**APPLICATION FORM FOR A NEW MARKETING AUTHORISATION FOR VETERINARY PHARMACEUTICAL, BIOLOGICAL AND IMMUNOLOGICAL PRODUCTS**

# *(Application form Adopted from the Regional Regulatory Harmonization for Livestock Products in Sub-Saharan Africa)*

*A separate application form is required for each strength and/or pharmaceutical dosage form. Different pack sizes of the same product can be included on the same form.*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION 1 - PRODUCT NAME(s)**   * 1. **Proposed trade name of product**  |  | | --- | |  |  * 1. **International Non-Proprietary Name (Generic Name)**  |  | | --- | |  |   **SECTION 2 – APPLICATION DETAILS**  **2.1 Product Type**  Please select either pharmaceutical OR Biological/Immunological   |  |  | | --- | --- | |  | Pharmaceutical | |  | Biological *A VMP sourced from a biological source that is not a vaccine* | |  | Immunological - *vaccine.* |   **2.2 Type of Drug Substance**  Please select only one   |  |  | | --- | --- | |  | Newly marketed Product with New Drug Substance | |  | Newly marketed Product with New Combination of Drugs Substances | |  | Newly marketed Product with Existing Drug Substance | |  | Re-evaluation of an Existing Product |   **SECTION 3 – PRODUCT DETAILS**  **3.1 Formulation** *(provide the full formulation details)*   |  |  |  |  | | --- | --- | --- | --- | |  | **Name of the substance** | **Concentration in the final product** | **Description of Function**  *(example, active substance, attenuated virus, adjuvant, excipient)* | | **1** |  |  |  | | **2** |  |  |  |   Please add extra rows, if required.  **3.2 Therapeutic Subgroup Classification** *(example, inactivated viral vaccine, diuretic drug)* **and ATC Code (if applicable)**   |  | | --- | |  |   **3.3 Dosage Form and Strength** *(example, solution for injection)*   |  | | --- | |  |   **3.4 Visual appearance** *including colour (example, clear, light yellow oily solution)*   |  | | --- | |  |   **3.5 Target Species and Route(s) of Administration**   |  |  |  |  | | --- | --- | --- | --- | |  | **Target Species** | **Route of Administration** | **Food-producing?**  **(tick as appropriate)** | | **1** |  |  | Yes  No | | **2** |  |  | Yes  No |   Please add extra rows, if required.  **3.6 Do all active substances have the appropriate Maximum Residue Limits (MRLs) set in the species and for the route of administration(s) for which they are indicated? For example, from Codex, EU or other.**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | YES |  |  | NO |  |   If yes, states the MRLS   |  |  |  |  | | --- | --- | --- | --- | | **Target Species** | **Tissue** | **MRLs** | **Reference (Codex, EU,…)** | |  |  |  |  | |  |  |  |  |     If no, please tell us what you are doing to obtain the appropriate MRL(s):   |  | | --- | |  |   **3.7 Pack type details**  Please provide information of all pack types including their container and closures.   |  |  |  |  | | --- | --- | --- | --- | |  | **Pack Size**  *(example, 100 ml)* | **Container**  *(example HDPE bottle)* | **Closure**  *(example, polyethylene screw-cap)* | | **1** |  |  |  | | **2** |  |  |  |   Please add extra rows, if required.  **3.8 Proposed shelf-life** (if applicable also include the proposed shelf life after reconstitution or dilution or after first opening container)   |  | | --- | |  | |  |

**SECTION 4 – CONTACT INFORMATION**

**4.1 Details of the proposed Marketing Authorization Holder (MAH) or Applicant contact:**

|  |  |
| --- | --- |
| Company Name: |  |
|  |  |
| Company Address: |  |
|  |  |
| Telephone No. |  |
|  |  |
| Email |  |

**4.2 Name, address and contact details of the proposed Manufacturers**

**4.2.1. Name, address and contact details of the proposed finished product manufacturer(s):**

*If the proposed named manufacturer is the same as the proposed MAH, simply enter ‘same as MAH’ in the field below.*

|  |  |  |
| --- | --- | --- |
|  | **Name, address and telephone number, Email** | **Brief description of functions performed** *(e.g. bulk manufacturing, batch release, primary or secondary packaging)* |
| **1** |  |  |
| **2** |  |  |

Please add extra rows, if required.

**4.2.2. Name, address and contact details of the proposed manufacturer (s) of Active pharmaceutical ingredient (s) or active Immunogenic Substance(s):**

|  |  |  |
| --- | --- | --- |
|  | **Name, address and telephone number, Email** | **Brief description of functions performed** *(e.g. bulk manufacturing, batch release, primary or secondary packaging)* |
| **1** |  |  |
| **2** |  |  |

Please add extra rows, if required.

**SECTION 5 – REGULATORY STATUS**

**5.1 Regulatory Status in Country of Origin.** *Provide the regulatory status in the country of manufacture and the authorisation number/reference.*

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**5.2 Regulatory Status in Other Territories.** *Regulatory status of the proposed product in other countries globally, including successful or pending, rejected, withdrawn, suspended or revoked applications.*

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| **Country/Region with successful authorisations** |
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Please add extra rows, if required.

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| **Country/Region where applications are pending** |
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|  |

Please add extra rows, if required.

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| **Country/Region where applications/authorisations have been rejected, withdrawn, suspended or revoked** |
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Please add extra rows, if required.

**SECTION 6 – DECLARATION**

**Contact details of the person responsible for the application:** *A legal representative of the applying company to take full responsibility for the application on behalf of the MAH and is answerable to the authority.*

|  |  |
| --- | --- |
| Name: |  |
| Company Name: |  |
|  |  |
| Address (including country): |  | |
|  |  |
| Telephone No. |  |
|  |  |
| Email Address: |  |
|  |  |
| Position and Affiliation: |  |

I confirm that the information provided in support of this application is correct at the time of submission.

I understand that if any information provided in this application is later found to be false or incorrect, the authorization may be suspended or revoked.

|  |  |
| --- | --- |
| **SIGNATURE:** |  |
| **DATE:** |  |

***\*Note****: - not signing this box will lead to your application being rejected at validation.*

*- If fees have been paid, attach proof of payment*

**ANNEX 1: Rwanda Specific Information**

*If applications are being made to a number of countries, please provide the following details for each country (please replicate this annex for each country)*

**A.1 Contact details of in-country Local Technical Representative:***An in-country legal representative of the company holding the original authorization to take full responsibility for the product on behalf of the MAH and is answerable to the authority.*

|  |  |
| --- | --- |
| Name: |  |
|  |  |
| Address (including country): |  |
|  |  |
| Telephone No. |  |
|  |  |
| Email Address: |  |

**A.2 Name and contact details of person responsible for pharmacovigilance:**

|  |  |
| --- | --- |
| Name: |  |
|  |  |
| Telephone No. |  |
|  |  |
| Email Address: |  |

**A.3 Proposed Distribution Category in country** *(example, controlled drug, drug requiring prescription by veterinarian etc.)*

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**A.4 Proposed Storage Conditions** (*if applicable, also include the proposed storage condition after first opening and after reconstitution*)

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**A.5 Intended Use**

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