PROCEDURES FOR REGISTRATION OF ANIMAL BIOLOGICS (EXCLUDING VACCINES)/ DIAGNOSTIC TEST KITS FOR ANIMAL USE IN MALAYSIA

Key word: biologic registration, diagnostic test kits registration, animal use

DEPARTMENT OF VETERINARY SERVICES
MINISTRY OF AGRICULTURE AND AGR0-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

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1. INTRODUCTION

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 readers on veterinary biologic registration
- To discuss and consider current issues pertaining importation, production, sale and use of vaccines and biologics in West Malaysia and Federal Territory of Labuan

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

2. SCOPE

2.1 The procedures shall apply to registration of biologics/ diagnostic test kits other than vaccines.

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

3. PURPOSE OF PROCEDURES

3.1 To provide the local manufacturer, importer and distributor with guidelines on preparing submissions for registration of biologics/ diagnostic test kits of animal origin and/or for animal use in Malaysia.

3.2 To regulate the sale and use of biologics/ diagnostic test kits for animal use in the country.

4. DEFINITION

4.1 **"animal"** includes any quadruped or bird either domesticated or otherwise fish, reptile or insect

4.2 **"live culture"** means live microorganism which is grown under controlled condition

4.3 **"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

4.4 **"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 biologics/ diagnostic test kits

4.5 **"local agent"** means any person or organization that has been appointed and authorized by the manufacturer to import and distribute the product.

4.6 **"manufacturer"** includes any person who, formulates, prepares, compounds, mixes, makes, packs or labels any veterinary biologics with a view to its sale or for own use but does not include a *bona fide* research or experiment relating

to biologics/ diagnostic test kits and any action forming part of or incidental to such research or experiment

4.7 **"premises"** includes any house, shop, store, room, cubicle, shed, conveyance, structure or any place whether open or enclosed

4.8 **"diagnostic test kit"** is a product that is used in the course of a chemical or analytical procedure for laboratory, industrial, educational, or research purposes.

4.9 **"vaccine"** means any culture or living preparation of the causative agent of any disease

4.10 **"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 micro-organisms, 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

5. APPLICATION

All applications for registration of animal biologics for importation, production, sale and use in Malaysia must be made by writing direct to:

Director General
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

Applications shall be made by a registered Malaysian company.

6. REGISTRATION OF BIOLOGIC/ TEST KIT

6.1 Any biologic/ diagnostic test kit of animal origin or to be used in animals is subject to risk and quality evaluation and required to be registered with DVS by the local agent.

6.2 Application for registration must provide details of importer and premises where the products shall be stored together with Form TACB 9.

6.3 Registration will be based on evaluation of technical information and complete supporting documents provided in the registration file of the biologic/ test kit together with a covering letter stating clearly the purpose of the application from the importer

6.4 Authorised English translation must accompany any material not published in English.

6.5 The local agent shall submit a valid document of appointment as sole agent by the manufacturer.

6.6 The local agent may appoint local distributors and shall provide the DVS the list of distributors as and when necessary.

6.5 Application must furnish the following detail for DVS evaluation;

6.5.1 <u>Registration of Microorganisms (Probiotic, Effective Microorganism, Competitive Exclusion Organism, etc live or killed) or enzyme or hormone and other biologics or combination of these with any drug (vitamins, minerals, amino acids, etc.)</u>

6.5.1.1 Application form (form TACB 9) must be filled and signed by the applicant

6.5.1.2 Product name

6.5.1.3 Name and address of the manufacturer

6.5.1.4 Name and address of local agents

6.5.1.5 Copy of establishment license and product license from competent authority of country

of origin approving sale and use of product in the country

6.5.1.6 Composition

Type of microorganism/ active ingredient/ inactive ingredient/ solvent

6.5.1.7 Product specification

Strength and nature of final product

6.5.1.8 Purpose/Use of Product

6.5.1.8.1 Target species, diseases and/or condition(s) that product is designed to treat, prevent or detect

6.5.1.8.2 Efficacy claims made for the product

6.5.1.9 Certificate of analysis with details on methods of inactivation/ purification/ sterilisation of the products

6.5.1.10 Clinical particulars

Dosage, route and method of administration, indications for use, contra-indications, undesirable effects, precautions for use, overdose, special warnings for each target species, major and minor incompatibilities, withholding period, special precautions for user/ administrator of product, first aid and safety directions

6.5.1.11 Product particulars

Pack sizes, shelf life, storage conditions, container specifications,

6.5.1.12 Copies or drafts of the labels, leaflets and packaging

6.5.2 Registration of Diagnostic Test Kits

6.5.2.1 Application form (form TACB 9) must be filled and signed by the applicant

6.5.2.2 Product name (Brand name)

6.5.2.3 Name and address of manufacturer

6.5.2.4 Name and address of local agents

6.5.2.5 Copy of establishment license and product license from competent authority of country of origin approving sale and use of product in the country

6.5.2.6 The name and quantitative details for each substance contained in the diagnostic test kit

6.5.2.7 Description of the kit

6.5.2.7.1 Description of the purpose use of the diagnostic test kit (principle of the test).

6.5.2.7.2 Directions for the use of the diagnostic test kit (list of equipment and reagents making up the kit, general description of the test interpretations and their limitations).

6.5.2.8 Technical specifications and physical description of the finished product

6.5.2.9 Process control/ test procedure and expected performance specification

6.5.2.10 Certificate of analysis with details on methods of inactivation/ purification/ sterilisation of the products

6.5.2.11 Copies of draft labels, leaflets and packaging

7. IMPORTATION OF VETERINARY BIOLOGICS FOR RESEARCH USE

Application to import veterinary biologics (e.g. cultures of microorganism or parts thereof, serum, plasma, blood, cells cultures, etc.) for research purpose may not be subjected to registration procedures as above but shall include the following details for DVS evaluation prior to importation;

7.1 Covering letter from the researcher/ institution explaining briefly and clearly the purpose of importing the product and the name of the farms/ clinics/ institutions/ company where the product will be used. A brief description of research work may be attached if necessary.

7.2 Brief description of the product including species of animals of origin or cell cultures involved

7.3 Certificate of analysis with details on methods of sterilization/inactivation (if any) and/or purification of the products

7.4 Copy of the product order from the Government, Universities or Research Institutes

Subject to DVS approval based on evaluation above, a person who wish to import biologics for research purpose must apply for an import permit via online (please refer to 10.2.2) or they could apply it through the registered forwarding agents (please refer to www.dvs.gov.my) or they could submit the application manually by completing Form B (Official form – Application to import/ export animals products) and send it directly to Import Export Counter, Level 5, DVS Putrajaya.

8. DEREGISTRATION OF BIOLOGIC/ TEST KIT

8.1 The Technical and Advisory Committee on Biologic (TACB) will, from time to time, advice the Director General of Veterinary Services (DGVS) Malaysia on the need for deregistration of any animal biologic/ diagnostic test kit.

8.2 The DVS reserves the right to withdraw the registration and stop issuance of import license for any veterinary biologic in the event that there is non-compliance of the biologic to safety, potency, efficacy and purity standards or adverse reactions or health hazard to human or animals.

8.3 If the samples of product taken during DVS monitoring fail to meet the specifications, the registration of the product will be suspended. The distributor/ manufacturer have 30 days to

identify the source/cause of quality defect and actions to be taken to improve quality. Failure to do so may effect in deregistration of the product.

9. PENALTIES

9.1 In the event that the company has brought in unregistered biologic/ diagnostic test kit, the registration of the company will be cancelled.

9.2 Failure to inform DVS of any serious contamination of the product by the importer may result in the cancellation of the registration of the importer.

10. OTHERS

10.1 Monitoring By DVS

10.1.1 The DVS has the right to inspect local manufacturer and importer premises, storage and transportation facilities without early noticed.

10.1.2 DVS may take samples of the biological products/ diagnostic test kit for the purpose of evaluation as when necessary.

10.1.3 In case of non-compliance to storage, handling and transportation facilities, the biologic/ diagnostic test kit may be placed under restriction until further evaluation and the non compliance corrected.

10.1.4 The manufacturer/importer/distributor is responsible to report any contamination associated with the use of the product in the field/ laboratory

10.1.5 Manufacturer/Importer/distributor are also responsible to dispose the contaminated products in a proper way

10.1.6 In the event that there is a consumer report or complaints, DVS may conduct an investigation and require the manufacturer/importer to provide data demonstrating the purity, safety, potency and

efficacy of the product and submit samples to DVS's laboratories for confirmatory testing.

10.2 Import of Biologics/ Diagnostic Test Kits

10.2.1 Biological/ diagnostic test kit products registered with DVS shall be imported for sale and use with an import license issued by Department of Veterinary Services.

10.2.2 A person/company who wish to import/ export biologics/ diagnostic test kit product for commercial purpose must first be registered with Dagang Net Technologies Sdn. Bhd. (www.dagangnet.com). An import/ export permit application shall be made via online at http:// epermit.dagangnet.com.

10.2.3 Every consignment shall be accompanied by a declaration by the authorities or manufacturer regarding safety of the product.

10.2.4 The DVS has the right to inspect any consignment of biologics/ diagnostic test kit at the ports or point of entry.

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

10.3 Appeal Against TACB Decisions

10.3.1 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.

10.3.2 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 stated time given without reasonable cause. A request for extension of this period will not be entertain.

10.3.3 The decision of the appeal is final.

11. ENQUIRY

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

Director General
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
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