

Annex III: Documents to be enclosed for applying registration and license for veterinary immunobiologicals

Item	Documents to be enclosed	Manufac- tured 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 test report of the raw materials	○	○
5	Two copies each of inspection specification, method, and report of the finished products	○	○
6	Manufacturing 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}
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 after inspection	X	○
13	Documents certifying that raw materials of ruminant origin from the countries (regions) where bovine spongiform encephalopathy has occurred have not been used in the manufacturing process and final products, or documents certifying that the central competent authority has reviewed and approved the use of raw materials of ruminant origin from the countries (regions) where bovine spongiform encephalopathy has occurred	○	○
14	The original copy of the certificate of manufacture issued by the manufacturing country	X	○
15	The original copy of the certificate of free-sale issued by the manufacturing country	X	○
16	The original copy of the certificated of label and insert to be put on the market issued by the manufacturing country	X	○
17	Research and development summary	○	○
18	Name, origin, character, and passage and preservation methods of the master/working seed for manufacturing	○	○
19	Laboratory test report (including various basic tests, safety and efficacy tests, with the manufacturing date, batch number, inspection date, and signatures of the inspector and quality control person indicated)	○	○
20	Field test report (including safety and efficacy tests)	○	○

Note: This document is only required in the first application.

Annotations:

- I. O : Documents are required. X: Documents are not required.
- II. Please refer to the instructions in Annex II for the relevant provisions on the application form, label and insert pasting sheet draft, inspection report of raw materials and finished products, formulation basis, Manufacturing 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. The following new veterinary immunobiologicals shall be handled in accordance with the testing procedures for new veterinary drugs:
 - (i) Contains genetically modified organisms.
 - (ii) An application submitted with the same viral (bacterial) strain that has been registered in Taiwan within the past two years.
 - (iii) An application submitted with the same viral (bacterial) species but different strains that have been registered in Taiwan within the past three years.
 - (iv) Manufactured by unique methods and approved by an experts and scholars committee-organized by the central competent authority.
 - (v) Viral (bacterial) vaccines for special needs of epidemic prevention or control, which have been reviewed by an experts and scholars committee organized by the central competent authority.
- IV. A complete report on the safety, efficacy, and stability and field tests and other research reports of veterinary immunobiologicals shall be provided, of which the stability test period shall exceed the calculated shelf life by at least three months. According to the notice of the central competent authority, the raw data of the report shall not be replaced by a general narrative, summary, or case reports.