GL6

East African Community

# GUIDANCE FOR

# PRE-SUBMISSION MEETINGS

# FOR A MUTUAL RECOGNITION APPLICATION

# FOR THE REGISTRATION OF VETERINARY MEDICINES AND IMMUNOLOGICALS

# IN THE EAST AFRICAN REGION

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|---|---|
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**Pre-Submission Meetings**

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Advice for Applicants planning to apply for Marketing Authorisations (MAs) through a Mutual Recognition Procedure (MRP).

**Introduction**:
Applicants are encouraged to contact their selected Reference Country (RC) to arrange a pre-submission meeting when intending to seek MAs through MRPs.

**Procedure for the Applicant**:

1. The Applicant must prepare a Registration Dossier for the product which is intended to be registered through MRP. The dossier should be formatted in accordance with the Dossier Structure Guideline, EAC GL1, PSS/1/1/21/79 and the content should be presented following the Technical Guideline, EAC GL2, PSS/1/1/21/80, both available at https://www.eac.int/documents/category/livestock

2. Contact the selected Reference Country to ask for a Pre-Submission Meeting.

3. Once a meeting has been arranged, the form below shall be completed by the Applicant and sent, with the dossier, to the RC.

**Procedure for the RC:**

1. Upon receiving an application for a Pre-Submission meeting, check the form completed by the Applicant and briefly review the dossier.

2. Confirm the eligibility of the product for MRP by completing the RC check list.

3. During the meeting, provide the Applicant with advice as appropriate.

See check lists overleaf

Form 1. for Applicant to complete:

**Pre-Submission meeting Request Form to be completed by the Applicant:**

**1. Name and address of Applicant**

**2. Name of Product**:

**3. Description of the Product**

**4. Composition of Product**:

**5. Current Registration Status**:
Indicate if the product is already registered in any country

**6. Reference Country**

Which EAC country is requested to be the Reference Country
……

**7. Concerned Country(s)**

Indicate in which EAC Concerned Countries you intend to seek MAs through MRP

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

**8. Certificate of Manufacture from Competent Authority**

Do you have a valid GMP Certificate? Yes/No

If so, name the Regulatory Authority(s) that issued it.
……
……
……

Give the date of the last GMP inspection
……

Provide the GMP Certificate number issued by the NRA
……

**9. Local Technical Representative**

Do you have LTRs in each of the RC and CCs indicated in point 7 above?

Form 2. Check List for Reference Country to use

**Check List for Reference Country**

1. Have LTRs been appointed in the intended markets? Yes/No

If not, explain that it will not be possible to market the product in countries where an LTR has not yet been appointed.

2. Is there a valid GMP Certificate? Yes/No

If not, explain that an inspection must take place as soon as the MRP begins.
If a joint GMP inspection is required, explain that the Applicant must pay the inspection fees for the RC and also all the CCs, and that in certain cases the MRP clock may be paused until the GMP inspection has taken place and a GMP Certificate issued by the NRA of a Partner State.

3. For third country applications, is the product registered in the Country of Origin? Yes/No

It is possible that a manufacturer may produce a vaccine for sale in Africa when the disease does no occur in the country of origin.

4. Is there a Certificate of Origin? Yes/No

5. In which other countries, including EAC Partner States, were field trials conducted? ……
It is possible that field trials carried out in one or more EAC countries are sufficient evidence of efficacy and safety in the other countries if the husbandry and geographical conditions are similar.

6. Is the vaccine strain(s) relevant to the RC and all the CCs ?

7. Is the product already registered in any EAC Partner States and if so which one(s) ……

If so, explain that the NRA that issued the original MA must act as the Reference Country.

8. Indicate countries in which a Site Master File is required in the dossier rather than for the GMP inspection.
……

9. Inform the applicant about the different fee structures for the RC and CCs and that fee structures can be found on the websites of most regulatory authorities.

10. Advise the Applicant on the number of samples to be submitted to the RC and CCs

11. Advise the Applicant that identical dossiers and the required number of samples must be submitted and that fees must be paid either by electronic bank transfer or by the respective LTRs to the RC and CCs all at the same time.

12. Explain to the Applicant the conditions for refusal by a Partner State to be a Concerned Country (GL5, section 7.4).

13. If the application is deemed eligible for MRP, consult the MR-C for the next available time slot and inform the Applicant of the proposed start date.

Name of Reviewer Signature and Date

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Regulatory Authority ……