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PROCEDURES FOR REGISTRATION OF VETERINARY VACCINESS IN MALAYSIA

DEPARTMENT OF VETERINARY SERVICES
MINISTRY OF AGRICULTURE AND AGR0-BASED INDUSTRY

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To be read in conjunction with
Animal Act 1953 (revised 2006), Animal Act (Amendment 2013), Feed Act 2009, Veterinary Surgeon Act 1974 and Animal Welfare Act 2015

ABBREVIATIONS

APC	Annual Practicing Certificate
DVS	Department of Veterinary Services
DGVS	Director General of Veterinary Services
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GQC	Good Quality Control
HACCP	Hazard Analysis and Critical Control Point
HSST	High Standard of Safety Test
MAH	Marketing Authorization Holder
MAQIS	Malaysian Animal Quarantine & Inspection Services
TACB	Technical and Advisory Committee on Veterinary Biologics
TACB1	Official Form for Submission of Dossier/ Dossier Check List for Registration of Veterinary vaccines in Malaysia
TACB2	Official Form for Submission of Dossier/ Dossier Check List for Registration of Marketing Authorization Holder of Veterinary vaccines in Malaysia
TACB3	Official form for submission of dossier/ dossier checklist for registration of veterinary vaccine plant in Malaysia
TCVP	Technical Committee on Veterinary Products

PROCEDURES FOR REGISTRATION OF VETERINARY VACCINES IN MALAYSIA

i. INTRODUCTION

Section 30(1) of the Animal Act 1953 (revised 2006) gives the power to the Director General of Department of Veterinary Services to issue license to the holder to possess live cultures or veterinary vaccines and to inoculate animals or birds with such culture or veterinary vaccines.

As stated in Animal Act 1953 (Amendment 2013) Section 84(1) No person shall knowingly import into Peninsular Malaysia or shall have in his possession any living noxious insect, or any living pest, or any living disease germ or virus or any bacterial culture, of a nature harmful or dangerous to animals or birds without the previous written permission of the Director General.

As the regulatory agency to enforce legislative requirements, Department of Veterinary Services (DVS) has set down specific procedures for registration of veterinary vaccines in Malaysia with regards to production, importation, distribution, sale and use for purpose for diagnosis, treatment, research and control or prevention of disease are safe for animal use.

The use of animal veterinary vaccines in Malaysia is subjected to approval, which based on the evaluation by DVS on the disease prevalence and change of epidemiological patterns of the animal disease occurrence.

The continuing need for the veterinary vaccines in the country will be evaluated by DVS based on disease incidences or reports, change of epidemiological patterns of certain animal disease and other/new technical information.

ii. SCOPE

The purposes of these procedures are:

(a) To provide the Marketing Authorization Holder (MAH), local manufacturer, importer and local distributor with guidelines on preparing submissions for registration of veterinary vaccines in Malaysia.

(b) To regulate the sale and use of veterinary vaccines in the country.

This procedure shall apply only to Peninsular Malaysia and Federal Territory of Labuan, Putrajaya and Kuala Lumpur.

iii. DEFINITION

(a) **Distributor** includes any organization/company that has been appointed by MAH to sell and distribute/retail the veterinary vaccines in Peninsular Malaysia and Federal Territory of Labuan.

(b) **Dossier** means a collection of documents containing detailed information about a particular veterinary vaccines to be registered.

(c) **Manufacturer**: includes any person or organization that formulates, prepares, compounds, mixes, makes, packs or labels any veterinary vaccines with a view to its sale or for own use and may include research or experiment relating to veterinary vaccines and any action forming part of or incidental to such research or experiment.

(d) **Marketing Authorization Holder (MAH)** means any organization/company that has been appointed and authorized by the manufacturer to import and distribute the veterinary vaccines into Malaysia; or any organization/company that has own the VVMP.

(e) **Registered veterinarian** means a veterinary doctor registered under Veterinary Surgeon Act 1974 who has been appointed by the local agent for the purpose of registration of veterinary vaccines in Malaysia.

(f) **Veterinary vaccines**: Includes all products designed to stimulate active immunisation of animals against disease, without regard to the type of microorganism or microbial component or toxin from which they may be derived or that they contain.

(g) **Veterinary vaccine manufacturing plant** a place that formulates, prepares, compounds, mixes, makes, packs or labels any veterinary vaccines with a view to its sale or for own use and may include research or experiment relating to veterinary vaccines and any action forming part of or incidental to such research or experiment.

(h) **Veterinary medicinal product** means any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal.

PROCEDURES FOR REGISTRATION OF VETERINARY VACCINES IN MALAYSIA

1. APPLICATION

1.1. Applications for registration of veterinary vaccines, VVMP, MAH must be made in writing to:

Director General of Veterinary Services
Department of Veterinary Services (DVS)
Ministry of Agriculture and Agro-Based Industry,
Wisma Tani, Podium Block, Lot 4G1, Precinct 4,
Federal Government Administration Centre,
62630 Putrajaya, Malaysia
(Attn : TACB Secretariat)
(Tel : 03 – 88702000)
(Fax : 03 - 8888 6472)

1.2. Applications shall be made using TACB1 Form and be supported by two (2) hardcopy and one (1) softcopy of dossier.

1.3. Applications to register veterinary vaccines, VVMP and MAH shall be made by a registered Malaysian company (MAH for the VVMP).

1.4. Registration of veterinary vaccines is subject to prior registration of MAH and VVMP.

2. REGISTRATION OF MARKERTING AUTHORIZATION HOLDER (MAH)

2.1. The MAH must be appointed by the manufacturer.

2.2 The MAH must provide detail information and complete documentation using TACB2 Form.

2.3 The MAH shall be responsible to:
- 2.3.1 Register the VVMP
- 2.3.2 Veterinary vaccines in order to import
- 2.3.3 Manufacturer the vaccine (for local MAH)
- 2.3.4 Distribute the veterinary vaccines.

2.4 The MAH must have in employment a registered veterinarian (with current APC) who must have full responsibility on all

aspects of veterinary vaccines registration, importation/exportation, distribution, storage, handling, sale and use in Malaysia (evidence of employment must be provided).

2.5 The MAH may appoint local distributors and detail information for every local distributor must be provided:

2.5.1 Name and address of company (must be a Malaysian registered company - with document evidence)
2.5.2 Cold chain facilities (cold storage, transportation)
2.5.3 Copy of registration certificate (ROC) of the company
2.5.4 Copy of memorandum and articles of association of the company
2.5.5 Standard operating procedures (SOPs) for handling and disposal of bio-hazardous materials.

2.6 DVS will carry out inspection of the facilities of the MAH and local distributors prior to registration if applicable.

3. REGISTRATION OF VETERINARY VACCINE MANUFACTURING PLANT (VVMP)

3.1 The MAH shall apply to register the VVMP using TACB3 Form (Official form for submission of dossier/ dossier checklist for registration of veterinary vaccine plant in Malaysia by providing detail information and complete documentation as per form.
3.2 Applicant shall furnish the compliance details of the manufacturing plant to International Standard with respect to GMP/GQC/ HSST/ HACCP.
3.3 Inspection of the VVMP by DVS Officials is required in certain circumstances to verify its status and operations.

4. REGISTRATION OF VETERINARY VACCINE

4.1. All veterinary vaccine shall be individually registered with DVS Malaysia prior to its sale and use in the country by the MAH.
4.2. A separate application for registration is required for products containing same ingredients (bio-equivalent) or part of the ingredients (sub-valent) with the currently registered product.
4.3. The MAH shall furnish the following for dossier evaluation:

i. Official application letter

ii. Application form (TACB1) must be completed, signed and endorsed by the registered veterinarian of the company.
iii. Each certificate requested in the application form (TACB1) must be valid for at least 12 months at the time of the application and shall be accompanied by a valid Malay or English translation
iv. Two (2) copies (one (1) hard copy and one (1) soft copy) of duly completed dossier or registration file for each type of veterinary vaccine to be registered.
v. Arrangement of information in the dossier shall follow the format as stated in TACB1. Please refer to the Guideline of Submission of Veterinary Vaccine for dossier detail.

4.4. All dossiers will be pre-screened by TACB secretariat within 30 working day.
4.5. Any application that fail to submit additional information within 60 days after pre-screening will be rejected and will be informed to the applicant.
4.6. Evaluation process of veterinary vaccines dossier will take within 404 working days before approval.
4.7. Application shall be submitted within 1st to 20th day of the month.
4.8. Only 10 applications will be accepted in a month. The number of applications received will be notified on DVS website every 10th of the month or when it reached 10 applications for that month.
4.9. Only two (2) application is permitted per company per month.
4.10. Only five (5) application is permitted per company per year
4.11. The update status for progress of application will be email to the relevant MAH on quarterly basis.
4.12. During the evaluation of the dossier, any queries will be handled by the TACB Secretariat.
4.13. Evaluation report by the dossier reader will be presented to the TCVP Committee. The recommendation by the TCVP will be tabled to TACB for approval and provisional registration will be granted.

5. PROVISIONAL REGISTRATION OF VETERINARY VACCINES

5.1. All veterinary vaccines approved shall be given one (1) year provisional registration and subjected to all deem requirements as stated in the approval letter.

5.2. All charges pertaining to the application and registration of the veterinary vaccines shall be borned by the company or the MAH.

5.3. In the event that the provisionally approved veterinary vaccines do not qualify for final registration, DVS reserves the right to withdraw the provisional registration and stop issuance of import license. A notification letter will be sent to the local agent.

6. FULL REGISTRATION OF VETERINARY VACCINES

6.1. The provisionally registered veterinary vaccines will be granted for Full Registration by TACB provided the below requirements and conditions have been fully and satisfactorily complied.

i. The MAH is required to submit an official request for Full Registration together with the payment as stated in Annex 1 within 30 days before the expiry of provisional registration.

ii. Any application for full registration applied after the expiry date shall be submitted within 14 days in written appeal letter with justification and will be charged accordingly.

6.2. Any application for full registration exceeded 14 days of expiry date will not be accepted.

6.3. In the case of 6.2, the applicant may submit a new application. (please refer to section 4).

6.4. A veterinary vaccine registration certificate will be issued by DVS upon full registration of the veterinary vaccine.

6.5. The validity of full registration of veterinary vaccines shall be **5 years**. Application for renewal of registration shall be made at least 90 days before the expiry of validity.

7. RENEWAL OF REGISTRATION OF VETERINARY VACCINES

7.1. The MAH is required to submit the official application in written for renewal of registration of veterinary vaccine with below requirement:

i. Letter of authorization from the manufacturer to the appointed local agent

ii. Copy of current registration certificate for veterinary vaccines to be renewed
iii. Importation records of veterinary vaccines for past 5 years (Please refer to Annex 2)

7.2. TACB will review the continuing need for the veterinary vaccine in the country before renewal for registration.

7.3. Registered veterinary vaccines which are not renewed will be deregistered.

8. VARIATION OF REGISTRATION OF VETERINARY VACCINES

8.1 Any variation on the relevant particulars or conditions of a registered veterinary vaccine where those changes may affect the quality, efficacy or safety of the formulated product.

8.2 MAH must notified any variations of the registered of veterinary vaccines. Please refer to the guideline for variations to registered veterinary vaccines

9. FEE

9.1. All fees related to application and registration of veterinary vaccine as stated in the Annex 1.

9.2. All fees made are non-refundable

10. GENERAL CONSIDERATION

10.1. Consideration for registration of veterinary vaccines for importation, production, sale and use in Malaysia shall be subject to the following conditions:

10.1.1. The use of animal veterinary vaccines in Malaysia is subjected to approval, which based on the evaluation by DVS on the disease prevalence and change of epidemiological patterns of the animal disease occurrence.

10.1.2. Any person, institutional bodies, government agencies, companies, organisation or association shall report any incidence/outbreak of animal disease to DVS.

10.1.3. The veterinary vaccines must be registered in at least 2 other reference countries and country of origin and subjected to the evaluation by DVS on effective regulatory mechanism on the control of production, use and sale of the veterinary vaccines (except for locally produced veterinary vaccines).

10.1.4. For veterinary vaccine manufactured by ASEAN countries, only one registration in another country is required.

10.1.5. No requirement of registration of veterinary vaccines in other countries for locally manufactured veterinary vaccines.

10.1.6. Veterinary vaccines in-cooperated in animal food producing shall not contain any porcine/canine origin.

11. IMPORTION OF THE APPROVED VETERINARY VACCINES

11.1. No veterinary vaccines shall be imported into Malaysia for processing, distribution, sale and use without an approval from DVS and a permit issued by MAQIS.

11.2. The MAQIS officers have the rights to inspect the consignment of veterinary vaccines at the port of entry

11.3. In case of non-compliance to import requirements, the consignment may be rejected and returned to country of origin, may be dispose or placed under provisional release to the premises/storage for further tests to be carried out.

11.4. All veterinary vaccines must be imported from the country of origin. However, if there is a need to import the veterinary vaccines from non-origin country, the MAH must furnished DVS with all information below before any decision can be made:

i. Confirmation letter from the manufacturer that the veterinary vaccines has been produced by their plant

ii. Copy of certificate of release from the manufacturer and the number of lot/batch of the veterinary vaccines which must be similar with the veterinary vaccines to be imported into the country

iii. Verification letter from the local authority (country of origin) that the veterinary vaccines is still in the original packaging.

12. FIELD AND LABORATORY STUDIES BY MAH

12.1. The approval for any field/laboratory studies of veterinary vaccines by the MAH must be obtained from DVS.

12.2. Each application for the trial must be accompanied by a trial design.

12.3. All field/laboratory studies must be supervised by DVS.

12.4. An approval from DVS must be obtained to import veterinary vaccines for the purpose of trials and research.

12.5. The applicant is required to submit complete reports on the studies together with the results/test after the completion of the studies to DVS.

12.6. Please refer to the guideline if any:

12.6.1. Guideline on Field Study Design to Evaluate the Safety and Efficacy of Fish Vaccine in Malaysia.

12.6.2. Guideline for Submission of Proposal on Local Laboratory and Field Trials of Animal Vaccines and Biologics In Malaysia.

13. RECALL AND DEREGISTRATION OF THE APPROVED VETERINARY VACCINE

13.1. The TACB will from time to time, advice the DGVS Malaysia on the need for deregistration of any veterinary vaccine.

13.2. DVS reserves the right to recall and deregister of any veterinary vaccine in the event of non-compliance of the veterinary vaccines to safety, sterility, potency, efficacy and purity standards or due to any other adverse consequences arising from the use of the veterinary vaccines.

13.3. If the samples of product taken during DVS monitoring fail to meet the specifications and standards, the registration of the product will be suspended. The MAH has to identify the source/cause of quality defect and taken necessary actions to improve quality within 30 days. Failure to do so may result in deregistration of the product.

13.4. A product may be deregistered if changes to its name, composition or labels or changes in operations, change of manufacturing site, are made without approval by the DVS.

14. PENALTIES

In the event that any MAH has imported, sold or used illegal veterinary vaccines/unregistered veterinary vaccines, the registration of the company will be suspended until proven otherwise and any actions deemed fit under the Animal Act 1953 (Amendment 2013) will be taken. Failure of the MAH to inform DVS of any defects, non-compliance or violations to standards and adverse reactions due to use of the product may result in the suspension or deregistered of the registration of the VVMP, veterinary vaccines and/or MAH.

15. APPEAL

15.1. Any appeal to the decision made must be in writing within fourteen (14) days from the day of the official notification.

15.2. A period of 60 days is given for submission of any supporting data/ information. The appeal is considered closed if all the required information is not submitted within the time given.

15.3. The decision over an appeal shall be final and no further appeals shall be considered.

16. ENQUIRY

Enquiries and further details pertaining to registration of veterinary vaccines and for importation, sale and use in Peninsular Malaysia and Federal Territory of Labuan can be obtained from:

Director General of Veterinary Services
Department of Veterinary Services (DVS)
Ministry of Agriculture and Agro-Based Industry,
Wisma Tani, Podium Block, Lot 4G1, Precinct 4,
Federal Government Administration Centre,
62630 Putrajaya, Malaysia
(Attn : TACB Secretariat)

{Tel : 03 – 88702000)
{Fax : 03 – 88886472)

STEPS TO DO VETERINARY VACCINES REGISTRATION

FLOW CHART OF PROCEDURE FOR REGISTRATION OF VETERINARY VACCINESS IN MALAYSIA

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
• Pre-screening of application by TACB secretariat within 30 working days • Local agent is given 14 days to submit complete information	• Evaluation by Dossier reader, correspondence with local agent	• Evaluation report in TWG	• Final report in TACB	• Provisional approval (1 year), send samples of veterinary vaccines for quality test	• Final approval (Renewable every 5 years)