BEST PRACTICE GUIDE

FOR

MUTUAL RECOGNITION PROCEDURES

FOR THE REGISTRATION OF VETERINARY MEDICINAL PRODUCT(S) IN THE EAST AFRICAN REGION

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ACRONYMS

AR: Assessment Report

CC: Concerned Country

CGMR: Coordination Group for Mutual Recognition

EAC: East African Community

ETS: EAC Tracking System

MA: Marketing Authorisation

MR: Mutual Recognition

MR-C: Mutual Recognition Coordinator

MRP: Mutual Recognition Procedure

PL: Package Leaflet

RC: Reference Country

SPC: Summary of Product Characteristics

TWG: Technical Working Group

VMP: Veterinary Medicinal Products

Introduction

Following the adoption of the Mutual Recognition Procedure (MRP) by the East African Community (EAC) and subsequent constitution of the EAC-Technical Working Group and the Coordination Group for Mutual Recognition (CGMR), a new Mutual Recognition Procedure has been created. If an applicant wishes to have a Marketing Authorization (MA) granted in more than one Partner State, then the Applicant will have to use a Mutual Recognition Procedure (MRP). Two types of MRP are possible. One is where an Applicant already holds a Marketing authorization in one or more Partner States and wishes to have this recognized in other Partner States. The second type is where an Applicant applies for Marketing Authorizations for a new product in several Partner States simultaneously.

Aim and Scope

This Best Practice Guide has been prepared for use in EAC Veterinary Medicines Mutual Recognition Procedures by Applicants and by the Reference Country and Concerned Countries to facilitate the smooth running of the entire procedure.

1. Description of the Mutual Recognition Procedure

Once an Applicant decides that they wish to register a veterinary medicinal product through the Mutual Recognition Procedure they should prepare a registration dossier for the product in accordance with the relevant EAC guidelines available at https://www.eac.int/documents/category/livestock

The Applicant selects a Reference Country to carry out the assessment of the product's safety, quality, and efficacy. If the Veterinary Medicinal Product in question has already been registered in one or more EAC Partner States, the Reference Country must be chosen from one of the Partner States that has already issued a Marketing Authorisation to the Applicant for that product. If the product does not already have a Marketing Authorisation in any EAC Partner States, the Applicant may choose any Partner State as the Reference Country.

When the Applicant has decided which country, they want to use as the Reference Country to obtain Marketing Authorisation for a veterinary medicinal product simultaneously in 2 or more EAC Partner States they must contact the National Regulatory Authority of that Partner State. A Pre-Submission meeting may be requested by the Applicant by completing the Pre-Submission Meeting Request Form and submitting it to the Reference Country. The Reference Country will advise the Applicant if their application is eligible for MRP and will

inform the MR-Coordinator that the request has been made and approved for a MRP.

1.1 General requirements

All official communications between the Reference Country and the Concerned Countries will be by e-mail. The MR Coordinator should be included in communications concerning MRPs. With respect to communications from the applicant, submission of the applicant's responses or other clarification by e-mail does not mean that hard copies are not needed. It is the duty of the applicant to check if and how all participating countries receive their documentation.

The Reference Country will be represented by their national member of the Coordination Group for Mutual Recognition. This person may not necessarily be the assessor assigned to the application.

The role of the CGMR representatives is described in the EAC document Terms of Reference for CGMR.

1.2 Pre-procedural phase:

1.2.1 Discussion with the RC

Having selected the Reference Country (RC) and requested a Pre-Submission meeting with them, the Applicant may submit an MRP Application Form together with the dossier to the RC for screening. At the pre-submission meeting, which may be either a physical or virtual meeting, the RC will provide advice to the Applicant on the eligibility of the product to be authorized through a Mutual Recognition Procedure. The RC shall use the pre-submission checklist (EAC Document Code PSS/1/1/21/96) to ensure that the applicant meets the basic requirements for MRP. If, during the discussion, it transpires that the Applicant/manufacturer does not have a valid GMP Certificate, a GMP inspection will be organized. The date of the GMP inspection will be notified to the Applicant subsequently.

Once the RC confirms that the Applicant's product is eligible for registration through a MRP, the RC informs the MR-C who notifies the relevant members of the Coordination Group for Mutual Recognition that an application for MRP has been requested and indicates the CC(s) in which Marketing Authorisation(s) will be sought. Only the CGMR members of the Countries where MAs are being sought (CCs) will be involved in the process. If the MRP is for a product that had previously been granted a Marketing Authorisation by the RC, the RC will discuss with the applicant whether the dossier needs updating by way of amendment/s prior to initiating the clock start of the MRP. In this case, the RC

should provide regulatory and scientific advice or recommendations to the applicant in order to facilitate the procedure. Once the RC is satisfied that the dossier meets the current requirements the MRP the RC informs the MR-C that the MRP clock may start. The MR-C informs the Applicant that they may submit their application form and dossier.

1.2.2 **The Application dossier** application to RC and CCs should be made in accordance with EAC Guidelines with the appropriate number of copies and in the required language (the official language in all EAC Partner States is English).

2.0 The Timetable for MRP

Both types of MR procedures then begin as follows:

2.1 Day -7 Submission to Reference Country and Concerned Countries

One week before <CLOCK START> the Applicant sends an identical, possibly updated, dossier and the Application Form to the RC and each National Authority of the CCs simultaneously. The applicant is required to give an assurance, usually in the cover letter accompanying the application, that the dossier is identical in all concerned Partner States.

The applicant should notify all Partner States (RC+CCs) of the dates of dispatch of the dossier. It is the duty of all CCs to react immediately if they have not received the application.

The RC is to submit within 7 Calendar days the screening report of the application dossier to the MR-C. The MR-C will note the dates of receipt of the screening report from RC.

The MR-C prepares a timetable for the MRP. The timetable gives the calendar dates for days 0, 90,120,130. The MR-C will further notify CGMR member(s) in the CC(s) of the proposed application and the timetable. If the procedure is extended beyond day 120, the MR-C will issue the calendar dates of the other critical procedure days.

During the same period, the MR-C creates the procedure in the EAC Tracking System (ETS) by allocating an Application Number to the MRP application according to the numbering system prescribed by the EAC. CCs will use the EAC Application Number allocated to the MRP application by the MR-C. Thus, the CGMR members of the RC and CCs are now in possession of the name of the Applicant, the name of the Product and the MRP application number allocated by the MR-C.

2.2 Step 1: Assessment Report Preparation Phase

Day 0

At this stage, the MR-C will send an e-mail to the RC to initiate the assessment then set the Clock to zero and notify the Applicant and the CCs that the assessment period has commenced (Clock has started.)

The RC starts preparing the Assessment Report (AR)

Before Day 90

The Reference Country prepares or updates the Assessment Report within 90 days. The Assessment Report should be written according to the relevant EAC Guideline and format.

During this time, the RC raises his/her questions for the Applicant to answer, including any request for commitments for the Applicant to carry out additional work, such that the Assessment Report that the RC sends to the CCs will preferably be a report that satisfies the RC that a Marketing Authorisation can be granted. If changes to the dossier are necessary because of responding to the RC's questions, the relevant replacement pages should be prepared by the Applicant and sent to the RC and CCs, preferably by Day 80.

2.3 Step 2: Day 90, RC sends Assessment Report to CCs for review

Day 90

The RC sends the Assessment Report to all CCs for review and notifies the MR-Coordinator that the AR is available and has been submitted to all Concerned Countries.

The CCs have 30 Calendar days within which to comment on the Assessment Report and send their comments to the RC copied the MR-C. The CGMR/TWG members may either review the AR themselves, if deemed suitable by their NRAs, or they may forward the AR to another member of the NRA for review as appropriate.

2.4 Step 3: Assessment Report Review Phase

Day 120

CC comments (by day 120)

Between day 90 and 120, the CGMR member(s) in CCs advise their respective Regulatory Authorities of either their or their nominee's opinions of the Assessment Report and communicate any queries on the Assessment Report to the Reference Country copied the MR Coordinator.

If the Concerned Countries raise no objections by Day 120, the procedure moves to **Step 5**.

At this stage, the CLOCK STOPS, the MR-C then informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorizations within 90 Calendar days = 240 days.

2.5 Step 4: If the CCs raise questions on the Assessment Report

If the CCs raise questions on the Assessment Report, they must send them to the RC, copied to the MR-C by Day 120. The CCs should present all questions and should include clear explanations of the grounds for the concern. Any concerns regarding a potential serious risk to human or animal health or the environment, should be communicated to the applicant at this stage.

Such concerns would include major issues regarding the Assessment Report on the quality, safety or efficacy of the product or SPC, Package leaflet (PL) and/or labelling.

Other points for clarification together with queries on the SPC, PL, and labelling will also be included in this list of questions. All questions should be carefully screened within the national agencies before they are forwarded to the MR-C. The MR-C records the dates on which questions from each CC were received and forwards them to the RC.

The RC collates the questions and sends them to the Applicant. Any duplicate queries are rephrased into a single question. Between day 120 and day 130, the CC and RC have 10 days to agree on the consolidated list of questions raised by their agencies before they are sent to the applicant. This brings the clock to day 130

Between Day 130 and Day 160 the Applicant sends their responses to the consolidated list of questions to the RC. The RC evaluates the responses to the consolidated list of questions provided by the applicant. The RC then sends the evaluation report to the CC, copying the MR-C. If RC evaluation report is positive and the CCs agree with it by day 190, then the procedure moves to **Step 5**.

If the RC and CCs are still not able to agree to responses from the applicant by day 190, they have additional 20 calendar days to resolve the concerns. If they agree, the procedure moves to **Step 5.**

If the concerns remain, the RC requests the applicant to provide additional clarification to the questions by day 240. Once the applicant provides satisfactory responses, the procedure moves to **step 5.**

2.6 Step 5: Day 120/190/210/240; CLOCK STOPS

CLOCK STOPS

If the CLOCK STOPS at day 120, the MR-C then informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorizations within 90 Calendar days = 210 days.

If the CLOCK STOPS at day 190, the MR-C then informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorizations within 90 Calendar days = 280 days

If the CLOCK STOPS at day 210, the MR-C then informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorizations within 90 Calendar days = 300 days.

If the CLOCK STOPS at day 240, the MR-C then informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorizations within 90 Calendar days = 330 days

3. Commitments

In principle, commitments should not be requested of the Applicant by competent authorities during the assessment of the application. Any post procedural commitments, which will be binding on all involved Partners States, should be exceptional and must be requested by the RC on behalf of the CCs by Day 130. The CCs who request such a commitment should provide full justification to the RC.

The Applicant must provide their Commitments in writing, in a company headed letter, by Day 190 clearly stating that they agree to meet the time limits set for the submission of the outstanding data.

On Day 300, or whenever the MRP ended successfully, the procedure is closed. The RC will circulate an e-mail to all CCs and the applicant to confirm this.

The following should be included in the e-mail:

- The expected renewal dates.
- The final SPC, PL and specific labelling requirements for each Partner State.
- The finished product specification.
- Any agreed commitments specified by the applicant in the technical document. The RC and MR-C to note deadline for the submission

4. Conclusion of the MRP

The RC should forward the approved SPC to the EAC database.

5.0 Post-procedural activities

For all variations or notification to a registered product, the applicants should refer to relevant variation guidelines (Guideline 9 and 15) and for Repeat use MRP application refer to Guideline 10 on the EAC website link.
https://www.eac.int/documents/category/livestock

5.1. Submission of an updated version of technical dossier to RC by Applicant

Within 60 Calendar days after the procedure has been completed, it is recommended that the applicant submit an update technical document capturing all issues that had been raised during the evaluation process by the RC. This is a requirement to facilitate repeat use procedures in future.

5.2 Submission of post-commitments to RC and CC

Documentation from the applicant relating to completion of post-approval commitments must be sent to the RC and all CCs simultaneously when available.

If time limits are exceeded or data are insufficient, the matter will be brought back to the TWG for discussion.

5.3 Duration of validity of the MA

Marketing authorizations granted through MRP are valid for 5 years. The renewal application date will be processed by the individual Partner States according to their regulatory framework.

6.0. Rules for progressing MRPs

6.1 Absence of CGMR representative

If a member of the CGMR/TWG knows that they will not be available to communicate their Partner State's response to the MR Coordinator by the deadline set for any steps in a MRP they may delegate that responsibility to another member of their regulatory authority, having notified the MR Coordinator of the name of that deputy.

6.2 Failure by CGMR to communicate

Failure by the CGMR/TWG representative of any Partner State to respond to the MR Coordinator by the deadline set for any stage during a MRP will be taken as an agreement that the CC has no objections.

6.3 Respect for Clock days

Once set, it is mandatory that the clock day dates are respected by the Applicant, the RC and the CCs. There is no possibility to extend them beyond the dates originally set by the MR-C.

6.4 Grounds for Refusal to take part in MRP by a Concerned Country

If a Concerned Country has a national eradication programme that would be adversely affected by the introduction of a veterinary vaccine subject to a MRP, that CC may refuse to be part of the MRP.

If a prospective Concerned Country can show that the disease, against which the vaccine protects, is not present in their country they may refuse to take part in the MRP.

If the molecule or vaccine strain have presented safety and efficacy concerns in that country.

6.5 Grounds for Suspension or Revocation of a Marketing Authorisation issued through a MRP.

If the authorized veterinary medicinal product continually fails to satisfactorily meet the finished product batch testing specification when samples from the market are tested, the Partner State may suspend the Marketing Authorisation and may alert the other Partner States in which the VMP is registered through the MR-C.

If the authorized veterinary Medicinal product has been found to have safety and efficacy issues in the field contrary to the declared specification, the Partner State may suspend the Marketing Authorisation and alert the other Partner States in which the VMP is registered through the MR-C.

6.6 Grounds for the Applicant to withdraw from MRP

The applicant can withdraw the application from any CC at any stage of the procedure.

References and related Documents

EMA/CMDv/63793/2006 VMDv/BPG/002, BEST PRACTICE GUIDE for Veterinary Decentralized Procedure (DCP), Edition Number:05; 7 November 2013; Co-ordination Group for Mutual Recognition and Decentralized Procedures-Veterinary