Annex II: Documents to be enclosed for applying registration and license of generic and active pharmaceutical ingredients of veterinary pharmaceuticals

Item	Documents to be enclosed	Generic drugs of veterinary pharmaceuticals		Active pharmaceutical ingredients of veterinary pharmaceuticals	
		Manufactured drugs	Imported drugs	Manufactured drugs	Imported drugs
1	Five pieces of application form for registration and license of the manufactured (imported) veterinary drugs	○	○	○	○
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	○	○	X	X
5	Two copies each of inspection specification, method, and report of the finished products	○	○	○	○
6	Manufacture and quality control information	○	○	X	X
7	Stability test information	○	○	○	○
8	Formulation basis	○	○	X	X
9	One copy of the factory registration certificate	○	X	○	X
10	Manufacturing plant master file	X	○Note 1	X	○ Note 1
11	One copy of the license for trading veterinary drugs	X	○	X	○
12	The original and one copy of the power of attorney; the original will be returned after inspection	X	○	X	○
13	The original copy of the certificate of manufacture issued by the manufacturing country	X	○	X	○
14	The original copy of the certificate of free-sale issued by the manufacturing country	X	○	X	X
15	The original copy of the certificate of label and insert to be put on the market issued by the manufacturing country	X	○	X	○
16	Target animal field test, bioavailability test, and bioequivalence test	○Note 2	○Note 2	X	X

Note：

1. This document is only required for the first application.
2. For new active ingredients of veterinary pharmaceuticals that have been approved to obtain veterinary drug licenses since January 1, 2019 (inclusive), field test and bioavailability test data or

bioequivalence test data for generic drugs shall be enclosed, unless one of the following circumstances applies:

(1) Intravenous injection (injection or powder for injection).
(2) Inhalant (gas or vapor for inhalation).
(3) Oral liquid (solution).
(4) Soluble powder whose excipients do not affect the absorption of the active ingredients.
(5) Various external preparations that are only for topical use and only have topical therapeutic effects, including powder for external use, solution for external use, eye drops, ointments, collars, sprays, tinctures, and elixirs.
(6) Intramuscular or subcutaneous injections (injections or powder for injections), those pH value and formula, excluding preservatives and buffers, are the same as those of the brand drug.
(7) Other items that have been approved as exempted by the central competent authority in accordance with the information enclosed in the application.

Annotation:

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

II. The application form shall include the name and address of the manufacturer (importer), the name and address of its responsible person, the name of the drug manager and relevant license number, drug name, dosage form, package, name and quantity of raw materials, manufacturing method, efficacy, usage and dosage, formulation basis, and name and address of the manufacturing plant. When applying for manufactured veterinary drugs, the factory registration license number shall be provided separately. When applying for imported veterinary drugs, the license number of the animal drug vendor and the name and address of the foreign manufacturer shall also be provided separately.

III. Label and insert pasting sheet

(i) One copy of the domestic market label and insert draft shall be pasted on the front of the pasting sheet. The domestic market label and insert draft must include the following information in Chinese:

1. For animal use;
2. Name and address of the manufacturer (importer);
3. Drug name;
4. Active ingredients, usage, and dosage;
5. Primary efficacy, performance, and indications;
6. Side effects, restrictions, and other matters requiring attention;
7. Drug withdrawal period;
8. Batch number;
9. Manufacturing date and term of validity or expiry date;
10. Package and content: For applications for registration and license of over-the-counter drugs for ornamental fish, the packaging content of the preparation shall comply with the following requirements:

(1) The volume shall not be more than 5 liters or weigh more than 500 grams,

with the package approved abroad provided. The volume of antibacterial agent shall not exceed 250 ml in volume or 100 g in weight.

(2) The unit content of copper sulfate, methyl blue, and malachite green shall not exceed 1%.

(3) The unit content of antibacterial agents shall not exceed 10%.

11. Dosage form;
12. Name and address of manufacturer;
13. Usage category of the drug prescribed by a veterinarian;

(ii) The label and insert of the active pharmaceutical ingredients of veterinary pharmaceuticals and the labels of veterinary drugs whose package is less than 5 ml may be exempted from recording the usage, dosage, primary efficacy, performance, indications, side effects, restrictions, withdrawal period, and usage category of drugs prescribed by a veterinarian.

IV. The certificate of analysis of raw materials and finished products shall include the drug name, batch number, manufacturing date, inspection date, and inspection items and results, as well as the signatures of the inspection and assessment personnel. The inspection results shall be enclosed with the output spectrum of the inspection instrument and other relevant information.

V. Formulation basis: This refers to the references concerning the dosage form, composition, content, efficacy, usage and dosage, which are consistent with the applied veterinary drugs for registration and license and can support their efficacy. However, if the formulation basis does not coincide with the applied veterinary drug~~,~~ a written reason shall be attached according to the actual change, and relevant necessary information shall be submitted to the central competent authority for approval. The source of aforesaid references is limited to the veterinary drug formularies announced by the central competent authority, the approved and registered veterinary drug labels and inserts~~,~~ the veterinary drug developed by manufacturers locally and abroad, and the test reports on their stability, safety, residue, and efficacy.

VI. Manufacturing plant master file: This refers to the following data of the veterinary drug manufacturer (hereinafter referred to as the manufacturer), which is bound in a volume and separately marked; for entrusted manufacturing by stages, all the entrusted manufacturers involved in the manufacturing process shall be included:

(i) The manufacturer's factory name, address, personnel organization chart, amount of employees in each department, and cleanliness control measures and clothing regulations in each operation area.

(ii) The complete aerial view of the manufacturing park, which clearly shows the range of the manufacturing plant and other buildings.

(iii) The complete plan of the plant, including the operation section of the applied dosage form, with the access routes and corridors for personnel and raw materials and cleanliness level of each operation area marked on the plan.

(iv) Live photos of the factory, including at least the operation section of the applied dosage form, quality control room, personnel operation status, and clear display of factory

name, entrance, and exit.

(v) Quantity and efficacy of the manufacturing and quality control equipment for each dosage form.

(vi) Documents signed by the central competent authority in charge of veterinary drugs in the manufacturing country, which proves that the manufacturer complies with Guidelines of Good Manufacture Practice (hereinafter referred to as GMP) for Veterinary Drugs Manufacturers. However, if the manufacturing country is Germany, the documents may be issued by the competent authority for veterinary drugs of the federal government.

(vii) The manufacturer of biological drugs for animals shall also enclose the documents issued by the competent authority of veterinary drugs in the manufacturing country within four years to prove that the manufacturer has not manufactured foot and-mouth disease vaccine, avian influenza vaccine, or other vaccines of major animal infectious diseases announced by the central competent authority, or that the vaccines are independently manufactured under appropriate biosafety facilities.

VII. Power of attorney: This refers to the documents certifying that the foreign manufacturer of the imported veterinary drugs or its head office or the foreign license holder authorizes the domestic importer to sell the veterinary drugs by proxy and records the following items. However, if the manufacturer holding the manufacturing license for veterinary drugs in the manufacturing country has established a branch of its company in Taiwan, the letter of authorization may be issued by the headquarters of the manufacturer in Asia:

(i) Name and address of the manufacturer;

(ii) Name and address of the domestic agent

(iii) Name of the veterinary drugs sold by proxy;

(iv) Expiry date of authorization;

(v) Date of issue, which cannot exceed one year from the date of application;

(vi) Signature by the foreign manufacturer, its head office, or foreign license holder.

VIII. Certificate of manufacture issued by the manufacturing country: This refers to the certificate issued by the central competent authority of veterinary drugs in the manufacturing country, which permits the manufacturing of the drug in that country and records the following items. However, if the manufacturing country is Germany, it may be issued by the competent authority of veterinary drugs of the federal government. If the manufacturing country is India, it may be issued by the provincial government. If the manufacturing country is an EU member state, it may be issued by the European Medicines Agency. If the manufacturing country is mainland China, it may be issued by the veterinary administrative department of the provincial, autonomous regional or municipal people's government:

(i) Name and address of the manufacturer;.

(ii) The name, composition, content, dosage form, package, and approved registration number of the animal drug. If the drug name is not recorded, the original manufacturer shall separately issue a document stating the name of the drug and the reason for failure to record the name. However, for the application for registration and license of active pharmaceutical ingredients, if the ingredient purity meets the specifications specified

in the pharmacopoeia and a copy of the pharmacopoeia is enclosed, the certificate of manufacture may be exempted from recording the ingredients and content. The application for registration and license of drugs for ornamental fish may be exempted from recording the dosage form and packaging.

(iii) Issue date: no more than two years from the date of application.

IX. Certificate of free-sale issued by the manufacturing country: This refers to the certificate issued by the central competent authority of veterinary drugs in the manufacturing country, which permits the free sale of the drug in that country and records the following items. However, if the manufacturing country is Germany, it may be issued by the competent authority of veterinary drugs of the federal government. If the manufacturing country is India, it may be issued by the provincial government. If the manufacturing country is an EU member state, it may be issued by the European Medicines Agency. If the manufacturing country is mainland China, it may be issued by the veterinary administrative department of the provincial, autonomous regional or municipal people's government. If the manufacturing of the drug is entrusted and the drug is not sold on the market of the manufacturing country, it may be issued by the competent authority of veterinary drugs in the country of the consignor:

(i) Name and address of the manufacturer;

(ii) The name, composition, content, dosage form, package, and approved registration number of the animal drug. If the drug name is not recorded, the original manufacturer shall separately issue a document stating the name of the drug and the reason for failure to record the name.

(iii) Free-sale of the drug~~s~~ in the country shall be clearly specified;

(iv) Issue date: no more than two years from the date of application.

X. Certificate of the text content on the label and insert to be put on the market issued by the manufacturing country: This refers to the certificate issued by the central competent authority of veterinary drugs in the manufacturing country, which approves the text content on the market label and insert of the drug. However, if the manufacturing country is Germany, it may be issued by the competent authority of veterinary drugs of the federal government. If the manufacturing country is India, it may be issued by the provincial government. If the manufacturing country is an EU member state, it may be issued by the European Medicines Agency. For the applications for new drugs, generic drugs, and active pharmaceutical ingredients for ornamental fish, it may be issued by the foreign manufacturer or its head office, or the foreign license holder.

XI. A complete report of the stability test of active pharmaceutical ingredients of veterinary pharmaceuticals, and the bioavailability, bioequivalence, field test, and stability test of generic drugs shall be submitted. The raw data of the report shall be submitted in accordance with the notice of the central competent authority and shall not be replaced by a general narrative, abstract, or case report.