or corrosive



franchise manufacturer or subcontract manufacturer, the house number, street (village), commune (ward, township), district (town, provincial city) and province (centrally run city) shall be displayed.

#### 8. Origin of veterinary drugs

The origin of a veterinary drug shall be presented as follows:

a/ For an imported drug. To present the phrase "manufactured in" or "origin" followed by the name of country or territory of manufacture.

b/ For a domestically manufactured and circulated drug whose label already indicates the place of manufacture, the presentation of the drug's origin is not required.

d/ The origin of a drug shall be presented on its outer and direct packagings.

#### 9. Use instructions

a/ Veterinary drugs labeled under this Circular must have a "use instructions" insert in Vietnamese. The contents of this insert may be printed on the direct packaging or intermediary label instead of a separate insert.

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

b/ A "use instructions" insert must contain the following information:

- Name of veterinary drug;
- Composition and formula for the smallest dose or packing unit. A formula must present all active ingredients and adjuvants in their original names or international non-proprietary names. Contents or strength of each active ingredient shall be presented while that for adjuvants is not required;

For an imported veterinary pharmaceutical material without Vietnamese name, its names in Latin and in the exporting country's language shall be presented.

- Preparation form of veterinary drug;
  - Packing specifications;
  - Indication;
  - Dose, use and route of administration:
    - + To specify the quantity of drug used for the treated animal each time or one day;
    - + To specify doses for each species and age of the treated animal;
    - + To specify the route of administration and time and how to use to achieve the highest effect.
  - Contraindication (if any): To specify contraindication cases for each species and age of animal;
  - Cautions: To specify precautionary warnings upon use; and special warnings for the environment, drug administrators and treated animals;
  - Drug interaction and types of other interaction (if any) that may affect a drug's effect;
    - Side effects (if any): To specify side effects that may occur upon use;
    - To specify cases to be suspended from use and cases to be reported to veterinary doctors.
  - Briefs of pharmacodynamics and pharmacokinetics (for new and proprietary drugs);
  - Overdose and remedy (if any): To indicate signs of overdose and remedy and first aid methods;
  - Remarkable signs and warnings: To display remarkable signs specified in Clause 6, Section B, Part II of this Circular,
  - Storage conditions: To specify necessary conditions to store the drug;
    - Expiry date: To present in compliance with Clause 5, Section B, Part II of this Circular or to specify the use duration from the date of manufacture (for example: expiry date: 24 months from the date of manufacture).
- For a drug which is not divided into doses, to indicate the expiry date from the time of opening its direct packaging.

- Name and address of organization or individual responsible for the drug.

#### 10. Presentation of supplementary labels

A supplementary label shall be attached to the outer 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 or individual shall take responsibility before law for the accuracy and truthfulness of additional contents. A supplementary label shall be presented as follows:

a/ For a label with sufficient space, to display all compulsory contents under Clause 1, Section A, Part II of this Circular.

b/ For a small label which cannot fully display compulsory contents, at least the following information shall be presented:

- Name of the drug;
- Active ingredients, content or strength;
- Name of organization or individual responsible for the drug;
- Circulation registration number;
- Packing specifications;
- Date of manufacture, expiry date, manufacture lot number;
- Origin of the drug.

Other remaining compulsory information shall be presented in the "use instructions" insert. The supplementary label must contain the phrase "see use instructions insert for other information" and the contents on the use instructions insert as indicated on the supplementary label are 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, original 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 it into Vietnamese or such translation bears no meaning;

- Name and address of foreign manufacturer or manufacture franchising grantor.

### III. ORGANIZATION OF IMPLEMENTATION

1. The Animal Health Department, Agriculture and Rural Development Services of provinces and centrally run cities, domestic and overseas organizations and individuals engaged in veterinary drug manufacture, trading, import and export activities and organizations and individuals engaged in veterinary drug circulation-related activities in Vietnam shall implement the Government's Decree No. 89/2006/ND-CP, the Science and Technology Ministry's Circular No. 09/2007/TT-BKHCN of April 6, 2007, and this Circular.

2. Veterinary drugs labeled under the Agriculture and Rural Development Minister's Circular No. 75/2000/TT-BNN-KHCN of July 17, 2000, which were circulated on the market prior to the effective date of this Circular, may be circulated until their expiry dates.

3. This Circular takes effect 45 (forty-five) days from the date of its signing. In the course of implementation, any arising problems should be promptly reported to the Ministry of Agriculture and Rural Development (the Animal Health Department) for consideration and settlement.

*For the Minister of  
Agriculture and Rural Development  
Vice Minister  
DIEP KINH TAN*