Annex I: Samples and documents to be enclosed for veterinary drug inspection submissions

I. Documents

Item	Documents to be enclosed	Manufactured drugs	Imported drugs
1	Two copies of certificate of analysis report of the finished product	○	○
2	Importation approval of animal drug samples and gifts	X	○

II. Quantity of samples shall be provided according to the drug category in the following table:

Item	Drug category	Quantity
1	Veterinary pharmaceuticals, active pharmaceutical ingredients, and disinfectants	5 pieces
2	Tissue culture live attenuated virus of freeze-dried lapinized hog cholera vaccines	30 bottles
3	Freeze-dried lapinized hog cholera vaccines	15 bottles
4	Inactivated foot and mouth disease vaccines	12 bottles
5	Other live attenuated vaccines for livestock	12 bottles
6	Other inactivated vaccines for livestock	10 bottles
7	Live attenuated vaccines for poultry	12 bottles
8	Inactivated vaccines for poultry	10 bottles
9	Live attenuated vaccines for aquatic animals	12 bottles
10	Inactivated vaccines for aquatic animals	10 bottles
11	Inactivated rabies vaccine	45 bottles
12	Other veterinary vaccines	27 bottles
13	Other veterinary biologicals	12 bottles
14	New drugs	The central competent authority requires applicants to provide appropriate amounts of samples for testing to be effectively conducted.

Annotation:

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

II. The samples submitted for inspection shall be kept in the original packaging and cannot be repackaged or divided into smaller quantities for inspection.

III. For testing to be effectively conducted, the central competent authority may ask applicants to provide appropriate amounts of reference standards.

IV. Mixed vaccines containing live and inactivated microorganisms shall be submitted for inspection according to the quantity of live vaccines.