BORANG PERMOHONAN
PENDAFTARAN VAKSIN VETERINAR DI MALAYSIA

APPLICATION FORM FOR
REGISTRATION OF VETERINARY VACCINES IN MALAYSIA

MAKLUMAT TEKNIKAL DAN DOKUMENTASI DI DALAM DOSIR *Technical Information and Documentation Provided in The Dossier*	**MUKA SURAT** *Page Number*	**CATATAN** *Remarks*
A. BAHAGIAN I: MAKLUMAT PENGURUSAN *PART I: ADMINISTRATIVE INFORMATION*		
Seksyen A (Maklumat Umum) *Section A (General Information)* *This section shall have the general information about the vaccine to be registered; from the manufacturing to the importation.*		
1. **Nama Penuh Pemohon** *Full Name of Applicant*		**Sila Nyatakan** *Please state*
2. **Nombor Kad Pengenalan Pemohon** *Identification Card (IC) Number of Applicant*		**Sila Nyatakan** *Please state*
3. **Alamat Lengkap Pemohon** *Complete Address of Applicant*		**Sila Nyatakan** *Please state*
4. **Nama Vaksin** *Name of vaccine*		**Sila Nyatakan** *Please state*
5. **Nama Pengilang Vaksin** *Name of Vaccine Manufacturer*		**Sila Nyatakan** *Please state*
6. **Alamat Lengkap Kilang Vaksin** *Complete Address of Vaccine Manufacturer*		**Sila Nyatakan** *Please state*
7. **Nombor Pendaftaran Pengilang Vaksin yang telah didaftarkan oleh DVS** *DVS Manufacturer Registration Number*		**Nyatakan & Lampirkan surat** *Please state and attach approval letter*
8. **Penyakit yang disasarkan** *Target Disease*		**Sila Nyatakan** *Please state*
9. **Spesis yang disasarkan** *Target Species*		**Sila Nyatakan** *Please state*
10. **Deskripsi Penyakit** *Disease Description*		**Sila Nyatakan** *Please state*

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a) etiologi *aetiology* ***b) Cara transmisi*** *mode of transmission* **c) Tanda klinikal** *d) clinical sign*		
11. **Negara asal (vaksin)** *Country of Origin (Vaccine)- COO*		**Sila Lampirkan** *Please Attach*
12. **Salinan Lesen Pembuat atau sijil pendaftaran kilang pembuat di negara pembuat** *Copy of manufacturing license or registration certificate of the manufacturer in the country of origin*		**Sila Lampirkan** *Please Attach*
13. **Sijil GMP Kilang Pembuat** *Certification of GMP for the manufacturer*		**Sila Lampirkan** *Please Attach*
14. **Nama dan alamat marketing Authorization Holder (MAH)** *Name and address of Marketing Authorization Holder (MAH)*		**Sila Nyatakan** *Please state*
15. **Salinan surat *attorney or authorization* oleh kilang pembuat vaksin** *Copy of letter of attorney or authorization letter by the manufacturer to appoint Marketing Authorization Holder*		**Sila Lampirkan** *Please Attach*
16. **Salinan SSM** *Copy of SSM*		**Sila Lampirkan** *Please Attach*
17. **Salinan sijil pendaftaran dan sijil penjualan vaksin dari negara pembuat** *Copy of registration certificate or free sale certificate of vaccine in country of origin*		**Sila Lampirkan** *Please Attach*

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18. **Salinan sijil pendaftaran dari dua negara lain bagi vaksin yang ingin didaftarkan di Malaysia** *Copy of registration certificate of the intended vaccine in two other countries*.		**Sila Lampirkan** *Please Attach*
Seksyen B (Perincian Produk) *Section B (Product Particular)* *This section must provide the Summary of Product Characteristic (document)*		
1. Nama vaksin *Name of vaccine (trade / generic name)*		**Sila Lampirkan** *Please Attach* *Summary of Product Characteristics (SPC)*
2. Vaksin Teknologi *Technology of Vaccine*		
a. Konvisional *Conventional*		
b. Recombinant - (subunit / DNA / vector / Gene Deleted / Artificial Cell Membrane)		
B. BAHAGIAN II: MAKLUMAT BAHAN MULA *PART II: STARTING MATERIAL INFORMATION*		
Seksyen A *(Master Seeds)* *Section A (Master Seeds)*		
1. **Maklumat sejarah Bibit Induk** *Information about the Master seed & working seed history*		
a. Sejarah pemerolehan bibit induk *history of acquisition of master seed & working seed* *-isolation passage history*		**Sila Lampirkan** *Please Attach*
b. Perjanjian pemindahan bahan *Material Transfer Agreement /letter of transfer agreement*		**Sila Lampirkan** *Please Attach*

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c. Nama penuh pathotype/ serotype/ strain *Full name of pathotype/ serotype/ strain*		**Sila Nyatakan** *Please state*
2. Maklumat identiti bibit induk *Information about the Master seed identity*		
a. Prosedur tetap perlu dilampirkan *SOP must be provided*		**Sila Lampirkan SOP** *Please Attach SOP*
b. **Keputusan (serologi/DNA sequencing/gen)** *Results (serology / DNA sequencing / gene)*		**Sila Lampirkan COA** *Please Attach COA of each master seed organism*
3. Maklumat ketulenan bibit induk *Information about the Master seed purity*		
a. Prosedur tetap perlu dilampirkan *SOP must be provided*		**Sila Lampirkan SOP** *Please Attach SOP*
b. **Keputusan (serologi/DNA sequencing/gen)** *Results (serology / DNA sequencing / gene)*		**Sila Lampirkan COA** *Please Attach COA*
4. Sistem Pengurusan Lot Bibit *Establishment of Seed Lot System* *- SOP on production control,* *- preparation, working, and production of seed*		**Sila Lampirkan SOP** *Please Attach SOP*
Seksyen B (Medium & Substrat) *Section B (Medium & Substrate)*		
1. Media/Substrat untuk pengembangan bibit induk/bibit bekerja/bibit produksi *Medium/ Substrate for Propagation of Vaccinal microrganisms (Master Seed/ Working Seed/ Production Seed, including Master Cell Stock information)* *i. SPF Egg or Tissue Culture (Virus)* *ii. Media (tissue culture & bacteria)*		**Sila Senaraikan dan lampirkan COA** *-To provide list of media/substrate used with their origin (name of species if animal) with COA*

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iii. Others (Please specify), e.g., Live animal **a) Status steril bagi telur SPF , sel kultur primer** *SPF status of production support (eggs, primary cell culture) *When master cell stock is not used.* **b) Lain-lain bahan pemula dari sumber haiwan** *Other starting material of animal origin *Part of culture media or freeze-drying excipient*.		**Sila Lampirkan** *Please Attach* **Sila Senaraikan & Lampirkan COA** *-To provide list of starting materials used (include name of species if animal) with COA*
C. BAHAGIAN III: PENGHASILAN & PENILAIAN VAKSIN *PART III: VACCINES PRODUCTION & EVALUATION*		
Seksyen A (Kawalan Kualiti) *Section A (Quality Control)* **1. Proses penghasilan vaksin** *Production outline/process flow* **2. Keadaan produk akhir** *Nature of final products* *a) Type of vaccine* ☐ *Live* ☐ *Killed* *b) Number of strain* ☐ *Monovalent* ☐ *polyvalent* *c) Form* ☐ *Lyophilised* ☐ *frozen* ☐ *emulsion* ☐ *suspension*		**Sila Lampirkan** *Please Attach* **Pilih (wajib isi semua)** *Choose (compulsory)*

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d) Technology of vaccine ☐ *whole cell vaccine* ☐ *recombinant vaccine* ☐ *virus vector vaccine* ☐ *DNA vaccine* ☐ *subunit vaccine* ☐ *peptide vaccine*		
3. Salinan sijil perlepasan untuk 3 batch terkini *Copy of assay certificate or certificate of release for latest 3 consecutive batches.*		**Sila Lampirkan** *Please Attach*
4. Komposisi Kimia *Chemical compositions & safety test (**chemical starting materials** used as adjuvant/ stabilizer/preservative)*		**Sila Senaraikan** *Please list of chemical used and safety report*
5. Kandungan kelembapan *Moisture contents (for Lyophilised vaccine)*		**Sila Lampirkan SOP & COA** *Please Attach written SOP & COA*
6. **Vakum** *Vacuum (for Lyophilised vaccine)*		**Sila Lampirkan SOP & COA** *Please Attach written SOP & COA*
7. Kestabilan emulsi *Emulsion stability (if applicable)*		**Sila Lampirkan SOP & COA** *Please Attach written SOP & COA*
8. Kelikatan Vaksin *Viscosity of vaccine (if applicable)*		**Sila Lampirkan SOP & COA** *Please Attach written SOP & COA*
9. Pengujian ketulenan *Purity test (for live vaccines)*		**Sila Lampirkan SOP & COA** *Please Attach written SOP & COA*
10. Pengujian steril (QC) *Sterility tests (QC)*		**Sila Lampirkan SOP & COA** *Please Attach written SOP & COA*

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Seksyen B (Keselamatan) *Section B (Safety)*		
1. Komposisi produk akhir *Composition of the final product (vaccine and diluent)* *-levels of toxic components* *-list of each component in FP packaging*		**Sila Lampirkan** *Please Attach*
2. Keselamatan Vaksin *Vaccine Safety*		**Sila Lampirkan** *Please Attach written SOP with safety report*
3. Pengujian innocuiti *Innocuity tests*		**Sila Lampirkan** *Please Attach written SOP with test result*
4. Proses melemahkan vaksin *Vaccine Attenuation process (for live/ attenuated vaccine)*		**Sila Lampirkan** *Please Attach written SOP with test result*
5. **Pengembalian kepada virulensi (LV) / kajian *back passage*** *Reversion to virulence (LV) / back passage study*		**Sila Lampirkan** *Please Attach written SOP with test result*
6. Proses penyahaktifan vaksin *Vaccine inactivation process (for killed vaccine/inactivated antigens)*		**Sila Lampirkan** *Please Attach written SOP with test result*
7. **Penentuan margin keselamatan kinetik penyahaktifan** *Inactivation kinetic safety margin determination*		**Sila Lampirkan** *Please Attach written SOP with test result*
8. Pengujian immunosupresi *Immunosuppression Test (if applicable)*		**Sila Lampirkan** *Please Attach written SOP with test result*
9. Pengujian inaktif residu *Residual inactivant test (for killed+live vaccine)*		**Sila Lampirkan** *Please Attach written SOP with test result*

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Seksyen C (Efikasi) *Section B (Efficacy)*		
1. Potency /Challenge test *Potency (Efficacy)*		**Sila Lampirkan** *Please Attach written SOP with report/technical data*
2. Ujian imunogenisiti *Immunogenicity test*		**Sila Lampirkan** *Please Attach written SOP with report/technical data*
3. Dos imunogenik minimum *Minimum immunogenic dose (Procedure for determination minimum dose (MID) / Probit analysis)*		**Sila Lampirkan** *Please Attach written SOP with report/technical data*
4. Kajian lapangan *Field trials* *-Field trials are conducted in 3 farms in different (3) locations with complete address*		**Sila Lampirkan** *Please Attach study report with technical data*
5. Tahap Imun dan tempoh di dalam hos *Immune level and duration in intended host*		**Sila Lampirkan** *Please Attach written SOP with report/technical data*
6. Tahap Imun dan tempoh di dalam progeny *Immune level and duration in progeny (maternal derived antibody-passive immunity) if applicable*		**Sila Lampirkan** *Please Attach written SOP with report/technical data*
7. Pengujian kestabilan *Stability test*		**Sila Lampirkan** *Please Attach written SOP with report/technical data*
8. Jangka hayat *Shelf life*		**Sila Lampirkan** *Please Attach*

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D. BAHAGIAN IV: PRODUK SIAP *PART IV: FINISHED PRODUCT*		
Seksyen A (Rejim Vaksinasi) *Section A (Vaccination Regime)*		
1. Risiko meggunakan vaksin bergantung kepada strain atau teknologi pembuatan vaksin *Risk of application of the vaccine based on strain used or type of manufacturing technology (Category II &III of Biotech vaccine)* - *Safe to host, human or environment*		**Sila Lampirkan** *Please Attach*
2. Jadual pemvaksinan *Vaccinating schedule*		**Sila Lampirkan** *Please Attach*
3. Kumpulan sasaran *Target age/group*		**Sila Lampirkan** *Please Attach*
4. Pencair *Diluent* - *Name of diluent*		**Sila Nyatakan dan Lampirkan COA** *Please specify & attach COA*
5. Dos dan cara pemvaksinan *Dosage and route of vaccination*		**Sila Lampirkan** *Please Attach*
Seksyen B (Maklumat Pembungkusan) *Section B (Packaging Information)*		
1. Maklumat Asas *General information*		
a. Isi isipadu/berat bekas *Fill volume/ weight of container*		**Sila Nyatakan** *Please state*
b. Jenis bekas *Type of container*		**Sila Nyatakan** *Please state*
c. Bahan yang digunakan bagi bekas primer *Material of the primary container*		**Sila Nyatakan** *Please state* **Sila Lampirkan** *Please Attach Certificate of compliance (COC)*

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d. Jenis dan bahan penyumbat *Type and material of stopper*		**Sila Nyatakan** *Please state* **Sila Lampirkan** *Please Attach Certificate of compliance (COC)*
2. **Maklumat label dan risalah** *Label information (all below information shall available on the product's label and pamphlet)*		**Sila Lampirkan maklumat label** *Please Attach*
a. Nama Produk *Product Name*		**a. Label asal/sebenar** *Original label*
b. Strain		**b. Label dicetak** *Printed label*
c. Dos setiap pakej *Doses per package*		**c. Risalah** *Pamphlet*
d. Maklumat pengeluar *Manufactured by*		
e. No. batch/siri , tarikh pembuatan dan tamat tempoh *Batch/serial number, manufacturing and expiry date*		
f. Spesis yang disasarkan *Target sepsis*		
g. Syarat penyimpanan *Storage condition*		
h. *Indikasi dan kontraindikasi *Indications and contra-indications*		
i. *Kesan sampingan dan langkah berjaga-jaga *Side effects and precautions (human & animals)*		
3. Gambar produk (dengan pembungkusan berbeza –jika ada) *Photo of product (with different packaging – if available)*		**Sila Lampirkan maklumat berkenaan (Muat naik)** *Please Attach (Upload)*

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Seksyen C (Dokumen Sokongan & Maklumat Lain) *Section C (Other Information & Supporting Documents)* ☐ Pharmacopeia ☐ ASEAN Standard ☐ VICH (Veterinary International Cooperation on Harmonization of Technical Requirement for Registration of Veterinary Medicinal Products) ☐ OIE ☐ Journal		**Pilih & Sila Lampirkan maklumat berkenaan** *Choose any and Attach File*

Important:
-Authorised English translation to be submitted if documents are in a foreign language.
-The competent authority must endorse a copy of the certificate
-Latest Certificate of Analysis (COA) must be provided with the endorsement by QA/QC
-All study report or technical data must be endorsed/verified by competent authority/ QA/QC
- Please arrange the dossier accordingly upon submission with proper tagging

Nota:
Borang ini perlu dilengkapkan, ditandatangani dan disahkan oleh Doktor Veterinar Bertauliah syarikat

Note:
This form must be completed, signed and endorsed by the registered veterinarian of the company

PENGESAHAN :

Declaration:

Saya, _____ Doktor Veterinar Berdaftar bagi syarikat _____ dengan ini mengesahkan bahawa semua maklumat teknikal dan dokumentasi yang disediakan di dalam dosir yang dilampirkan adalah lengkap sebagaimana keperluan Jabatan Perkhidmatan Veterinar Malaysia untuk Pendaftaran Vaksin / Kultur Veterinar di Malaysia.

I, _____ the registered veterinarian of company _____ hereby certify that the technical information and documentation provided in the dossier is complete in accordance with the Department of Veterinary Services Malaysia requirements for a registration of veterinary vaccine / cultures in Malaysia.

Permohonan ini diserahkan pada: (tarikh) ……

Submitted on:.

……

(Tandatangan)

(Signature)

(Cop Syarikat)
(Company Stamp)

(Nama Doktor Veterinar Bertauliah)

(Name of Registered Veterinarian)

(Nombor Pendaftaran MVC) :
(MVC Registration Number) :