



APPLICATION INFORMATION

LICENCE TO POSSESS VETERINARY BIOLOGICS (COMMERCIAL / RESEARCH AND DEVELOPMENT)

1. Licence to Possess Veterinary Biologics

In accordance with the Animals and Birds Act (Chapter 7), a Licence to Possess Veterinary Biologics (Commercial Purpose) or Licence to Possess Veterinary Biologics (Research and Development) is required to import/handle veterinary biologics, defined as;

any viruses, serums, toxins, and analogous products of natural or synthetic origin, including genetically modified organisms, diagnostics, antitoxins, vaccines, live micro-organisms, killed micro-organisms, and the antigenic or immunizing component of micro-organisms intended for use in the diagnosis, treatment, or prevention of diseases of animals and birds, or for purposes of research in animals and birds.

2. Validity of licence

The licence is valid for a year and should be renewed prior to expiry.

3. Application of licence

An application form is available. Supporting documents should be attached to the application form, and mailed/emailed in to the address listed in the application form.

4. Facility Inspection

Following receipt of the application, an inspection visit of the facility will be arranged. AVA officers will contact you to arrange a suitable date and time. The inspection will involve checking of:

- a) Biosafety and biosecurity procedures
- b) Laboratory practices
- c) Storage of veterinary biologics
- d) Standard Operating Procedures relating to:
 - Transportation of biologic(s)
 - Work procedures
 - Personnel protection
 - Biohazardous waste disposal
 - Decontamination in event of spillage
 - Incident reporting
- e) Documentation/records including inventory records, incident reporting mechanisms and general maintenance and servicing of equipment
- f) Staff training initiatives

Inspectors may provide on-the-spot recommendations/ advices to licensee on areas that need improvement (especially on deficiencies that are critical eg. mishandling of biologics, cross-contamination, inappropriate biohazard waste disposal).

5. Fees

Invoices will be prepared for licence fee payments. Payment may be made via GIRO*, online or at our office.

*Upon approval of GIRO application

Annual Licence Fee	\$45
Inspection Fee	\$63 per hour or part thereof

6. Conditions of licensing

The conditions of licensing for the two categories are attached at Annex A.

- Licence to Possess Veterinary Biologics (Commercial Purpose)
- Licence to Possess Veterinary Biologics (Research and Development Purpose)

7. Import permit for veterinary biologics

After the Licence to Possess Veterinary Biologics has been obtained, the applicant is then required to apply for a separate Import Permit to import veterinary biologics into Singapore. The application for an import permit can be made online at <http://www.ava.gov.sg/AnimalsPetSector/ImportExportTransOfAnimalRelatedPrd/VeterinaryBiologicsAndPathogens/>

For further questions relating specifically to the Import Permit for veterinary biologics, please contact:

Agri-Food & Veterinary Authority
Quarantine & Inspection Group
Import & Export Regulation Department
Tel: 6805 2992

E-mail: AVA_Import&Export_Animals@ava.gov.sg or
<https://www.ifaq.gov.sg/ava/apps/feedback.aspx>.

**ANNEX A
LICENSING CONDITIONS FOR POSSESSION OF VETERINARY BIOLOGICS**

LICENCE TO POSSESS VETERINARY BIOLOGICS (COMMERCIAL PURPOSES)

- a. The licensee shall have in his possession only those veterinary biologics approved by the Agri-Food and Veterinary Authority (AVA).
- b. The licensee shall have adequate facilities to store veterinary biologics and ensure that the veterinary biologics are stored under optimum conditions at all times.
- c. The licensee shall withdraw from sale any batch or lot of veterinary biologics, which have been subjected to sub-optimal storage conditions and surrender the said batch or lot of veterinary biologics to AVA for destruction.
- d. The licensee shall only sell veterinary biologics to persons who are licensed to inoculate animals with veterinary biologics or to possess veterinary biologics.
- e. The licensee shall maintain a register of all transactions of purchases and sales of veterinary biologics, and shall submit a 3-monthly return of the purchases, sales and stock balance of each type of veterinary biologics to AVA within the first ten days of the following month. The Director-General, Agri-Food and Veterinary Services may direct the licensee to submit more frequent returns if and when he deems it necessary. The register shall be subject to verification by AVA.
- f. The licensee shall subject each batch or lot of veterinary biologics for sampling for quality control test by AVA, and shall pay the fee levied for testing, where applicable at the time of sampling. Where a batch or lot of veterinary biologic is found to be unsatisfactory, the licensee shall withdraw from sale the remainder of the batch or lot and surrender it to AVA for destruction.
- g. The licensee shall not manufacture, re-process, re-bottle or re-label veterinary biologics without the approval of AVA.

LICENCE TO POSSESS VETERINARY BIOLOGICS (RESEARCH AND DEVELOPMENT PURPOSES)

- a. The licensee shall have in his possession only those veterinary biologics approved by AVA and shall keep a record of these biologics for inspection by AVA.
- b. The licensee shall not sell any of the veterinary biologics without the permission from the Director-General, Agri-Food and Veterinary Services.
- c. The licensee shall ensure that any transfer of the veterinary biologics within Singapore are carried out to a holder of the AVA Licence to Possess Veterinary Biologics.
- d. The licensee shall not dispose of any veterinary biologics unless they have been adequately treated so as to destroy any infective materials.
- e. The licensee shall not use the premises for trading in veterinary biologics (i.e. vaccines, sera, etc.).
- f. The licensee shall ensure that no infective materials are intentionally or accidentally carried out of the premises.
- g. The licensee shall inform AVA immediately should there be a loss of any veterinary biologics, eg. due to theft.