

**THE MINISTRY OF AGRICULTURE AND
RURAL DEVELOPMENT**

**Circular No. 02/2009/TT-BNN of
January 14, 2009, guiding the
procedures for withdrawal and
disposal of veterinary drugs**

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 November 21, 2007 Law No. 05/2007/QH12 on Product and Goods Quality;

Pursuant to the April 29, 2004 Animal Health Ordinance;

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

The Ministry of Agriculture and Rural Development guides the procedures for withdrawal and disposal of veterinary drugs and biological preparations, microorganisms and chemicals used in animal health (including aquatic veterinary drugs) as follows:

I. GENERAL PROVISIONS

1. Scope of regulation and subjects of application

a/ This Circular applies to veterinary drugs and biological preparations, microorganisms and chemicals used in animal health, including aquatic veterinary drugs (below collectively referred to as veterinary drugs), specified in Article 50 of the Animal Health Ordinance and Article 62 of the Government's Decree No. 33/2005/ND-CP of March 15, 2005, detailing a number of articles of the Animal Health Ordinance.

b/ State agencies, Vietnamese and foreign organizations and individuals engaged in veterinary drug production and trading activities in the Vietnamese territory shall comply with this Circular.

2. Interpretation of terms

The terms referred to in this Circular are construed as follows:

a/ *Use duration* means the time limit for using of a drug lot. Past this time limit, the drug may not be circulated and used.

b/ *Lot* means a certain quantity of products which are manufactured in a given production cycle under a specific production order and have the same specifications and quality.

c/ *Poor quality drug* means a drug failing to meet quality standards registered with the Animal Health Department.

d/ *Fake veterinary drug* means a veterinary drug without a production registration certificate granted by a competent agency, or a product in drug form falling under one of the following cases:

- Containing no or insufficiently containing pharmaceutical substances as registered;
- Containing pharmaceutical substances other

than those indicated on the label;

- Using the name, model or product circulation registration code of another manufacturer;

- Using the name or industrial design of another manufacturer's product already registered for industrial property protection.

e/ *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.

f/ *Drug of unclear origin* means a drug whose original label fails to specify or insufficiently specifies the manufacturer's name and address; or fails to specify the country or territory of manufacture, for an imported drug.

g/ *Establishment responsible for veterinary drugs* means a veterinary drug manufacturer, importer or trader.

II. WITHDRAWAL OF VETERINARY DRUGS

1. Veterinary drugs subject to withdrawal include:

a/ Those on the list of veterinary drugs banned from circulation in Vietnam;

b/ Those not on the list of veterinary drugs permitted for circulation in Vietnam;

c/ Fake veterinary drugs, veterinary drugs of unclear origin or with expired use duration;

d/ Unlabeled veterinary drugs or veterinary drugs improperly labeled under law;

e/ Those with changing appearance (or properties), such as being curdled, turbid, discolored, sedimented, layered or deformed.

f/ Those on the list of veterinary drugs permitted for circulation in Vietnam which are being circulated on the market, but detected

through state inspection as failing to meet registered quality standards.

2. Procedures for veterinary drug withdrawal:

a/ When detecting veterinary drugs subject to withdrawal under Points a, b, c, d and e, Clause 1, Part II, competent state agencies shall seal up those drugs and issue withdrawal decisions.

b/ Veterinary drugs specified at Point f, Clause 1, Part II shall be withdrawn as follows:

- For a veterinary drug whose samples are taken at a manufacturer, exporter or importer:

The Animal Health Department shall notify the drug owner of test results of drug samples and request it to immediately withdraw the lot of such drug by itself. Within 7 days, for a pharmaceutical product or chemical, or 45 days, for a vaccine or biological preparation, from the date of receiving the Animal Health Department's notice, the enterprise may lodge a complaint about test results with the Animal Health Department. Past this time limit, if no complaint is lodged, the Animal Health Department shall issue a decision to withdraw such drug nationwide.

When a complaint is lodged, the Animal Health Department shall take samples for re-testing. If test results still show that the drug fails to meet quality standards, the Animal Health Department shall issue a decision to withdraw the drug nationwide. When test results show that the drug meet quality standards, the lot of such drug may be circulated again on the market.

- For a veterinary drug whose samples are taken in a province or centrally run city:

After having test results, the sample-taking agency shall immediately seal up the lot of drugs failing to meet quality standard and issue a decision to withdraw the drug in a province or centrally run city; and simultaneously notify such to the Animal Health Department and the

manufacturer or importer of the drug lot. Within 7 days, for a pharmaceutical product or chemical, or 45 days, for a vaccine or biological preparation, from the date of receiving the Animal Health Department's notice, an enterprise may lodge a complaint about test results with the Animal Health Department. Past this time limit, if no complaint is lodged, the Animal Health Department shall issue a decision to withdraw the drug nationwide.

When a complaint is lodged, the Animal Health Department shall take samples at the manufacturer or importer for re-testing. If test results still show that the drug fails to meet quality standards, the Animal Health Department shall issue a decision to withdraw it nationwide. When test results show that the drug lot meets quality standards, the Animal Health Department will not issue a decision for withdrawal nationwide.

c/ A manufacturer, importer or trader that has a drug subject to withdrawal shall withdraw the drug on its own under the decision of a competent agency. Upon completion, it shall report such to the agency which issues the withdrawal decision.

d/ For a veterinary drug subject to withdrawal nationwide, the Animal Health Department shall issue a withdrawal decision and publicize it on a central mass media. Provincial-level Sub-Departments of Animal Health shall supervise the withdrawal in their localities.

e/ For a veterinary drug subject to withdrawal in a province or centrally run city, a Sub-Department of Animal Health shall issue a withdrawal decision and publicize it on a local mass media.

f/ The Animal Health Department shall issue a decision for withdrawal nationwide, publicize it on a central mass media and withdraw the registration number for the following special cases of violation:

- Veterinary drugs containing active ingredients on the list of veterinary drugs banned from circulation in Vietnam.

- Veterinary drugs detected as failing to meet quality standards in three regular or random examinations in a year by a competent agency.

- Veterinary drugs with unclear treatment effects or side effects that may harm human or animal health or pose risks to humans, animals and the environment.

III. DISPOSAL OF WITHDRAWN VETERINARY DRUGS

1. Provincial-level Sub-Departments of Animal Health shall destroy the following veterinary drugs:

a/ Those on the list of veterinary drugs banned from circulation in Vietnam;

b/ Those not on the list of veterinary drugs permitted for circulation in Vietnam;

c/ Fake veterinary drugs, veterinary drugs of unclear origin or those with expired use duration;

d/ Veterinary drugs with changing appearance (or properties), such as being curdled, turbid, discolored, sedimented, layered or deformed.

e/ Unlabeled veterinary drugs.

A Sub-Department of Animal Health shall issue a decision to set up a veterinary drug destruction council. Such a council must have at least three members: a leader of the Sub-Department of Animal Health, an inspector and a representative of the local environment agency.

2. For a veterinary drug on the list of veterinary drugs permitted for circulation in Vietnam, which is being circulated on the market, but is improperly labeled under law or fails to meet registered quality standards, the establishment responsible for the drug shall promptly:

a/ Withdraw and destroy veterinary drugs violating quality regulations at level 1, including:

- Erroneous contents that may cause serious consequences;

- Erroneous active ingredients that may cause serious consequences;

- No active ingredients or lack of the main active element indicated on the label;

- Vaccines failing to meet one of the three criteria: sterility, safety and effect;

- Veterinary drugs subject to urgent withdrawal under decisions of foreign management agencies (for imported veterinary drugs).

b/ Withdraw and dispose of veterinary drugs violating quality regulations at level 2 according to manufacturers' regulations:

- Veterinary drugs that are improperly labeled under law;

- Veterinary drugs that fail to meet one of the registered quality indicators on appearance, physico-chemical properties; microorganisms; or have contents beyond the $\pm 10\%$ limit for the contents indicated on the label; or net weight (actual volume) beyond the $\pm 5\%$ limit for the weight indicated on the label.

3. In case of destruction, an establishment responsible for the drug shall cover all expenses for destroying the drug and take responsibility for the consequences of such destruction under law.

IV. ORGANIZATION OF IMPLEMENTATION

1. Responsibilities of competent agencies

a/ The Animal Health Department shall guide the destruction of veterinary drugs, and forms of documents related to veterinary drug withdrawal.

b/ The Animal Health Department and provincial-level Sub-Departments of Animal

Health shall organize the withdrawal and disposal of veterinary drugs under this Circular.

2. Effect

This Circular takes effect 45 days from the date of its signing.

In the course of implementation, any arising problems should be reported to the Ministry of Agriculture and Rural Development (the Animal Health Department) for timely adjustment and supplementation.-

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