



GUIDELINE FOR APPLICANTS

INTENDING TO USE THE EAC MUTUAL RECOGNITION PROCEDURE FOR REGISTERING VETERINARY MEDICINES

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Introduction

This document is intended as guidance for applicants intending to apply for registration of veterinary medicinal products in the East African Community (EAC) through Mutual Recognition Procedures (MRP). Initially, the Mutual Recognition Procedure will be available for applicants to use when registering immunological veterinary products (IVPs) since this is the first group of veterinary medicines for which a harmonised process has been developed in the EAC. The basis for this harmonised approach is the availability of harmonised technical documents developed through a consultative approach by a Technical Working Group (TWG). This group was established in 2012 with support from GALVmed and AU-PANVAC. It comprises experts from the Regulatory Authorities in Partner States of the EAC.

The documents that were developed were specifically designed to provide guidance on the requirements for registering Immunological Veterinary Products in the EAC. They consist of guidelines for use by both applicants and regulators. The harmonised documents include templates for labelling and packaging of IVPs, guidance on the technical information to be included in a registration dossier, the format for preparing registration dossiers for IVPs and a harmonised Application Form for applicants wishing to use Mutual Recognition Procedures. The documents were adopted by the (EAC) Partner States' Heads of National Medicines Regulatory Authorities and the Chief Veterinary Officers in Arusha, Tanzania on 25th June 2013. Since then, more guidelines have been developed to assist both applicants and regulators and to enable the smooth running of Mutual Recognition Procedures in the region. The aim of these guidelines is to foster harmonisation of registration of veterinary immunological products and also Mutual Recognition Procedures in line with Article 47 of the EAC Common Market Protocol, which provides for approximation and harmonisation of policies, laws and systems. The documents are now available on the EAC's website.

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Table of Contents	PAGE
1. ADMINISTRATIVE INFORMATION FOR DOSSIER	4
2. TECHNICAL INFORMATION FOR DOSSIER	4
3. DOSSIER FORMAT	4
4. OTHER GUIDANCE	5
4.1 SITE MASTER FILE	5
4.2 GMP CERTIFICATE	5
4.3 LOCAL TECHNICAL REPRESENTATIVE	6
4.4 FEES	6
4.5 SAMPLES	7
4.6 LABEL LANGUAGE	7
4.7 APPLICANTS GUIDE TO MRP	7
4.8 PRE-SUBMISSION GUIDE	7
4.9 ADDRESS OF REGULATORY AUTHORITIES	7

The documents to be used by applicants preparing registration applications for Immunological Veterinary Products in the EAC are as follows:

1. ADMINISTRATIVE INFORMATION

PART 1A, the Application Form, can be found on <https://www.eac.int/documents/category/livestock>

PART 1 B includes the following documents:

1. Summary of Product Characteristics
2. Label
3. Primary packaging
5. Secondary packaging
6. Pack Leaflet

Templates for these documents can be found on:
<https://www.eac.int/documents/category/livestock>

2. TECHNICAL GUIDELINE

The guideline for the technical section of the registration dossier includes the following sections:

PART 2 MANUFACTURE AND CONTROL

PART 3 SAFETY

PART 4 EFFICACY

PART 5 BIBLIOGRAPHY

This technical guideline can be found at:
<https://www.eac.int/documents/category/livestock>

3. FORMAT FOR A REGISTRATION DOSSIER FOR AN IMMUNOLOGICAL VETERINARY PRODUCT

This guideline explains the different sections, or Parts of the dossier and their sequence. It can be found at:
<https://www.eac.int/documents/category/livestock>

4. OTHER GUIDANCE

Guidance on how to prepare other documentation required for registration of IVPs can be found as follows:

4.1. SITE MASTER FILE

This document is required prior to GMP inspections.

INFORMATION REQUIRED FOR THE SITE MASTER FILE

4.1.1 Description of the manufacturing facility

4.1.2 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.

4.1.3 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.

4.1.4 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.

4.1.5 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.

4.2 GMP CERTIFICATE

All applicants' manufacturing facilities must have a GMP certificate that is valid in one of the countries in the EAC. If the manufacturing site does not have a valid GMP Certificate the applicant should discuss this with the selected Reference Country. Arrangements will be made by the RC to carry out a GMP inspection. The required fees for the inspection must be paid to the RC by the applicant. This can be done directly by electronic bank

transfer, where possible, or through the local technical representative (LTR), before the agreed date for the inspection. Following submission of an application for an MRP, the manufacturer must have been issued with a GMP Certificate, valid in the EAC, before MRP Marketing Authorisations can be issued.

Copies of GMP certification of the manufacturer from the competent authority in the country of manufacture should be included as Annex 3 to the Application Form for a Marketing Authorisation.

4.3 LOCAL TECHNICAL REPRESENTATIVE (LTR)

Applicants shall appoint the LTRs who will represent them in all communications with the National Regulatory Authorities in each Partner State. One LTR shall be appointed per product. Details of the LTRs should be included in the application form, as shown below:

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

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

4.4 FEES

Fees Payable for Applications for Marketing Authorisations in the East African Community

Fees may be paid to NRAs through the relevant LTRs or directly by electronic bank transfer.

4.4.1 National Fees for applications for Marketing Authorisations are applicable for the Reference Country (RC) and the Concerned Countries (CC).

Please consult the websites of the RC and CCs for current guidance.

EAC Regulatory Authorities' websites are:

Burundi: www.minagrie.gov.bi

Kenya: www.vmd.go.ke

Rwanda www.rab.gov.rw

South Sudan

Tanzania www.tfda.go.tz

Uganda www.nda.or.ug

4.4.2 Fees are also payable for **GMP inspections**. The Reference Country (RC) will advise you about the current fees.

4.5.SAMPLES OF THE VETERINARY IMMUNOLOGICAL PRODUCT

The number of samples to be submitted will be as per the respective country's requirements. Currently these are:

Burundi	5
Kenya	3
Rwanda	3
South Sudan	
Tanzania	5
Uganda	2

4.6. OFFICIAL LANGUAGE

The registration dossier must be written in English

Labels, packaging and package leaflets The following table indicates which countries require labelling to be printed in more than one language:

Country	Primary Language	Any additional languages
BURUNDI	French	English
KENYA	English	
RWANDA	English	French
SOUTH SUDAN		

TANZANIA	English	Kiswahili
UGANDA	English	

4.7. APPLICANTS' GUIDE TO MUTUAL RECOGNITION PROCEDURES

A booklet about the EAC-MRP is available on the EAC's website.

<https://www.eac.int/documents/category/livestock>

4.8. PRE-SUBMISSION GUIDANCE

A guideline for applicants on discussion with the Reference Country before submitting an application dossier is available on

<https://www.eac.int/documents/category/livestock>

4.9. ADDRESSES FOR SUBMISSIONS OF REGISTRATION DOSSIERS

Partner State	Number of copies of dossiers &/or CDs	Address where dossier is to be sent	Contact e-mail and phone numbers
BURUNDI	2 CDs	Ministère de l'Agriculture et de l'Élevage P.B.1850 BUJUMBURA-BURUNDI	E-mail: Phone :+257 222087 +257 225141 +257 222873 FAX : +257 222873 +257 22404221
KENYA VMD	One hard copy and 2 CDs	Ag. CEO, Veterinary Medicines Directorate, P.O. Box 66171-00800, Westlands, Nairobi, Kenya.	Tel: 0743795395, Email: infodvs@kilimo.go.ke / nsongok@kilimo.go.ke / songoknat@yahoo.com
RWANDA	2 CDs	Rwanda Agriculture Board (RAB) P. O Box 5016 Kigali-Rwanda Email: infos@rab.gov.rw	Toll free: 4675, , <u>Tel:+250788596253,</u>

		Website: www.rab.gov.rw	
SOUTH SUDAN	Not yet available	Not yet available	Not yet available
TANZANIA	1 dossier 2 CDs	Tanzania Food and Drug Authority (HQ) P.O.Box 77150 Dar Es Salaam	Tel: 2450512/2450751 Email: info@tfda.go.tz http://www.tfda.go.tz
UGANDA	2CDs	Plot 19 Lumumba Avenue P.O. Box 23096 Kampala Uganda	Tel: +256 417 788100/1 +256 417 788124 +256791 415555 Fax: +256 414 255758 Email: ndaug@nda.or.ug www.nda.or.ug

For further information please contact the EAC Secretariat.