Chapter II Registration and license

Article 7

1. The manufacturer or importer shall fill out an application form to apply for registration and license of veterinary drugs, enclose said application with the materials required under Articles 9 to 13, and then submit the complete application with supporting documents to the central competent authority, pay the fees before the deadline indicated in the notice of the central competent authority, and provide the samples and documents specified in Annex I. However, those applying for manufacturing veterinary drugs exclusively for export do not need to provide samples and are exempted from inspection procedures.

2. If the registration and license application for veterinary drugs in the preceding paragraph falls under any of the following circumstances, separate applications must be submitted:
   (1) More than two dosage forms of the same drug.
   (2) More than two preparation concentrations or unit contents for the same dosage form.

3. Once the application specified in Paragraph 1 has been approved by the central competent authority, a license shall be issued for that application.

Article 8

The central competent authority shall invite experts and scholars to participate in the deliberation of the aforesaid application in the event that any of the following circumstances apply:

(1) New drugs.
(2) Registration and license of live or inactivated vaccines for foot and mouth disease.
(3) Registration and license of live vaccines for classical swine fever, pseudorabies, porcine reproductive and respiratory syndrome, Newcastle disease, infectious bronchitis, or infectious bursal disease in which viral strains are different from the strains approved in Taiwan.

Article 9

Applications for registration and license of generic drugs or active pharmaceutical ingredient of veterinary pharmaceuticals shall comply with Annex II.

Article 10

Applications for registration and license of veterinary immunobiologicals shall comply with Annex III.

Article 11

Applications for registration and license of veterinary disinfectants shall comply with Annex IV.

Article 12

Applications for registration and license of new veterinary pharmaceuticals shall comply with Annex V.

Article 13

Applications for registration and license of manufacturing veterinary drugs exclusively for export shall comply with Annex VI.

Article 14

If the applicant fails to pay the fees, provide documents, provide samples or have any other circumstances arise that require correction, the central competent authority shall notify the applicant to make such corrections before a deadline. If corrections are not made before the deadline, the central competent authority may not accept the application, or review and make its decision based solely on the existing information enclosed in the application.

Article 15

Applications for registration and license of veterinary drugs will not be approved if any of the following circumstances occur:

(1) A non-approved manufacturer applies for registration and license of manufactured veterinary drugs or a non-approved manufacturer which is also a dnon-approved importer applies for registration and license of imported veterinary drugs.
(2) The animal drug manufacturer fails to comply with the "Guidelines of Good Manufacture Practice (GMP) for Veterinary Drug Manufacturers".
(3) The animal drug manufacturer fails to comply with the "Establishment Standards for Veterinary Drugs Manufacturers".
(4) The principle efficacy of the veterinary drugs is not clear, the animal drug has no significant therapeutic effect, or it fails to pass reassessment.
(5) The veterinary drugs cause serious side effects or have safety concerns.
(6) The prescription, preparation, or dosage form of the veterinary drugs is inappropriate.
(7) The compound mixing proportion of the veterinary drugs is inconsistent with the formulation basis, and a complete test report is lacking.
(8) Incompatibility or an adverse interaction is present among the compound ingredients.
(9) The use of compound ingredients will increase toxicity or cause serious side effects.
(10) The use of compound ingredients does not increase the antibacterial range or antibacterial effect.
(11) Cross-resistance is present among the compound ingredients.
(12) The dosage form of the preparation has not been approved by the central competent authority.
(13) The samples provided under Article 7.1 do not pass testing.