

DEPARTMENT OF VETERINARY SERVICES

GUIDELINES FOR VETERINARY BIOLOGICS FOR RESEARCH USE

1. INTRODUCTION

Veterinary biologics for research purpose may not be subjected to registration procedures but shall have written permission from Department prior to importation.

Under certain special circumstances, permission to import veterinary biologics for research use which are not registered under Department, for use under the importing veterinarian's or researcher's supervision, in research or emergency situations. These permissions may or may not be issued, after a review of the rationale for use submitted by the importing veterinarian and a case-by-case evaluation of specified minimum product information.

The permission (if granted) would specify conditions and requirements based on a risk assessment of the product and its proposed use. Applications to import unlicensed products are reviewed on a case-by-case basis and a decision is made to either allow or refuse the importation. Imported products must then be shipped directly from the manufacturer, and used under the supervision of the importing veterinarian.

2. APPLICATION PROCESS

2.1. Application must be separated for each product.

2.2. Prior to submitting an application veterinarians/researcher should confirm that the manufacturer of the product being sought is willing and able to ship the requested product, and prepared to provide the Department with the required supporting documents, including product information, samples of labelling, and test results for the serial(s) to be imported.

2.3. Covering letter from the veterinarian/researcher

The application must include a letter, signed by the veterinarian/researcher, briefly explaining the rationale for importing purpose and use in Malaysia. The following details should be provided:

- a. Information about the unlicensed veterinary biologic product including of animals of origin or cell cultures involved,
- b. All veterinary biological product shall labeled with the name and address of the manufacturer, instructions proper use of the product including all warnings and cautions and any other information deemed necessary by administrator.
- c. The reason for deciding to use the proposed product.
- d. A brief description of research work must attached together. Brief description of scientific capabilities of the applicant/ researchers/ investigators to be adequate to safeguard domestic animals and protect public health, interest or safety from any deleterious effects which might result from use of such product.
- e. Copy of the product order from the Government, Universities or Research Institutes.
- f. The number of doses or vials, or diagnostic tests or kits to be imported.
- g. The name and address of the farms, clinics, or laboratories where the product will be used.

2.4. Read and sign the Declaration Form

2.5. Product labels

Product labels may have specific requirements, such as using the statement, **"For experimental use only"** or **"Not for sale in Malaysia"**.

2.6. Information on the materials of animal origin

The manufacturer must provide a list of all materials of animal origin used in preparing the veterinary biologic, including the ingredients of the media on which master seeds were grown. For each ingredient, the animal species and tissue/organ from which it was derived, the country of origin of the animal, and the name and address of the supplier should be given (e.g. Trypsin – porcine – pancreas – Poland – ABC Inc., U.S.). This information helps characterize the product's potential risks for contamination with extraneous micro-organisms and transmissible spongiform encephalopathy agents.

2.7. Note that the Department may request additional documents, such as experimental protocols, facility inspection or certification reports, environmental assessments, and summary of suspect adverse reaction reports/vaccine-vigilance data, from the veterinarian or researcher or manufacturer, as appropriate.

3. The approval is subject to the conditions below:

- 3.1 Applicant should apply and obtain import permit from MAQIS to import the above products.
- 3.2 The consignment shall be accompanied by a certification from the veterinary authority of the country of origin stating that the products are prepared and packed in sterile manner in accordance to any international standard.
- 3.3 The products are to be packed and transported in accordance to any international standards on safety and security.
- 3.4 Please be informed that the products are under the applicant responsibility, and to be used for laboratory experimental purpose only. DVS has the right to monitor the usage of the products and withdraw the approval of importation if the above conditions are not fulfilled.
- 3.5 Applicant is required to report to DVS immediately should any undesirable outcomes arise from the usage of the above products.