TACB 1

TECHNICAL AND ADVISORY COMMITTEE ON BIOLOGIC
DEPARTMENT OF VETERINARY SERVICES
MINISTRY OF AGRICULTURE AND AGRO-BASED INDUSTRY
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OFFICIAL FORM FOR SUBMISSION OF DOSSIER / DOSSIER CHECK LIST FOR REGISTRATION OF ANIMAL VACCINES IN MALAYSIA

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	REMARKS
Submission of Dossier in two (2) copies : **1. General Information :** (a) Name of vaccine/biologic (Trade / Generic Name) (b) Name and address of manufacturer (c) Name and address of manufacturing facility/ premise (if different from (b)) (d) Country of origin (e) Copy of manufacturing license or registration certificate of the manufacturer in the country of origin (f) Name and address of local agent/Malaysian company (g) Copy of letter of attorney or authorization letter by the manufacturer **2. Other Informations and Supporting Documents** (a) Copy of assay certificate or certificate of release for latest 3 batches (b) Copy of registration certificate or free		

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sale certificate of vaccine in country of origin (c) Copy of registration certificate of the vaccine in two other countries **3. Vaccination Regime** (a) Vaccinating schedule (b) Target age/group (c) Dosage and route of vaccination (d) Diluent **4. Packaging Information (text)** (a) Doses per package (b) Instructional pamphlet and specimen of label *- usage instructions/ indications/ precautions/ vaccinations schedules/ dose/ route/ storage conditions* (c) Storage condition/ requirement (d) Indications and contra-indications (e) Side effects and precautions (f) Batch serial number & expiry date **5. Technical information** **5.1 Vaccine production, control & shelf life** (a) Master seed history - *pathotype/ serotype/ strain* - *history of acquisition of master seedlot* (b) Vaccine attenuation process (for live/ attenuated vaccine)		

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(c) Master seed identity (d) Master seed purity (e) Substrate for propagation (including Master cell stock information) - *substrate composition* - *substrate purity/ sterility/ safety* (f) SPF status of production support (eggs, primary cell culture) (g) Other starting material of animal origin * Part of culture media or freeze-drying excipient (h) Vaccine inactivation process (for inactivated antigens) (i) Inactivation kinetic studies information (for inactivated antigens) (j) Chemical starting material * Chemical compositions: chemical starting material used in adjuvant/ emulsion/ suspension etc. **5.2 Quality Control on finished product** (k) Sterility tests (l) Inocuity tests (m) Moisture contents (for live vaccines) (n) Viscosity of vaccine (for inactivated vaccines) (o) Purity test of live vaccines (p) Composition of final product (q) Nature of final products * Lyophilised/ inactivated/ Live attenuated/ Recombinant/ subunit/ Transgenic/ Combination/ vectored		

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5.3 Stability study **5.4 Vaccine Safety** (r) Field trials (s) Reversion to virulence (for live vaccines) **5.5 Vaccine Efficacy** (t) Potency/ Challenge tests (u) Minimum immunogenic dose (Procedure for determination MID) (v) Immune levels and duration (challenge and serology results) (w) Transmitted passive immunity in progeny (serology and/ or challenge) (x) Shelf life		

(Note : Must be completed,signed and endorsed by the registered veterinarian of the company / local agent)

I, _____ the registered veterinarian of company/local agent _____ hereby certify that the technical information and Documentation provided in the dossier is complete in accordance with the DVS requirements for Registration of animal vaccine/biologics in Malaysia.

Submitted on : _____ by :

Company Stamp :

_____
(Signature)

_____
(Name of Veterinarian)

_____
(Registration Number)