Content

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| Title： | Veterinary Drugs Control Act Ch |
| Date： | 2008.12.03 |
| Legislative： | 1.Promulgated on August 16, 1971.<br>2.Amendment to Articles 2, 15, 19, 22, 25, 26, 29, 30, 46 promulgated on June 19, 2002.<br>3.Amendment to Articles 7, 12, 16, 18, 23, 24, 32, 40, 41 and addition of Articles 3-1, 3-2, 12-1~12-4, 16-1, 18-1, 32-1~32-3<br>4.promulgated on December 18, 2002.<br>5.Amendment to Articles 26, 32-3, 33, 35, 36, 39~41 and deletion of Articles 34, 37, 38, 45 promulgated on December 3, 2008. |
| Content： | **Article 1**<br>This Act is enacted to improve the quality of veterinary drugs, maintain animal health and promote the development of the livestock industry.<br><br>**Article 2**<br>For the purposes of this Act, the term "competent authority" denotes the Council of Agriculture of the Executive Yuan at the central government level, the municipal city government at the municipal city level, and the county/city government at the county/city level.<br><br>**Article 3**<br>For the Purposes of this Act, the term "veterinary drugs" denotes any of the following bulk materials, formulated preparations, or over-the-counter drugs:<br>1. Serum, preventive inoculum, diagnostics and other medicines with the efficacy of veterinary biological products exclusively for preventing, diagnosing and treating animal diseases;<br>2. Antibiotics exclusively for preventing or treating animal diseases;<br>3. Medicines other than those under the previous two sub-paragraphs exclusively for preventing or treating animal diseases or enhancing or regulating the physiological functions of animals.<br><br>**Article 3-1**<br>The said formulated preparation indicated a veterinary drug is produced from raw materials by formulation process, which prepared as a proper formulation and dosage.<br>Central competent authority shall announce the category of formulated preparation.<br>The formulated preparation shall classify into veterinarian (or |

veterinarian assistance) prescribed drugs as well as non-prescribed drugs. The items prescribed by veterinarian, their sales conditions as well as the indications on applying such prescription of veterinarian (or veterinarian assistance) prescribed drugs as described in the previous paragraph shall be announced by central competent authority.

Article 3-2

The said new drug indicated new chemical entity, new combination, new indication , new route of administration, new dosage form, or new dose of veterinary drugs, which examine by central competent authorities.

Article 4

For the purposes of this Act, the term "counterfeit drugs" denotes any veterinary drugs in any of the following situations confirmed upon inspection:

1. Where the drugs are manufactured without the prior approval of the competent authority;
2. Where the drugs are substituted for or mixed with products of third parties;
3. Where the labeling in respect of the validity has been crossed out or altered;
4. Where the description of the ingredients contained does not conform to what has been approved;
5. Where approval seals are not affixed in accordance with Article 18.

Article 5

For the purposes of this Act, the term "forbidden drugs" denotes any of the following veterinary drugs:

1. Toxic and hazardous drugs the manufacture, prescription, importation, export, sale or display of which is banned by the central competent authority by way of public notice; or
2. Drugs imported without the prior approval of the competent authority.

Article 6

For the purposes of this Act, the term "inferior drugs" denotes any veterinary drugs the product registration of which has been duly approved and with respect to which occurrence of any of the following situations is confirmed upon analysis:

1. Where the quality, quantity or strength of the ingredients do not conform to the prescribed criteria;
2. Where the drugs are contaminated or have deteriorated either in whole or in part;
3. Where the shelf life has expired;
4. Where the main therapeutic efficacies do not conform to what have been approved.

The central competent authority shall prescribe the criteria under the

first sub-paragraph.

Article 7

For the purposes of this Act, the term "veterinary drug manufacturers' denotes companies engaged in the manufacture or processing of veterinary drugs, the wholesale or export of their products, and/or the importation of bulk materials for sale.

The central competent authority shall prescribe the criteria, procedures, and all required guidelines for veterinary drug manufacturer that apply for importing bulk materials for their production.

Bulk materials shall not shift or re-sale unless permitted by central competent authority.

Article 8

For the purposes of this Act, the term "veterinary drug dealers" denotes companies engaged in the wholesale, retail, importation and/or export of veterinary drugs.

Article 9

For the purposes of this Act, the term "label" denotes an identification article used to specify, in words, picture or symbol, the contents of a container or package of veterinary drugs.

Article 10

For the purposes of this Act, the term "packing insert" denotes the description sheet attached to veterinary drugs.

Article 11

For the purposes of this Act, the term "approval seals" denotes the seals, which the competent authority has allowed to be affixed to veterinary biological drugs after the drugs, have passed the inspection.

Article 12

To manufacture or import veterinary drugs, one shall apply to the central competent authority for product registration and shall not proceed to manufacture or import the drugs until the application has been duly approved and a license obtained from the authority. The application shall specify the ingredients, efficacy, summary of preparation, analytic method and relevant information, and shall be supported by certificates, labels, packing inserts and samples. Payment of the license fees and inspection fees shall also be attached.

The central competent authority shall prescribe the registered material facts under the preceding paragraph.

Manufacture or import veterinary drug license, their criteria to issue or extension of its validate year based on Good Manufacture Practice (GMP) by which shall be prescribed by the central competent authority.

Any veterinary new drug applies for registration shall submit by them or entrust to an organization or institution that having been recognized by central competent authority to perform safety and efficacy test depends on

the characteristics of the drug. The cost shall responsible by the applier. The central competent authority shall prescribe the rules for safety and efficacy test.
Lost or damage by soiling of veterinary drug license shall describe the reason and apply for reissuance or replacement the license against central competent authority after paying a certificate fee. In case of losing such certificate shall be cancelled by the central competent authority. In case of damage by soiling, shall submit the original certificate upon application.

**Article 12-1**
A veterinary drug license shall describe the following items in full.
1. License number.
2. Name of the drug
3. Name and address of the manufacturer or importer.
4. Name and address of the owner
5. Name and address of the manufacture factory
6. Formulation and package
7. Ingredients and contents.
8. Efficacy (Indications).
9. Other items assigned by central competent authorities.

**Article 12-2**
Label and packing insert of a veterinary drugs shall apply and get permission in advance and describe the following items in full.
1. For animal use only
2. Name and address of the manufacturer
3. Name of the drug and the license number
4. Ingredients, contents, usage, and dosage.
5. Indications
6. Side effect, contradiction, and other points for attentions
7. Withdraw period
8. Expired date or valid date
9. Others
Unless the item described in the previous paragraph has been announced by central competent authority may be exempted, all item must described in full.

**Article 12-3**
The documentation required for administration that related with this Act as well as license issuing, extending, alteration, shifting, reisssuing, and replacement shall be prescribed by the central competent authority.

**Article 12-4**
The standard of competent authority in charging against administrating license, testing, and the central competent authority shall prescribe examining under this Act.

**Article 13**
Unless otherwise approved by the central competent authority, change in any

of the registered material facts concerning any veterinary drugs the registration of which for manufacture or importation has been duly approved shall not be permissible.

Article 14

A veterinary drug license for manufacture or importation purposes shall be valid for four years. Where continuing manufacture or importation is contemplated upon expiration of the validity, an application for extension of the validity shall be filed with the central competent authority for approval; provided each such extension shall not exceed two years.
The central competent authority may, for health or other major reasons, revoke said license during its validity.

Article 15

Upon the incidence of statutory infectious diseases of domestic animals or if said incidence is apprehended, the central competent authority may take emergency measures to order or approve the manufacture or importation of veterinary biological drugs.

Article 16

In addition to the factory registration in accordance with law, a veterinary drug factory shall conform to the veterinary drug factory establishment criteria,
Veterinary drug manufacturer shall apply for a veterinary drug manufacturer against local agriculture competent authority. Such application will then transfer to central competent authority to classifying and confirming its category on drug manufacturing. Therefore, may proceed to registration for manufacturing establishment.
Central competent authority in cooperating with the central industry competent authority shall prescribe the criteria of the establishment as described in the preceding paragraph.

Article 16-1

Any production of veterinary drug shall not entrust to other manufacturer for production or entrusted to production unless approved by central competent authority. The guidelines for entrusting production shall be prescribed by the central competent authority.

Article 17

A veterinary drug factory manufacturing veterinary biological drugs shall employ veterinarians and one manufacturing veterinary antibiotics or ordinary drugs shall employ pharmacists to supervise the manufacture of drugs at the factory,

Article 18

Veterinary biologics once having been produced or taxed after importation by manufacturers or importers should take sampling against the competent authority by batch.
No manufactured or imported veterinary biological drugs shall be sold unless and until they have passed the inspection and have been duly sealed.

Article 18-1
Inspection according to the previous paragraph however could not pass the standard, municipal city or county (city) competent authority shall send the report to the applier. Applier may request for re-testing, once only, after paying a re-test fees within fourteen days on receiving this report. Veterinary drug could not pass the test and applier does not apply for re-test within the assigned period. Municipal city or county (city) competent authority shall monitor them to be destroyed or send-back by importer within a time limit.

Article 19
No veterinary drug dealer shall commence its business until the application, which it has filed with the local municipal city or county/city competent authority has been considered “acceptable” by the competent authority, and issue a veterinary drug dealer's license.
The management guidelines concerning the licensing requirement, items listed within the license certificate, and any modification of the license, facility in the place to carry on business and other regulation that veterinary drug dealer shall comply with, shall be prescribed by the central competent authority.

Article 20
Labels shall be affixed and packing inserts attached to veterinary drugs. The words, "For animal use only" shall also be indicated.
The material facts to be specified on the labels and packing inserts under the preceding paragraph shall be prescribed by the central competent authority.

Article 21
A veterinary drug dealer shall in no event repack veterinary drugs.
Veterinary drugs which are imported in bulk and sold using the original brand name after being repacked shall be repacked by a duly registered veterinary drug manufacturer or a public organization designated by the central competent authority.
No repacked veterinary drugs shall be sold unless and until they have been duly affixed with a repacking label and sealed.

Article 22
No salespersons in the employ of a veterinary drug manufacturer or dealer shall proceed with their sales until their employer has caused them to be duly registered against the municipal city/county competent authority, which includes any alteration of the salesperson.
Veterinary drug salesperson shall not sale drug(s) by whom do not own ownership or dealership, and directly sale at the booth by the street, opened the sealed of the container, repack or any advertisement not legally approved.

Article 23
No samples or complimentary items of veterinary drugs the importation of

which has been duly approved shall be sold.
Any approved imported veterinary drug license or controlled veterinary drug under this Act shall not request for importation by the name samples or complimentary items.
Control of the samples or complimentary items under the preceding paragraph shall be in accordance with theregulations prescribed by the central competent authority.

Article 24
No veterinary drugs the manufacture of which has been duly approved shall be exported unless and until the particular veterinary drug manufacturer has obtained an export permit from the central competent authority.
The export permit as described in the preceding paragraph is valid for three months at the date of issue.
Apply for veterinary drug exporting permit shall meet the guidelines of Good Manufacture Practice (GMP) for their establishment. Central competent authorities or assigned organization shall sampling and submit to assigned organization for inspecting their quality.

Article 25
The municipal or county/city competent authorities shall from time to time assign their officers to inspect veterinary drug manufacturer's place of manufacture and facilities as well as manufacturing process, devices, quality control and relevant information.
The central competent authority may, if necessary, assign officers to conduct random inspection of the material facts under the preceding paragraph.
In no event shall a veterinary drug manufacturer, without good cause shown, refuse the random inspection or inspection conducted by the competent authorities.
Municipal, or city/county competent authority request improvement within a deadline against manufacturer after site inspection, however, without any improvement can be shown. Competent authority may report to central competent authority to order a partial or full shutdown its factory.
Production of any veterinary drug(s), which has been condemned illegal, shall report to central competent authority to cancel its veterinary drug production license.

Article 26
The competent authorities may assign officers to the offices of a veterinary drug manufacturer, dealer, veterinary hospital or clinic or other users of veterinary durgs to conduct random inspections of their drugs and to take samples at the original prices thereof to inspect their quality.
The competent authorities may assign officers to animal, aquatic farms or feed manufactuers to audit the usage of veterinary drugs, and may conduct random physical examinations on animals.
In no event shall a veterinary drug manufacturer, dealer, veterinary hospital or clinic , animal, aquatic farmer, feed manufacturer or other user of veterinary drugs evade, hinder or refuse the above inspection,

sampling, audit, and examination.

Article 27
In performing the duties under the first and second paragraphs of Article 25 and the first paragraph of Article 26, inspectors of veterinary drugs shall show their identification certificate.

Article 28
Where taking of samples of veterinary drugs for appraisal purposes is considered necessary in order to see if the drugs are counterfeit, forbidden or inferior drugs suspected, the competent authority shall cause the drugs to be sealed and order the manufacturer of the drugs to issue an undertaking to hold them under penalty of law.
Samples taken in accordance with the preceding paragraph shall be appraised and disposed as soon as possible, at most within two months of the discovery.

Article 29
Where inspection discloses that the particular veterinary drug domestically manufactured and found to be an inferior drug in accordance with this Act will be usable after reprocessing, the municipal or city/county competent authority shall assign officers to supervise and order the manufacturer to complete the reprocessing within a prescribed time limit. If the drug is imported under the approval of the competent authority, the authority shall cause the drug to be sealed, and the central competent authority shall order the original importer to request the foreign-based manufacturer to accept the return of said drug within a prescribed time limit.

Article 30
Any and all veterinary drugs, which are examined or inspected to be counterfeit, forbidden, or inferior drugs shall be disposed in accordance with the provisions of this Act; In addition, the following actions shall also be taken:
1. The authority which issued the original license shall have the discretion to revoke all veterinary drug the relevant license if the wrongdoer is discovered to have manufactured, imported or repacked counterfeit, forbidden or inferior veterinary drugs, or loaned its license to any other person for production, importing or repacking veterinary counterfeit or forbidden drugs.
2. Where counterfeit, forbidden or inferior veterinary drugs are offered for sale or displayed or stored with intent to offer them for sale, the municipal, city/county competent authority shall, after the punishment has been imposed on the wrongdoer, publish a public notice in the newspapers on the name and address of the business firm, name of its responsible person, name of the drugs concerned, and the material facts that constitute the crime charged. In case of repeated offenses, the competent authority, which issued the original license, shall have the authority to revoke all veterinary drug license

or veterinary drug sales license.

3. Where inferior veterinary drugs are manufactured, imported, repacked and, offered for sale or displayed or stored with intent to offer them for sale, the city/county competent authority shall have the authority to publish a public notice in the newspapers on the name and address of the business firm, name of the responsible person, name of the drugs concerned and the material facts that constitute the crime charged. In case of gross violations or repeated offenses, the competent authority, which issued the original license, shall have the authority to revoke the related veterinary drug license and the veterinary drug sales license.

**Article 31**

Rewards shall be given to encourage the supply of information to officers about counterfeit, forbidden or inferior veterinary drugs banned under this Act. The central competent authority shall prescribe the incentive program.

**Article 32**

Animal applied, usages, administrative methods, dosages, withdraw period, points for attentions shall follow the rules prescribe by central competent authority.

**Article 32-1**

Bulk materials shall supply to the manufacturer that own a valid such license only.

**Article 32-2**

Veterinary drug manufacturer and importer shall report their seasonal production quantity, variety, sales volume, sales target against local municipal city, and county/city competent authority at January, April, July, and October yearly.

Municipal city, county/city competent authority shall submit such report to central competent authority at the end of January and July yearly.

**Article 32-3**

Animal and aquatic farmers and feed manufacturers shall not use veterinary drugs of unknown origin, manufacture or import without authorization, or human drugs to prevent animal diseases or regulate the physiological functions of animals.

Animal and aquatic farmers and feed manufacturers shall not use the raw veterinary drug or human drug to prevent animal disease or regulate the physiological functions of animals.

Animal and aquatic farmers when applying a veterinary drug that required withdrawal period limitation shall not sell animals, aquatic species, milk, eggs, or other edible products produced prior to the expiry of withdrawal period for slaughter, processing, or consumption.

**Article 33**

Whoever is guilty of manufacturing or importing forbidden veterinary drugs

under the first paragraph of Article 5, shall be imprisoned for no less than one year and no more than seven years; in addition, a fine of not more than NTD 4.5 million may also be imposed.
Whoever is guilty of manufacturing counterfeit veterinary drugs under Article 4, or importing forbidden veterinary drugs under the second paragraph of Article 5, shall be imprisoned for no less than half year and no more than five years; in addition, a fine of not more than NTD 2.5 million may also be imposed.
Whoever is guilty of making an attempt to commit the crime under the preceding two paragraphs shall also be punishable.

Article 34
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Article 35
Whoever is guilty of repacking, sale, transporting, consigning for storage, brokering, assigning displaying or storing with intent to offer for sale counterfeit veterinary drugs under Article 4, or forbidden veterinary drugs under Article 5, shall be imprisoned for no more than three years; in addition, a fine of not more than NTD4.5 million may also be imposed.
Whoever is guilty of committing the offense under the preceding paragraph out of negligence shall be detained or fined not more than NTD750,000.

Article 36
Whoever is guilty of manufacturing or importing any inferior veterinary drugs under the first paragraph of Article 6, shall be fined no less than NTD50,000 and no more than NTD2.5 million.
Whoever is guilty of repacking, sale, transporting, consigning for storage, brokering, assigning displaying or storing with intent to offer for sale inferior veterinary drugs under the first paragraph of Article 6, shall be fined no less than NTD250,000 and no more than NTD1.25 million.

Article 37
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Article 38
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Article 39
A veterinary drug manufacturer or dealer who is guilty of misrepresenting or exaggerating any advertisement or sales promotion beyond what is registered with the competent authority with respect to the ingredients or efficacy of its veterinary drugs manufactured or offered for sale shall be fined no less than NTD200,000 and no more than NTD1 million.

Article 40
A fine ranging from NTD90,000 to 450,000 shall be imposed if a person:
1. Violates the fourth paragraph of Article 3-1;
2. Violates the third paragraph of Article 7;
3. Violates Article 13 by changing the original registered

material facts without the prior approval of the competent authority;
4. Violates the third paragraph of Article 16 by failing to meet the factory establishment criteria on the buildings, environment, equipments, facilities, and measures in factory, operation sites, inspection and storage sites, or health management of workers.
5. Violate Article 16-1 by entrusting or being entrusted to produce veterinary drugs without permission.
6. Violates Article 17 by failing to employ a veterinarian or a pharmacist;
7. Violates the first paragraph of Article 19 by operating business without a license; or the second paragraph of Article 19 on application of changing the original registered material facts of license, the hanging location of license, making or displaying of sales clerk identification cards, application of operation suspension, resumption or close, qualification and training of veterinary drugs management technicians, environment and equipment of operation sites, storage, transport, operation and recording sale information of drugs, duties of notifying information of drugs to buyers, reporting adverse response cases or offering of drug sale information to the competent authorities ;
8. Violates Articles 20, 21, 24, the third paragraph of Article 25 or the third paragraph of Article 26;
9. Violates the first or third paragraph of Article 23 on labeling of samples or complimentary items of veterinary drugs, setting, recording and keeping the records of related information;
10. Violates Article 32 by failing to meet the criteria on the drugs application of target animals or aquatic spieces, purpose, usage, amount, withdrawal period and notice matters, user qualification, preparation, setting, recording and keeping the records of related information;
11. Violate Article 32-1, 32-2, or Article 32-3.

Animal or aquatic farmers in violation of the fourth paragraph of Article 3-1, third paragraph of Article 26, Article 32, or 32-3 shall be fined ranging form NTD30,000 to 150,000.

Whoever violates the first paragraph of Article 32-3 two times within one year shall be fined ranging from NTD250,000 and 1.25 million. Provided the behavior endangers human health, they will be imprisoned for no more than three years; in addition, a fine of not more than NTD 4.5 million may also be imposed.

Article 41

A fine ranging from NTD100,000 to 500,000 shall be imposed if a person:
1. Violates Article 12-2 by printing un-authorised items on the lable and packing insert;
2. Volates Article 15 without showing a good cause;
3. Violates the first paragraph of Article 22 by performing

sales promotion without registering with the competent authority of the place of the sales promotion or paragraph 2 ;
4. Violates the first paragraph of Article 28 by refusing to issue an undertaking to hold the drugs in trust under penalty of law.

Article 42
Where the representative of a legal person, the agent, employee or other practitioners of a legal or natural person violates any of Articles 33 to 38 in the performance of their duties, not only the wrongdoer shall be punished, but also the legal person or natural person concerned shall also be fined according to the particular Article.

Article 43
The equipment used for the manufacture and processing of veterinary drugs, which are discovered in accordance with this Act to be counterfeit or forbidden veterinary drugs, shall be confiscated regardless of whether it is owned by the wrongdoer. The counterfeit and forbidden drugs discovered shall also be cremated.
Any and all veterinary drugs which are discovered in accordance with this Act to be inferior but are neither reprocessed nor returned within a prescribed time limit pursuant to Article 29 shall be confiscated and cremated.

Article 44
Whoever is guilty of refusing to pay any fine imposed in accordance with this Act shall be referred to the court for compulsory execution.

Article 45
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Article 46
The municipal government or county/city government shall be authorized to impose fines in accordance with this Act.

Article 47
The central competent authority shall establish the Enforcement Rules of this Act.

Article 48
This Act shall become effective as of the date of promulgation.