

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

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

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<p>(c) Master seed identity</p> <p>(d) Master seed purity</p> <p>(e) Substrate for propagation (including Master cell stock information)</p> <ul style="list-style-type: none"> - <i>substrate composition</i> - <i>substrate purity/ sterility/ safety</i> <p>(f) SPF status of production support (eggs, primary cell culture)</p> <p>(g) Other starting material of animal origin * Part of culture media or freeze-drying excipient</p> <p>(h) Vaccine inactivation process (for inactivated antigens)</p> <p>(i) Inactivation kinetic studies information (for inactivated antigens)</p> <p>(j) Chemical starting material * Chemical compositions: chemical starting material used in adjuvant/ emulsion/ suspension etc.</p> <p>5.2 Quality Control on finished product</p> <p>(k) Sterility tests</p> <p>(l) Inocuity tests</p> <p>(m) Moisture contents (for live vaccines)</p> <p>(n) Viscosity of vaccine (for inactivated vaccines)</p> <p>(o) Purity test of live vaccines</p> <p>(p) Composition of final product</p> <p>(q) Nature of final products * Lyophilised/ inactivated/ Live attenuated/ Recombinant/ subunit/ Transgenic/ Combination/ vectored</p>		

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

(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)