Article Content

Title : Veterinary Drugs Control Act CH

Amended Date : 2016-11-09

Category : Council of Agriculture, Executive Yuan（行政院農業委員會）

Article 1 This Act is enacted to improve the quality of veterinary drugs, to enhance animal health, and to foster a robust livestock industry.

Article 2 The term " competent authority " in this Act refers to one of the following: the Council of Agriculture of the central government; or the municipal government of a special municipality, or a city/county at the local level; hereinafter " municipal competent authority " for the two preceding items.

Article 3 The term " veterinary drug " refers to one of the following substance in the form of bulk chemical compound, formulated preparation, or over the counter drug:
3.1 Biologics specifically made for preventing and treating animal diseases based on microbiology, immunology or molecular biology.
3.2 Antibiotics specifically made for preventing and treating animal diseases.
3.3 Diagnostics announced and designated by the central competent authority for the diagnosis of animal diseases.
3.4 Drugs other than those in Sections 3.1 to 3.3 to enhance or regulate animal physical functions specifically for preventing and treating animal diseases.

Article 3-1 3-1.1 The term " formulated preparation " in this Act refers to a veterinary drug formulated from bulk chemical compounds and prepared into a specific form and dosage.
3-1.2 Categories of formulated preparations are to be declared by the central competent authority.
3-1.3 Some formulated preparations require a prescription by a veterinarian (or a veterinarian assistant); the others do not.
3-1.4 Regarding prescription drugs mentioned in Section 3-1.3, the category names, sales terms, usage, entries in the prescription, mandatory bookkeeping for storage and sales, and other guidelines are to be prescribed by the central competent authority.

Article 3-2 The term " new drug " in this Act refers to a veterinary drug that has been reviewed and recognized by the central competent authority as associated with new ingredients, new combinations, new indications,

new routes of drug delivery, new dosage forms, or formulated preparat
usage and dosage.

Article 4 The term " counterfeit veterinary drug " in this Act refers to a drug – after testing – found to:
4.1 have been manufactured without government approval,
4.2 relpacing or mixing ingredient of an existing product,
4.3 show a defaced or altered expiration date,
4.4 contain ingredients whose name is not consistent with what have been approved, and
4.5 have failed to affix the seal of approval required by Article 18.

Article 5 5.1 The term " banned veterinary drug " in this Act refers to the one in either of the following situations:
5.1.1 Declared by the central competent authority that its manufacturing, dispensing, importation, exportation, sales, or display is prohibited, or
5.1.2 Imported without a permit. However, a drug can be exempt if it is other than a biologic described in Section 3.1, brought in by a tourist or member of transport service staff for use in one ' s own pet, and compliant with guidelines about specific drug categories, dosage forms and quantities.
5.2 The guidelines about specific categories, dosage forms and quantities in Section 5.1.2 are to be declared by the central competent authority in collaboration with the Ministry of Finance.

Article 6 6.1The term " substandard veterinary drug " in this Act refers to a veterinary drug that had been approved for registration but – upon subsequent testing – found to:
6.1.1 contain ingredients of a quality, quantity or strength not conforming to stipulated standards,
6.1.2 contain some or all ingredients that are contaminated or have degraded,
6.1.3 exceed the expiration date, or
6.1.4 make assertions that are inconsistent with approved indications.
6.2 The standards mentioned in Section 6.1.1 are to be prescribed by the central competent authority.

Article 7 7.1 The term " veterinary drug manufacturer " in this Act refers to an entity engaged in manufacturing and processing of veterinary drugs, wholesale and exportation of such products, and importation of materials for its own use.
7.2 The criteria, procedure, guidelines, and other items to comply with – for veterinary drug manufacturers to apply for importation of self-use materials – are to be prescribed by the central competent authority.
7.3 Unless approved by the central competent authority, such

imported-for-self-use materials must not be assigned or resold to a thi

Article 8 The term " veterinary drug dealer " in this Act refers to an entity engaged in the wholesale, retail sale, importation and exportation of veterinary drugs.

Article 9 The term " label " in this Act refers to an identification article with text, picture or symbol affixed on the container or package of a veterinary drug.

Article 10 The term " package insert " in this Act refers to the instruction sheet that comes with the veterinary drug.

Article 11 The term " seal of approval " in this Act refers to a seal (such as a sticker) to seal off a veterinary biologics to indicate the drug has passed testing and inspection, therefore approved by the central competent authority.

Article 12 12.1 To apply for product registration and license to manufacture or import veterinary drugs, one shall submit documents (about ingredients, functionality, essential manufacturing process, assay, and relevant information or certificates) along with samples (of the label, package insert and drug) and fees (for the license and testing) to the central competent authority. One must not begin to manufacture or import the drug until the license is obtained.
12.2 Guidelines for product registration in Section 12.1 – its review process, license-related matters (the change, renewal, reissuance, replacement, annulation, and other items to comply with thereof) and rules to follow – are to be prescribed by the central competent authority.
12.3 The central competent authority may cite Good Manufacturing Practice (GMP) for veterinary drugs as a criterion for the issuance or renewal of manufacture/import licenses. The Good Manufacturing Practice (GMP) for veterinary drugs is to be prescribed by the central competent authority.
12.4 The review criteria and procedure for a made-for-export-only manufacture license may be simplified made less onerous; however, the veterinary drug thus produced must not be sold domestically or used for other purposes.
12.5 Before a new drug is approved for product registration, it shall be subject to safety and efficacy tests conducted by the central competent authority itself or an accredited agency delegated by the said authority; the applicant for product registration shall bear the cost of such tests; the testing methodology is to be prescribed by the central competent authority.

Article 12-1 A veterinary drug license shall contain the following information:
12-1.1 License number,
12-1.2 Name of the veterinary drug,

12-1.3 Names and addresses of the manufacturer and/or importer,
12-1.4 Name and address of the person in charge,
12-1.5 Name and address of the manufacturing factory,
12-1.6 Dosage form and packaging,
12-1.7 Name and the amount of each active ingredient,
12-1.8 Indications,
12-1.9 Other information required by the central competent authority.

Article 12-2 12-2.1 The label and package insert of a veterinary drug shall contain the following information as approved:
12-2.1.1 It is for animal use,
12-2.1.2 Name and address of the manufacturer/importer,
12-2.1.3 Drug name and license number,
12-2.1.4 Name and level of each active ingredient, route of drug delivery, and dosage,
12-2.1.5 Indications,
12-2.1.6 Side effects, contradiction and other signs to watch for,
12-2.1.7 Withdrawal period (the time between the last drug use and human consumption),
12-2.1.8 Manufacture date and lot number,
12-2.1.9 Shelf life or expiration date, and
12-2.1.10 Other information required.
12-2.2 Some of the entries listed in Section 12-2.1 may be omitted if so declared and approved by the central competent authority.

Article 12-3 (Deleted)

Article 12-4 Regarding fees charged by competent authorities – for license document, testing, inspection and so on – according to this Act, the fee scales are to be prescribed by the central competent authority.

Article 13 Once approved for registration, a manufactured or imported veterinary drug must not change the entries on its registration unless so approved by the central competent authority.

Article 14 14.1 A license to manufacture or import veterinary drugs is valid for a maximum of five years; entities intending to continue to manufacture or import shall apply with the central competent authority for renewal two to six months before expiration date; such renewal may not exceed five years each; licenses are rendered invalid if no renewal is sought on expiration date or the renewal is denied; such invalidated licenses are to be declared by the central competent authority in a government gazette.
14.2 During the valid period of a license described in Section 14.1, the central competent authority may – for protection of animal and human health or other major concerns – re-evaluate the specific licensed veterinary drug and restrict its usage and scope; when necessary a license described in Section 14.1 may be annulled.

14.3 For the review of importation license application, renewal, re-eval
Section 14.2, or for actual needs, the central competent authority may
to the specific veterinary drug ' s overseas manufacturing factory for v
expenses incurred shall be governed by relevant regulations, and be b
importing the said drug.

Article 14-1 14-1.1 The central competent authority shall reject the application for product registration, license renewal or change to registration if false information or document has been submitted by the applicant (the veterinary drug manufacturer or importer); in case an approval has been granted, the specific veterinary drug license shall be revoked.
14-1.2 The central competent authority shall ignore any follow-up application by the entity (involved in conducts described in Section 14-1.1) for a period of two yeas starting from the date of application rejection or license revocation.

Article 14-2 When there is a concern for animal or human health over a veterinary drug whose license has been annulled or revoked, the central competent authority may order the veterinary drug manufacturer or dealer to recall or destroy the said veterinary drug by a set deadline.

Article 14-3 14-3.1 Sample veterinary drugs from trial production by academic research institutes or veterinary drug manufacturers – with central competent authority ' s prior approval –– may be exempt from seeking product registration and/or license; an exclusive label issued by the central competent authority shall be affixed to the container of sample drug indicating that it has been approved for trial production and it must not be used for other purposes.
14-3.2 Field study of a sample veterinary drug described in Section 14-3.1 shall not start until an approval of the central competent authority is obtained.
14-3.3 Guidelines for the sample veterinary drug in Section 14-3.1(its application procedure, required documents, criteria for approval, the trial production facility and how to affix the label) and guidelines for the field study in Section 14-3.2 (application procedure, required documents, criteria for approval) and rules to follow are to be prescribed by the central competent authority.

Article 15 When there is an outbreak, or an imminent outbreak, of a notifiable animal infectious disease, the central competent authority may take emergent measures to order or approve (without lengthy reviews) the manufacture or importation of veterinary biologics.

Article 16 16.1 Veterinary drugs shall be produced in a facility exclusively for making drugs for animal use. However, a facility approved by the central competent authority for trial-production described in Section 14-3.1 may be exempt from this requirement.
16.2 A veterinary drug factory shall be set up in compliance with

establishment standards for veterinary drug factories, and conduct facl
in compliance with relevant regulations.
16.3 Standards for establishing veterinary drug factories in Section 16.
prescribed by the central competent authority in collaboration with the
regulatory authority.

Article 16-1

16-1.1 A veterinary drug manufacturer shall obtain central competent authority ’ s approval before giving or taking consignment to make veterinary drugs.
16-1.2 Qualification and criteria to give or take the said drug-making consignment in Section 16-1.1, the approval procedure, and relevant guidelines are to be prescribed by the central competent authority.

Article 17

A facility making veterinary biologics shall have veterinarians on staff, whereas a facility making antibiotics or regular veterinary drugs shall have pharmacists on staff to supervise drug production.

Article 18

18.1 After veterinary biologics are produced or have cleared the customs with all tariffs paid, the manufacturer or importer shall apply to the municipal competent authority for batch-by-batch sample testing; such a drug may not be sold until it has passed sample testing and inspection and is secured with the seal of approval by personnel dispatched from the relevant competent authority.
18.2 Regulations governing the inspection in Section 18.1 are to be prescribed by the central competent authority.

Article 18-1

18-1.1 The municipal competent authority shall notify the applicant if the drug has failed the test in Article 18; the applicant may pay a re-test fee to apply for a re-testing – allowed only once – within fourteen days of the notice.
18-1.2 Regarding the disqualified veterinary drugs, the municipal competent authority may (1) supervise destruction of the goods should the original applicant fails to seek re-inspection within the time limit in Section 18-1.1, or (2) require the original importer to return the goods by a specific deadline.

Article 19

19.1 A veterinary drug dealer shall initiate business registration only after a veterinary drug dealer license is obtained from the local municipal competent authority.
19.2 The license in Section 19.1 is valid for a maximum of five years; an entity intending to continue to deal shall apply with the local municipal competent authority for renewal within two to six months before expiration date; such renewal may not exceed five years each time; a license becomes invalid if no renewal is sought on expiration date or the renewal is denied;
19.3 Regarding veterinary drug dealer license in Sections 19.1-19.2, regulations governing the license (qualification and criteria for application; issuance, replacement, reissuance, renewal, annulation,

mandatory entries of the license), changes to business registration, fac
the business venue, and other rules to follow are to be prescribed by tl
competent authority.
19.4 A veterinary drugs shall display or sell only veterinary drug from a
manufacturer of a veterinary drug that can verify the sources.

Article 19-1

19-1.1 Presentation, promotion and advertisement of a veterinary drug is to be performed by veterinary drug manufacturers or dealers only.
19-1.2 The presentation, promotion and advertisement of a veterinary drug in Section 19-1.1 must not claim, suggest or insinuate ingredients or efficacy that are false or exaggerated beyond the scope of the drug ' s product registration.
19-1.3 Non-veterinary drugs must not be presented, promoted or advertised as capable of preventing or treating animal diseases, or enhancing or regulating animal physiological functions.
19-1.4 Interviews, news reports or promotions – that suggests or insinuates the efficacy of preventing or treating animal diseases, or enhancing or regulating animal physiological functions – are deemed as advertisements defined in Sections 19-1.1 to 19-1.3.

Article 20

A veterinary drug shall have the label affixed onto it and be accompanied with the package insert. However, specific drugs – for which the central competent authority ' s approval is sought and obtained to use other options for labeling and package insert – may be exempt from this requirement.

Article 21

21.1 A veterinary drug dealer must not repack drugs into smaller sizes. However drugs imported in large packs is exempt if (1) central competent authority ' s prior approval is sought and obtained – and (2) meeting the following conditions:
21.1.1 to be repackaged by a registered veterinary drug factory,
21.1.2 to be sold under the original brand name,
21.1.3 indicating the name and address of the re-packer besides the labeling and package insert required in Article 22-2, and
21.1.4 to be sealed with a label specifically for repacked goods.
21.2 The municipal competent authority shall send personnel to supervise the repackaging in Section 21.1.

Article 22

22.1 When hiring a sales person, the employer (a veterinary drug manufacturer or dealer) shall register the employee with the municipal competent authority and revise the registered information whenever there is a change.
22.2 A veterinary drug sales person must not promote products not manufactured or distributed by his employer; he must not peddle products out of a street stand, break the seal of veterinary drugs, repack the goods or make false claims for promotion purposes.

Article 23

23.1 Veterinary drugs used for samples or complimentary gifts – though imported with an approval – must not be sold for a price.
23.2 Veterinary drugs with existing import license or under import control must not be named on an import application under the pretense of samples or gifts.
23.3 Rules governing samples and gifts in Section 23.1 are to be prescribed by the central competent authority.

Article 24

Veterinary drugs approved for manufacturing shall require export licenses if to be shipped abroad; the veterinary drug manufacturer shall file the application for an export license with the central competent authority in advance.

Article 25

25.1 The municipal competent authority shall dispatch personnel to inspect the premises and equipment of a veterinary drug manufacturer – regarding its manufacturing process, apparatus, quality control and record-keeping – on a regular basis.
25.2 When necessary, the central competent authority may send personnel to conduct spot-checking within the scope set in Section 25.1.
25.3 When the competent authority arrives to conduct an inspection or a spot-checking, the veterinary drug manufacturer must not refuse without due cause.
25.4 If the municipal competent authority decides there are still rooms for improvement after the inspection described in Section 25.1, it shall inform the entity to rectify the issues before a set deadline; failure to rectify may result in a report to central competent authority seeking an order to suspend the entity ’ s production of part or all veterinary drugs at the factory. Continued production – despite a suspension order – may result in a report to central competent authority seeking to annul the entity ’ s veterinary drug manufacture license.

Article 26

26.1 The competent authority may send personnel to the premises of an entity – a veterinary drug manufacturer or dealer, veterinarian care facility, or a user of veterinary drugs – and may obtain samples at the original price for quality inspection.
26.2 The competent authority may send personnel to animal farms (of livestock, poultry and aquaculture) and feed factories to audit the use of veterinary drugs, and may conduct biopsies on some animals.
26.3 Regarding the sampling, audit and biopsy in Sections 26.1 and 26.2, the entities (veterinary drug manufacturers and dealers, veterinary care facilities, farms of livestock, poultry and aquaculture) must not evade, obstruct or refuse such reqests.
26.4 After the competent authority ’ s inspection and/or testing, if an entity (a veterinary drug manufacturer or dealer, veterinary care facility, farm of livestock, poultry or aquaculture, or feed manufacturer) is found to have used veterinary drugs not compliant

with this Act, the entity may be ordered to provide relevant informatio
The entity must not evade, obstruct, refuse the order or provide false i

Article 27 Veterinary drug inspector shall identify oneself with an identification badge/paper when performing tasks describe in Sections 25.1, 25.2 and 26.1.

Article 28 28.1 Regarding suspicious counterfeit, banned or substandard veterinary drugs pending sampling verification, the competent authority shall seal them off for the related entity to sign an affidavit to take them into custody.
28.2 The samples taken in Section 28.1 shall be subject to verification and disposal as soon as possible – no later than two months after the date suspicious drug is uncovered.

Article 29 Regarding substandard veterinary drug uncovered under this Act, (1) if it is made domestically and – upon inspection – can be modified and made usable, the municipal competent authority shall send personnel to supervise the original manufacturer to modify the drug before a set deadline; (2) if it is imported with approval, the authority shall have it sealed and put in custody while the central competent authority orders the importer to initiate a goods-for-return process with the original overseas manufacturer.

Article 30 Besides disposing of dubious veterinary drugs – deemed counterfeit, banned or substandard after audit or testing – as stipulated in this Act, the party involved shall be dealt with as follows:
30.1 Regarding the entity that manufactures, imports or repackages counterfeit/banned veterinary drugs, or the one provides licenses for others to do so, the original license-issuing agency may annul all the entity ’ s veterinary drug licenses or dealership license.
30.2 Regarding the entity that displays or stockpiles counterfeit/banned veterinary drugs to sell or having intent to sell, the municipal competent authority is to publicize the (1) name and address of the entity, (2) name and address of the person in charge, (3) names of the drugs and (4) specifics of the offense. For a repeat offender, the original license-issuing agency may annul all the entity ’ s veterinary drug licenses or dealership license.
30.3 Regarding the entity that deals with (manufactures, imports or repackages; displays or stockpiles to sell or intent to sell substandard drugs, the municipal competent authority is to publicize the (1) name and address of the entity, (2) name and address of the person in charge, (3) names of the drugs and (4) specifics of the offense. Regarding a major or repeat offender, the original license-issuing agency may annul each specific veterinary drug license or dealership license.

Article 31

Whistle blowers shall be rewarded for offering information to uncover counterfeit, banned and substandard veterinary drugs. Rules governing the reward are to be prescribed by the central competent authority.

Article 32 Regarding the usage of veterinary drugs (target animal, purpose, route of drug delivery, dosage, withdrawal period and precautions to take), users shall abide by usage guidelines prescribed by the central competent authority.

Article 32-1 Bulk chemical compound material shall only be supplied or sold to veterinary drug manufacturers making drugs containing such a material.
However, bulk chemical compound material imported with central competent authority ’ s approval may be sold to a veterinary drug dealer to be resold to a veterinary drug manufacturer making drugs containing such a material; each batch of material can be resold only once.

Article 32-2 32-2.1 By the end of each January and July, veterinary drug manufacturers and importers shall compile and submit data (drug type, quantity produced or imported, quantity sold, and customer names) to the municipal competent authority for the record, and also retain the data for three years.
32-2.2 By the end of each February and August, municipal competent authorities shall summarize and submit the data in Section 32-2.1 to the central competent authority.

Article 32-3 32-3.1 Animal farmers (of livestock, poultry and aquaculture) and feed manufacturers must not use any of the following formulated preparations or drugs on animals or in animal feed:
32-3.1.1 Counterfeit veterinary drugs described in Sections 4.1, 4.2 or 4.4,
32-3.1.2 Banned veterinary drug,
32-3.1.3 Formulated preparations for animal use but of dubious origin (besides those cited in Sections 32-3.1.1 and 32-3.1.2),
32-3.1.4 Formulated preparations for human use, or
32-3.1.5 Bulk chemical compound materials for veterinary or human drugs.
32-3.2 In either of the following situations, the animal or product must not be moved, assigned to a third party, or supplied for slaughtering, food processing or human food.
32-3.2.1 An animal (livestock, poultry or aquaculture) found to contain specific banned veterinary drugs in a pre-market test, or
32-3.2.2 Other than the situation above, an animal (livestock, poultry or aquaculture) or animal product (milk, egg or edible parts thereof) that fails to meet the standards for veterinary drug residues in a pre-market test.
32-3.3 An animal described in Section 32-3.2 may be re-tested by the

municipal competent authority if such an application is filed. For anima
3.3.1, one shall apply for re-testing within a certain time limit. Regardi
which no re-testing is sought within the time limit, or those fail the re-
municipal competent authority shall order the (livestock, poultry or aqu
to dispose of – by rendering, composting, destruction or necessary me
animal within seven days.
32-3.4 The owner of animals/products described in either situation in S
shall clearly mark the animal/product for easy differentiation.
32-3.5 Details about the " specific banned veterinary drugs " (Section
limit " (Section 32-3.3) and " marking method " (Section 32-3.4) are t
the central competent authority.
32-3.6 The fee for re-testing in Section 32-3.3 shall be compliant with
regulations, and to be borne by the specific (livestock, poultry or aqua

Article 33 33.1 The person making or importing counterfeit/banned veterinary drugs – except for the one described in Section 5.1.2 – shall be subject to a prison term of one to seven years, and a fine of under NT$4.5 million.
33.2 The person causing human death due to the offense in Section 33.1 shall be subject to life sentence or a prison term of over seven years; or a prison term of three to ten years if the offense leads to severe injury.
33.3 The person committing the offense in Section 33.1 out of negligence is subject to a prison term of under three years, penal servitude or a fine of under NT$ 500,000.
33.4 The person/entity having attempted the act in Section 33.1 is subject to penalty.

Article 34 (Deleted)

Article 35 35.1 The person handling counterfeit or banned veterinary drugs – repacking, selling, transporting, holding for oneself or others, brokering, assigning to a third party, or displaying/caching with intent to sell – is subject a prison term of six months to five years, and may also be fined up to NT$5 million.
35.2 The person committing the offense in Section 35.1 causing human death is subject to a prison term of over seven years; or a prison term of one to seven years if the offense leads to severe injury.
35.3 The person committing the offense in Section 35.1 due to negligence is subject to a prison term of under two years, penal servitude or a fine of under NT$300,000.
35.4 The person/entity having attempted the act in Section 35.1 is subject to penalty.

Article 36 36.1 The person manufacturing or importing substandard veterinary drugs is subject to a fine of NT$60,000 to NT$300,000.
36.2 The person handling substandard veterinary drugs – repacking, selling, transporting, holding for oneself or others, brokering,

assigning to a third party, or displaying/caching with intent to sell – is s
of NT$30,000 to NT$150,000.

Article 37 (Deleted)

Article 38 (Deleted)

Article 39 39.1 A person in any of the following situations is subject to a fine of NT$200,00 to NT$1 million:
39.1.1 Violation of Section 14-3.1, namely using trial-produced sample veterinary drugs for other purposes.
39.1.2 Violation of Section 14-3.2, namely proceeding to field study without the central competent authority ' s approval.
39.1.3 Violation of Section 19-1.1 or 19-1.2, namely conducting drug presentation, promotion or advertisement without approval.
39.1.4 Violation of Section 19-1.3, namely branding, promoting or advertising non-veterinary drugs for animal use.
39.1.5 Violation of Section 32-3.1 by a feed manufacturer, namely using the drugs or formulated preparations listed there on animals or in animal feed.
39.2 A second violation within one year of Section 32-3.1 by a feed manufacturer – namely using drugs or prepared formulation listed in Section 32-3.1.1 to 32-3.1.4 on animals or in animal feed – is subject to a fine of NT$1.5 million to NT$7.5 million.
39.3 A person whose act described in Section 39.1.1, 39.1.2, 39.1.5 or 39.2 causing harm to human health is subject to a prison term of under seven years, and may also be fined from NT$2.5 million to NT$10 million.
39.4 Regarding the offender of Sections 39.1.5 or 39.2, the competent authority shall publicize the name and address of the entity, name of the person in charge and specifics of the offense.

Article 40 40.1 A fine of NT$90,00 to NT$450,000 is to be imposed for any of the following offenses:
40.1.1 Violation of Section 3-1.4 by someone other than a livestock, poultry or aquaculture farmer, namely failure to follow rules about prescription drug in Section 3-1.4 – sales terms, usage, entries and retention of prescription records, and/or mandatory sales data.
40.1.2 Violation of Section 7.3, namely assigning or reselling for-self-use material to a third party without approval.
40.1.3 Violation of Section 12.4, namely selling for-export-only veterinary drug on the domestic market, or using it for other purposes.
40.1.4 Violation of Article 13, namely making statements different from those in original drug registrations.
40.1.5 Violation of Articles 14-2, 20, 24, and Section 25.3, or a non-farmer violating Section 26.3.
40.1.6 Violation of Section 14-3.1, namely failure to affix the

exclusive label issued by the central competent authority on the contai
produced sample veterinary drug.
40.1.7 Violation of guidelines – about the exclusive sample drug label a
venue – prescribed according to Section 14-3.3.
40.1.8 Violation of standards – for the structure, environment, equipm
measures of a facility (factory or venue for operation, inspection or sto
prescribed according to Section 16.3.
40.1.9 Violation of Section 16-1.1, namely giving drug-making assignm
such assignment from, another veterinary drugs manufacturer without
central competent authority.
40.1.10 Violation of Article 17, namely failure to hire in-house veterina
pharmacists as required.
40.1.11 Violation of Section 19.1, namely engaging in the business wit
40.1.12 Violation of regulations prescribed according to Section 19.3 to
license (seeking change to and placement thereof), sales people (issua
and wearing/presenting guideline), major event notification (business t
resumption or suspension), drug management technician (qualification
business venue (environment and equipment), drug handling (storage,
manipulation, record-keeping, duty of disclosure, notification of advers
sales data submission.
40.1.13 Violation of Section 19.4, namely displaying or selling veterina
dubious origin – not from legitimate veterinary drug dealer or manufac
without any proof of origin.
40.1.14 Violation of Section 21.1, namely repacking veterinary drugs in
portions.
40.1.15 Violation of Section 23.1, or regulations prescribed Section 23
samples and complimentary gifts such as marking, access to a logbook
and retention.
40.1.16 Non-farmers ' violation of guideline prescribed according to Art
drug usage (target animal, purpose, route of drug delivery, dosage, wit
and precautions to take), user qualifications, access to a logbook, reco
retention.
40.1.17 Violation of Article 32-1 or Section 32-2.1
40.2 The person committing the offense in Section 40.1.5 – specifically
causing harm to human health – is subject to a prison term of under se
may also be fined NT$2.5 million to NT$10 million.
40.3 The person violating Section 26.4, namely evading, obstructing or
provide information, or providing false information, about the source of
that contravene this Act, is subject to a fine of NT$30,00 to NT$150,00

Article 40-1

40-1.1 An animal farmer (of livestock, poultry or aquaculture) in any of the following situations is subject to a fine of NT$60,00 to NT$300,000:

40-1.1.1 Violation of Section 32-3.1, namely using drugs or formulated preparations in Section 32-3.1.1 to Section 32-3.1.4 on animals or in animal feed.

40-1.1.2 Violation of Section 32-3.2.1, namely moving, assigning to a

third party, or supplying (for slaughter, food processing, or human fooc
40-1.1.3 Violation of Section 32-3.3, namely failure to follow municipal
authority ' s order to do disposal (rendering, compost, destruction or o
within seven days.
40-1.2 An animal farmer ' s repeat offense of Section 32-3.1 within on
using the drug or formulated preparation in Sections 32-3.1.1 to 32-3.
in animal feed – is punishable with a fine of NT$500,000 to NT$2.5 mil
40-1.3 The person committing the offense in Section 40-1.1.1, 40-1.1.
causing harm to human health is subject to a prison term of under sev
may also be fined NT$2.5 million to NT$10 million.
40-1.4 Regarding the offender of Section 40-1.1.1 or 40-1.2, the comp
shall publicize the name and address of the entity, name of the person
specifics of the offense.

Article 40-2

40-2.1 An animal farmer (of livestock, poultry or aquaculture) in any of the following situations is subject to a fine of NT$30,000 to NT$150,000:
40-2.1.1 Violation of regulations prescribed according to Section 3-1.4 to govern sales condition and usage of prescription drugs, or retention of prescription records.
40-2.1.2 Violation of Section 26.3.
40-2.1.3 Violation of guidelines prescribed according to Article 32 to govern drug usage (target animal, purpose, route of drug delivery, dosage, withdrawal period and precautions to take), user qualifications, access to a logbook, record keeping and retention.
40-2.1.4 Violation of Section 32-3.1.5, namely using bulk chemical compound materials (for veterinary or human drug) on animal or in animal feed.
40-2.1.5 Violation of Section 32-3.2.2, namely moving, assigning to a third party, or supplying (for slaughter, food processing or human food) the animal or product.
40-2.1.6 Violation of Section 32-3.4, namely failure to mark the dubious animal/product in the manner designated by the central competent authority.
40-2.2 Regarding the offender in Sections 40-2.1.1 to 40-2.1.4, the competent authority shall publicize the name and address of the entity, name of the person in charge, and specifics of the offense.

Article 41

The person in any of the following situations is subject to a fine of NT$100,000 to NT$500,000:
41.1 Violation of Article 12-2, namely failure to list pre-approved entries on the label or package insert.
41.2 Failure to follow central competent authority ' s order issued according to Article 15 without due cause.
41.3 Violation of Section 22.1, namely performing sales/promotional tasks without having registered with local competent authority, or violation of Section 22.2.

41.4 Violation of Section 28.1, namely refusing to sign the affidavit to

Article 42 If an individual commits any offense from Article 33 to Article 38 while performing job duty on behalf of another party – as the representative of a legal entity, or as the agent, employee or hired help of a legal entity or natural person – besides punishing the responsible individual for the specific offense, the (underlying) legal entity or natural person is also subject to the corresponding fine.

Article 43 Substandard veterinary drugs uncovered under this Act – if not modified or returned by a deadline set according to Article 29 – may be confiscated for destruction.

Article 44 Insistent refusal to pay a fine imposed under this Act will be referred to the court for compulsory execution.

Article 45 (Deleted)

Article 46 Monetary fines in this Act are to be imposed by the municipal competent authority.

Article 47 Enforcement rules of this Act are to be prescribed by the central competent authority.

Article 48 This Act takes effect on the date of promulgation.
