# APPLICATION FORM

# FOR A MUTUAL RECOGNITION APPLICATION

# FOR THE REGISTRATION OF IMMUNOLOGICAL VETERINARY PRODUCT(S)

# IN THE EAST AFRICA REGION

| | |
|---|---|
| Draft agreed by Technical Working Group | 25 October 2012 |
| Draft released for consultation by representatives of East African region regulatory agencies | 1 January 2013 |
| End of consultation period | 30 June 2013 |
| Adoption by EAC | 28 November 2014 |
| EAC code | EAC/PSS/AGRI-LIV/IVP-REG AF/Ver.2 |
| Enters into force | 18 March 2015, revised on the 11 May 2016 |

**APPLICATION FORM FOR NATIONAL OR MUTUAL RECOGNITION REGISTRATION OF IMMUNOLOGICAL VETERINARY PRODUCT(S) FOR THE EAST AFRICA REGION**

**1.A Particulars of the Applicant**

- Name:
- Physical address:
- Postal address:
- Phone: Fax: e-mail:

**1.B Particulars of the Immunological Veterinary Product**

- Product name:
- Pack size(s):
- Description of the Immunological Veterinary Product (e.g. inactivated/ attenuated / freeze-dried)
- Main indication(s):

**1.C Particulars of the Manufacturer(s) and Activity** (Include the contract manufacturing and quality control laboratories)

| | **Name** | **Manufacturing plant address** | **Activity** |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |

Attach copies of certification of recognition of manufacturer from competent authority in the country of manufacture.

**2. Authorised Local Technical Representative (LTR) in Member States**

| Member State | Name of Local Technical Representative | Address of Local Technical Representative |
|---|---|---|
| Burundi | | |
| Kenya | | |
| Rwanda | | |
| Tanzania | | |
| Uganda | | |
| South Sudan | | |

**3. Current Registration and Licensing Status**

3.1 Registration status in the country of manufacture (attach validated copy of marketing authorisation of Immunological Veterinary Product issued by the appropriate regulatory authority).

3.2 If not registered in the country of origin, provide Certificate of Origin issued by the competent authority in the country of manufacture.

3.3 If the Immunological Veterinary Product has been refused/deferred/cancelled/ withdrawn in any country or territory supply details.

3.4 List of countries where the Immunological Veterinary Product is already registered.

## 4. Purpose of the application

☐ **4.1 A National Marketing Authorisation**

☐ **4.2 A Mutual Recognition Procedure for a new product**

- Reference Member State:
- Procedure number: [*To be allocated by Co-ordination Group for MR*]
- Concerned Member State(s) (tick appropriate boxes below):

| **Member State** | |
|---|---|
| Burundi | |
| Kenya | |
| Rwanda | |
| Tanzania | |
| Uganda | |
| South Sudan | |

☐ **4.3. A Mutual Recognition Procedure for a product already licensed in one or more Member States**

- Reference Member State:
- Date of authorisation: (dd-mm –yyyy):
- Licence number:

(a copy of the authorisation should be provided)

- Procedure number: [*To be allocated by Co-ordination Committee*]
- Concerned Member State(s) (tick appropriate boxes below):

| **Member State** | |
|---|---|
| Burundi | |
| Kenya | |
| Rwanda | |
| Tanzania | |
| Uganda | |
| South Sudan | |

Enclose a copy of the manufacturing license issued by the appropriate regulatory authority in the country of manufacture.

**5. Product Composition**
Give the composition of the product in terms of units per dose

**5.1. Active (immunogenic) ingredients**

| Name | Quantity per dose | Specification or reference text |
|---|---|---|
| | | |
| | | |

**5.2. Inactive ingredients (adjuvant/excipients/preservative)**

| Name | Quantity per dose | Specification or reference text | Reason for inclusion |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

**5.3. Additional Starting materials**
Give details of any additional starting materials used in the manufacturing process but not found in the final product.

**6. Type of Review Requested**
Tick one of the options. Give reason(s) for the accelerated review request

| Request | Give reasons (if applicable) |
|---|---|
| Normal Review | |
| Accelerated Review | |

**7. General Information and Supporting Documentation**
For submission of the dossier, refer to guideline on dossier structure.

**8. Declaration by applicant**

I the undersigned hereby apply for registration of the product detailed above and declare that all the information herein and in the appendices is correct and true.

Fee enclosed:

Signed: Date:

**Full name of Signatory:**

**APPENDIX**

## INFORMATION REQUIRED FOR THE SITE MASTER FILE

### 1. Description of the manufacturing facility

#### 1.1 Particulars of the manufacturers

The application shall include the name(s), address(es) and other pertinent organizational information for each manufacturer responsible for any portion of the manufacture or testing operations for the active immunogenic substance.

#### 1.2 Manufacture of other products

A comprehensive list of other vaccines that are manufactured or handled in the same area(s) shall be provided. Include a brief description of the type and development status of the additional active immunogenic substances/product and indicate the areas into which these other products will be introduced. The applicant should also indicate whether the manufacture of other products will utilize the same contact equipment and if so, how that equipment will be cleaned and validated between operations for the manufacturing of different products. Data for the validation and cleaning in the appropriate section should be provided.

#### 1.3 Layout

The applicant shall submit a simple flow diagram of the general layout of the facilities, which traces the immunogenic substance through the manufacturing process. The diagram(s) should be sufficiently clear to enable visualization of the production flow and to identify adjacent operations that may create particular concerns.

#### 1.4 Precautions against contamination

Information concerning precautions taken to prevent contamination or cross contamination during preparation of cell banks and manufacturing, including areas for the handling of animals used in production shall be provided.