Annex V: Documents to be enclosed for applying registration and license of new veterinary pharmaceuticals

I. Basic information

Item	Basic information	Manufactured drugs	Imported drugs
1	Five pieces of application form for registration and license of the manufactured (imported) veterinary drugs, five copies	○	○
2	Five pieces of label and insert pasting sheet	○	○
3	One name card of the veterinary drugs in both Chinese and another foreign language, or Chinese and English	○	○
4	Two copies each of inspection specification, method, and report of the raw materials	○	○
5	Two copies each of inspection specification, method, and report of the finished products	○	○
6	Manufacture and quality control information	○	○
7	Stability test information	○	○
8	Formulation basis	○	○
9	One copy of the factory registration certificate	○	X
10	Manufacturing plant master file	X	○Note 1
11	One copy of the license for trading veterinary drugs	X	○
12	The original and one copy of the power of attorney; the original will be returned	X	○
13	The original copy of the certificate of manufacture issued by the manufacturing country	X	○
14	The original copy of the certificate of free-sale issued by the manufacturing country	X	○
15	The original copy of the certificate of label and insert to be put on the market issued by the manufacturing country	X	○

II. Technical information (relevant technical data shall be enclosed according to the new drug category)

Category of new drugs		Background information	Pharmacodynamics information	Toxicological and safety information		Residue test		Effect test	Stability data	Antibacterial data
				Experimental animal	Target animal	Metabolism data of experimental animal	Residue data of target animal			
New active ingredient		○	○	○	○	○	○	○	○	○
New active ingredient with different bases		○	○Note 2	○ Note 2	○Note 2	○	○	○Note 2	○	○
New compound		○	○	○ Note 3	○	○	○	○	○	X
New dosage form		○	○	X	○Note 2	X	○	○Note 2	○	X
New usage and dosage	New unit content (including the preparations of different concentrations)	○	X	X	○Note 2	X	○Note 2	○Note 2	○	X
	New target animal	○	X	X	○	X	○	○	X	X
	New dosage	○	X	X	X	X	○	○	X	X
New administration route	New administration route	○	X	X	○	X	○	○Note 2	X	X
New efficacy	New therapeutic effect	○	X	X	X	X	X	○	X	X

Note:

1. This document is only required for the first application.
2. This information can be replaced by bioequivalence data.
3. The applicant may only provide single-dose toxicity testing, short-term toxicity testing, and genotoxicity testing data.

Annotation:

I. ○: Documents are required. X: Documents are not required.

II. Please refer to the instructions in Annex 2 for the relevant provisions on the application form, label and insert pasting sheet draft, inspection report of raw materials and finished products, formulation basis, manufacture plant master file, power of attorney, certificate of manufacture issued by the manufacturing country, certificate of free-sale issued by the manufacturing country, and the certificates of the text content on the label and insert to be put on the market issued by the manufacturing country.

III. For domestically manufactured veterinary drugs for non-food production animals, whose active ingredients and dosage form are the same as an approved human drug in Taiwan, the pharmacodynamics data and toxicological data in experimental animals may not be required.

IV. For imported veterinary drugs for non-food production animals whose pharmaceutical ingredients have been internationally approved for marketing for more than five years, that have been licensed in the exporting country for at least three years, the pharmacovigilance regulations and reports of side effects for veterinary drugs are required to be enclosed as well as the pharmacovigilance reports for no side effects for veterinary drugs, the applicant may replace the required test data with the scientific literature, except for stability test data.

V. For domestically manufactured veterinary drugs for non-food production whose dosage form, composition, content, efficacy, usage, and dosage are the same as products approved abroad and and pharmaceutical ingredients have been internationally approved for marketing for more than five years, the pharmacovigilance regulations and reports of side effects for veterinary drugs of the referenced products in the licensed country are required to be enclosed as well as the pharmacovigilance reports for no side effects for veterinary drugs, the applicant may replace the required test data with the scientific literature, except for stability test data.

VI. If the final use concentration or dosage of a new unit strength preparation added to feed or drinking water is the same as that of an approved animal drug in Taiwan, and provided that their excipient is the same, the registration and license shall be processed with the generic drug.

VII. The main components of nuclear category crystal Infusion preparation products are only sodium ion (Na), potassium ion (K+), calcium ion (Ca), magnesium ion (Mg), chloride ion (Cl), hydrogen phosphate ion, phosphate ion, bicarbonate, Lactic acid, acetate, gluconate, glucose or any other ingredient recognized by the competent authorities and with the excipient of water. If its composition and content are the same as those of drugs approved for human use in our country, data on pharmacokinetics, toxicological safety tests, residual tests and effect tests may be exempted.

VIII. Background information: Including structural formula, physical and chemical properties, general pharmacology and specifications, and test methods.

IX. Pharmacodynamics information: Including absorption, distribution, metabolism, and excretion of animals.

X. Toxicological and safety information: Including a single dose toxicity test, short-term toxicity testing, chronic toxicity testing (such as teratogenic, genotoxic, or carcinogenic) on the experimental animals and toxicity and tolerance testing data of the target animals.

XI. Residue test: Not required if the target animal is a non-food production animal.

XII. Efficacy test: Including *in vitro* effect, effective dose selection, effective dose confirmation, and field efficacy test data.

XIII. Antibacterial data: The annual consumption amount, side effects and usage status, cross-drug resistance mechanism, drug resistance test data, importance in treating animal diseases and testing data compared with more than one commonly used and most effective antibacterial agent shall be provided for antibacterial drugs.

XIV. Except for the aforesaid exemption provisions, a complete report on the pharmacodynamics, toxicological and safety, residue, efficacy and stability testing data, and other research reports of new veterinary pharmaceuticals shall be provided, and according to the notice of the central competent authority, the raw data of the report shall not be replaced by a general narrative, abstract, or case report.