



PROCEDURES FOR REGISTRATION OF ANIMAL VACCINES IN MALAYSIA

Key word: vaccine registration

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

ABBREVIATIONS

DVS	Department of Veterinary Services
GMP	Good Manufacturing Practice
GQC	Good Quality Control
HSST	High Standard of Safety Test
HACCP	Hazard Analysis and Critical Control Point
TACB	Technical and Advisory Committee on Biologics

i. INTRODUCTION

Section 30(1) of Animal Ordinance 1953 gives the power to the Director General of Department of Veterinary Services to issue license to the holder to possess live cultures or vaccines and to inoculate animals or birds with such culture or vaccine. Section 84 requires a person to get a written permission from the Director General to import any living disease germ or virus or any bacterial culture or part of them used for diagnosis, treatment, research and control or prevention of disease.

As the regulatory agency to enforce legislative requirements, Department of Veterinary Services (DVS) has set down specific procedures for registration of biologics in Malaysia with regards to production, importation, distribution, sale and use.

The Department through Technical and Advisory Committee on Biologics (TACB) acts as a licensing authority to register animal vaccines and other biologics. The committee members are appointed by Director General consists of;

- Deputy Director General (Animal Health)
- Director of Bio-security and SPS Management Division
- Head of Zoonosis and Public Health Section
- Head of Disease Control and Eradication Section
- Head of Quarantine Services & Import Export Section
- Director of Veterinary Research Institute
- Director of Regional Veterinary Laboratory, Petaling Jaya.
- Biologics and Veterinary Drug Control Unit (secretariat)

The main functions of TACB committee are;

- To study and confirm recommendations proposed by dossier reader on veterinary biologic registration
- To discuss and consider current issues pertaining importation, production, sale and use of vaccine and biologic in West Malaysia and Federal Territory of Labuan

TACB meetings to be held at least once every 4 months.

ii. SCOPE

The purposes of these procedures are;

- (a) To provide the local manufacturer, importer and distributor with guidelines on preparing submissions for registration of vaccines in Malaysia.
- (b) To regulate the sale and use of vaccines in the country.

This procedure shall apply only to Peninsular Malaysia and Federal Territory of Labuan.

iii. DEFINITION

- (a) **“animal”** includes any quadruped or bird either domesticated or otherwise fish, reptile or insect.
- (b) **“live culture”** means live microorganism which is grown under controlled condition.
- (c) **“Director-General”** means the Director General of Veterinary Services appointed under section 3 of Animal Act 1953 and includes the Deputy Director-General under the same section.
- (d) **“distributor”** includes any person who has been appointed by local agent to sell and distribute the vaccines.
- (e) **“dossier”** means a collection of documents containing detailed information about a particular vaccine.
- (f) **“importer”** includes any person who, whether as owner, consignor, consignee, agent or broker, is in possession of, or is otherwise entitled in the custody or control, of the imported vaccine.
- (g) **“inoculate”** means to introduce a vaccine into the animal body to boost immunity against a specific disease.
- (h) **“local agent”** means any person or organization that has been appointed and authorized by the manufacturer to import and distribute the product.

- (i) **“manufacturer”** includes any person or organization that formulates, prepares, compounds, mixes, makes, packs or labels any vaccine with a view to its sale or for own use but does not include a *bona fide* research or experiment relating to vaccine and any action forming part of or incidental to such research or experiment.
- (j) **“premises”** includes any house, shop, store, room, cubicle, shed, conveyance, structure or any place whether open or enclosed.
- (k) **“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 biologics in Malaysia.
- (l) **“vaccine”** means any culture or living preparation of the causative agent of any disease
- (m) **“veterinary biologics”** means any viruses, serums, toxins, and analogous products of natural or synthetic origin, including genetically modified organism, diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing component of micro-organisms intended for use in the diagnosis, treatment, or prevention of diseases of animals or birds, for the purposes of research in animals or birds.
*(based on the new amendments of Animal Act)

PROCEDURES FOR REGISTRATION OF ANIMAL VACCINES IN MALAYSIA

1.0 APPLICATION

- 1.1 Applications for registration of animal vaccines, manufacturing plant, importer/ distributor must be made by writing directly to:

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

(Tel : 03 - 88702000/ 2099/ 2102/ 2105)
(Fax : 03 - 8888 6472)

- 1.2 Applications shall be made using TACB 1 form (*Official form for submission of dossier/ dossier check list for registration of animal vaccines in Malaysia*) (Appendix A) and be supported by two (2) copies of dossier.
- 1.3 Applications to register vaccines, manufacturing plants and the distributors shall be made by a registered Malaysian company (local agent for the manufacturing plant).
- 1.4 Registration of vaccine is subject to prior approval of manufacturer and importer/ distributor.

2.0 REGISTRATION OF MANUFACTURING PLANT

- 2.1 The local agent (legally appointed by manufacturer as sole local agent) shall apply to register the manufacturing plant by providing detail information and complete documentation as below.
- 2.2 Applicant must furnish compliance details of the manufacturing plant to International Standard with respect to GMP/GQC/HSST/ HACCP.

- 2.3 Application must contain the following detail for DVS evaluation:
- 2.3.1 Name and address of manufacturing plant and company
 - 2.3.2 Company profile and background
 - 2.3.3 Organisation chart of the company
 - 2.3.4 List of key personnel - qualifications & job responsibilities
 - 2.3.5 Blueprints, legends and photographs of the establishment
 - 2.3.6 List of equipment in each room
 - 2.3.7 Production processes diagram and records
 - 2.3.8 Contamination precautions
 - 2.3.9 Copy of manufacturing license or registration certificate
 - 2.3.10 Copy of license of establishment for vaccine production
 - 2.3.11 Copy of certificate of satisfactory plant inspection or GMP/GQC/HSST/HACCP certificate by government authorities or accredited international inspectors
- 2.4 If necessary, inspection of the manufacturing plant by DVS Officials may be required to verify its GMP, GQC, HSST and HACCP status and operations.
- 2.5 Upon approval, the manufacturer/exporter in the country of origin shall be registered with DVS.

** Local established manufacturing plant may apply directly to register the plant or may do so through a sole local agent.*

3.0 REGISTRATION OF LOCAL AGENT/DISTRIBUTOR

- 3.1 The local agent must provide detail information and complete documentation.
- 3.2 Local agent shall be responsible to register the manufacturing plant and vaccines and to import and distribute the vaccines.
- 3.3 The local agent must have in employment a registered veterinarian (with current annual practicing certificate) who must have full responsibility on all aspects of vaccine registration, importation, distribution, storage, handling, sale and use in Malaysia (evidence of employment must be provided).
- 3.4 Local agent shall provide confirmation of appointment as a local agent by manufacturer.
- 3.5 Application must include the following details for DVS evaluation:
- 3.5.1 Name and address of company (must be a Malaysian registered company - with document evidence)

- 3.5.2 Cold chain facilities (cold storage, transportation)
 - 3.5.3 Company profile and organisation chart
 - 3.5.4 Copy of registration certificate (ROC) of the company
 - 3.5.5 Copy of memorandum and articles of association of the company
 - 3.5.6 Name, address and registration number of the veterinarian of the company (with proof of employment)
 - 3.5.7 Copy of annual practicing license/certificate of the veterinarian
 - 3.5.8 Letter of attorney/authorization letter by the manufacturer
 - 3.5.9 Standard operating procedures (SOPs) for handling and disposal of bio-hazardous materials.
- 3.6 The local agent may appoint local distributors by providing the following information for every distributor;
- 3.5.1 Name and address of company (must be a Malaysian registered company - with document evidence)
 - 3.5.2 Cold chain facilities (cold storage, transportation)
 - 3.5.3 Copy of registration certificate (ROC) of the company
 - 3.5.4 Copy of memorandum and articles of association of the company
 - 3.5.5 Standard operating procedures (SOPs) for handling and disposal of bio-hazardous materials.
- 3.7 DVS may carry out inspection of the facilities of the local agent/distributor.
- 3.8 Upon approval, the local agent/ distributor shall be registered with DVS.

4.0 REGISTRATION OF VACCINE

- 4.1 Each type of animal vaccine produced locally or imported must be individually registered with DVS Malaysia prior to its sale and use in the country by the local agent
- 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 Local agent must furnish the following for dossier evaluation;
 - 4.3.1 Official application letter
 - 4.3.2 Application form (TACB 1) must be completed, signed and endorsed by the registered veterinarian of the company.

- 4.3.3 Application fee.
- 4.3.4 Each certificate requested in the application form (TACB 1) must be valid at the time of the application and shall be accompanied by a valid English translation.
- 4.3.5 Two (2) copies of duly completed dossier or registration file for each type of animal vaccine to be registered.
- 4.3.6 Failure to furnish any additional information requested within the time specified may result in the cancellation of the evaluation of the dossier.

** Arrangement of information in the dossier shall follow the format as stated in TACB 1.*

- 4.4 Registration may be subject to technical evaluation (laboratory/field trial) prior to provisional approval and payment of technical evaluation service fee.
- 4.5 Field trials on the vaccine may be required either during/after basic evaluation or dossier evaluation or TACB evaluation.
- 4.6 Provisional Registration of Vaccine
 - 4.6.1 All animal vaccines (*live or killed*) granted approval for registration for production, importation, sale and use in Malaysia shall first be given a **"Provisional Registration"** for a period of **1 year for monitoring/evaluation/trial purposes**. The provisional registration may be extended for an additional year upon request.
 - 4.6.2 A provisional approval letter/certificate and product registration number will be issued by DVS upon approval of the product.
 - 4.6.3 During this period;
 - 4.6.3.1 DVS Malaysia may conduct monitoring of the storage, distribution and usage as well as trials on safety, sterility, purity, potency and efficacy of the vaccine.

- 4.6.3.2 The local agent concerned may be required to undertake 'field trial', supervised by DVS to further evaluate the safety, potency and efficacy of the vaccine in any designated local farm(s).
- 4.6.3.3 In this period, DVS will further monitor and evaluate any new technical information/data on the vaccine from the respective manufacturer in the country of origin as well as from other manufacturers in other countries currently registered with or recognised by DVS Malaysia.
- 4.6.3.4 The continuing need for the vaccine in the country will be evaluate by DVS based on disease incidences or reports, change of epidemiological patterns of certain animal disease and other/new technical information.
- 4.6.4 In the event that the provisionally approved vaccine does 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 importer/ distributor.

4.7 Final Registration of Vaccine

- 4.7.1 After the monitoring/ trial period, all provisionally registered animal vaccines will be considered for "**Final Registration**" by TACB provided the above (4.6.3) requirements and conditions have been fully and satisfactorily complied.
- 4.7.2 The local agent is required to submit an official request for "Final Registration" together with the payment not more than one month before expiry of provisional registration.
- 4.7.3 An approval letter/ certificate will be issued by DVS upon final registration of the product.
- 4.7.4 The validity of final registration of animal vaccines shall be **5 years**. Application for renewal of registration shall be made at least 3 months before the expiry of validity.

4.8 Renewal of Registration of Vaccines

The local agent is required to submit the official application for renewal of registration of vaccine using the form TACB 2 (*Official form for renewal of registration of animal vaccines and in Malaysia*) together with the renewal fee, at least 3 months prior to the expiry of validity.

- 4.8.1 Form TACB 2 must be completed, signed and endorsed by the registered veterinarian of the company.
- 4.8.2 Other new technical information or additional information (if required) must be provided along with form TACB 2.
- 4.8.3 TACB will review the continuing need for the vaccine in the country before renewal for registration.
- 4.8.4 Registered vaccines which are not renewed after 3 years will be deregistered.

5.0 FEES

Fees for registration and renewal of registration of animal vaccines are as follows;

- 5.1 Application fee of RM 200.00 for processing and preliminary evaluation payable at the time of application together with vaccine dossier and other documents.
- 5.2 Dossier evaluation fee of RM 800 to be payable prior to forwarding document to dossier reader.
- 5.3 Technical evaluation services (field trial and laboratory evaluation) payable prior to technical evaluation:
 - 5.3.1 Monovalent vaccine (RM2000)
 - 5.3.2 Polyvalent vaccine (RM3000)
 - 5.3.3 Genetically Modified vaccine (RM4000)
- 5.4 Fee for Final Registration of RM 500 payable upon approval by TACB
- 5.5 Fee for renewal of registration of animal vaccine is RM 350.00

- 5.6 Fee for reinstatement of the deregistered vaccine is RM 500.
- 5.7 Charges for inspection of manufacturing plant shall be based on cost-recovery principle.

6.0 GENERAL CONSIDERATION

- 6.1 Consideration for registration of animal vaccines for importation, production, sale and use in Malaysia shall be subject to the following conditions:

6.1.1 National requirement for animal vaccine

Consideration for registration of vaccine will be given based on DVS records and reports from other institutional bodies or government agencies or farmers association on animal disease incidences/outbreaks and the types and strains of pathogen involved.

6.1.2 Type and strain of the vaccines similar to VRI Products

- 6.1.2.1 Viral or bacterial vaccines with type and strain **similar** to Veterinary Research Institute (VRI) products (*live or killed*) will not be approved.
- 6.1.2.2 Vaccines other than viral/bacterial origin which are strain **similar** in type/strain to VRI products may be considered subject to study and evaluation of dossier.

- 6.2 Registration in two other countries

- 6.2.1 The vaccine must be registered in at least 2 other countries which in the opinion of DVS have effective regulatory mechanism on the control of production, use and sale of the vaccine (except for locally produced vaccines).
- 6.2.2 When the requirement above is not fulfilled, the product must be evaluated through field trial to prove that the product is safe and effective in local condition.
- 6.2.3 Vaccine manufactured by local company is exempted from above requirement.

- 6.3 Animal vaccines used in food animals for Muslim consumption shall not contain porcine products.

7.0 OTHERS

7.1 Changes in Manufacturing Details

- 7.1.1 In case of any change in management or ownership of the manufacturing plant registered with DVS Malaysia, both parties (current and former management/owner) and the local agent must immediately inform the DVS, in writing.
- 7.1.2 The new management/owner must furnish detail information as per requirement under item 2.3. DVS Malaysia reserves the right to request additional information or documentation for further evaluation.
- 7.1.3 Letter of attorney/ authorization letter to the currently registered local agent must also be issued by the new management/owner.
- 7.1.4 In the event of change of manufacturing site, the new site must fulfill all the requirements of item 2.0.
- 7.1.5 Upon approval of the new manufacturing site, an approval letter/certificate and company registration number will be issued by DVS.
- 7.1.6 In case of any physical or operational changes to the manufacturing facility, the revised blueprints and legends, GMP, GQC, HSST and HACCP must be submitted immediately to DVS for evaluation.

7.2 Transfer of Agency / Distributor

- 7.2.1 Any transfer of local agent in Malaysia by the registered manufacturer must be notified immediately to the DVS, in writing.
- 7.2.2 Letter of attorney/authorization letter to the newly appointed local agent must be issued by the manufacturer.
- 7.2.3 The newly appointed local agent must fulfill all the requirements in 3.0.

7.3 Change of Company Veterinarian

- 7.3.1 Any change in employment of veterinarian of the local agent currently registered with DVS Malaysia must be notified to the DVS in writing within 14 days.
- 7.3.2 The local agent must furnish a copy of the current APC to DVS.

7.4 Monitoring by DVS

- 7.4.1 The DVS may inspect premises and storage and transportation facilities of local manufacturer and local agent/distributor and others without prior notice.
- 7.4.2 DVS may take samples of the vaccines for the purpose of evaluation as and when necessary.
- 7.4.3 In case of non-compliance to storage, handling and transportation standards, the vaccines may be placed under restrictions until corrective actions are taken.
- 7.4.4 Local agent/ distributor are responsible to report immediately any suspected adverse events associated with the use of the vaccines in the field.
- 7.4.5 In the event that there is a consumer complaint, DVS may conduct an investigation and require the local agents to provide data demonstrating the purity, sterility, safety, potency and efficacy of the product and submit samples to DVS's laboratories for testing.

7.5 Field and Laboratory Studies by the local agent

- 7.5.1 The approval for any field/laboratory studies of vaccine by the local agent must be obtained from DVS.
- 7.5.2 Each application for the trial must be accompanied by a trial design.
- 7.5.3 All field/laboratory studies must be supervised by DVS.

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

7.5.5 The veterinarian is required to submit complete reports on the studies together with the results/test data immediately after the completion of the studies.

7.6 Import of Biologics

7.6.1 No biologics shall be imported into Malaysia for processing, distribution, sale and use without a permit issued by Department of Veterinary Services.

7.6.2 Application to import vaccine shall be made by the registered veterinarian of local agent/distributor either manually or via electronic system as determined by DVS.

7.6.3 The DVS have the rights to inspect the consignment of biologics at the port of entry.

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

7.6.5 The registered veterinarian may apply for special approval from the Director General for importation of animal vaccines which are not registered in Malaysia for emergency or limited use.

7.6.6 The application above (7.6.5) should be accompanied by minimum product information and the purpose of import such as research or field trial with full details and any other justifications for special approval.

8.0 RECALL AND DEREGISTRATION OF VACCINE

8.1 The Technical and Advisory Committee on Biologics (TACB) will from time to time, advise the Director General of Veterinary Services (DGVS) Malaysia on the need for deregistration of any animal vaccine.

8.2 The DVS reserves the right to deregister, recall and stop issuance of import license for any animal vaccine in the event of

non-compliance of the vaccine to safety, sterility, potency, efficacy and purity standards or due to any other adverse consequences arising from the use of the vaccine.

- 8.3 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 local agent/distributor 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.
- 8.4 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.

9.0 PENALTIES

- 9.1 In the event that a company has imported, sold or used illegal vaccine/unregistered vaccine, the registration of the company will be suspended until proven otherwise and any actions deemed fit under the Animal Ordinance 1953 will be taken. The company or veterinarian is liable to a fine of Ringgit Malaysia one hundred (Animal Ordinance 1953).
- 9.2 Failure of the manufacturer or local agent/distributor 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 of the registration of the manufacturer and/or local agent/distributor.
- 9.3 The registration of the local agent may be cancelled if the change of ownership of the manufacturing plant or change of company veterinarian is made without approval by the DVS.

10.0 REINSTATEMENT OF REGISTRATION STATUS

- 10.1 Local agent who wishes to reinstate the vaccine registration after it has been deregistered must write a formal application letter together with the justification for the reinstatement of the vaccine registration status.
- 10.2 The reinstatement can only be made on the same vaccines manufactured by the previously registered manufacturer.

11.0 APPEAL AGAINST TACB DECISIONS

- 11.1 Any applicants aggrieved by the decision of TACB committee may make a written appeal to the DVS within fourteen (14) days from the day of the notification.
- 11.2 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 without reasonable cause.
- 11.3 The decision TACB over an appeal shall be final and no further appeals shall be considered.

12.0 ENQUIRY

Enquiries and further details pertaining to registration of animal vaccines and for importation, sale and use in Malaysia can be obtained from:

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

{Tel : 03 – 88702000/ 2099/ 2102 / 2105)
{Fax : 03 - 88886472)

PENDAFTARAN VAKSIN

