BEST PRACTICE GUIDE

FOR

MUTUAL RECOGNITION PROCEDURES

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

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Best Practice Guide for Veterinary

Mutual Recognition Procedures in the EAC

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 Authorisation (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 Authorisation in one or more Partner States and wishes to have this recognised in other Partner States. The second type is where an Applicant applies for Marketing Authorisations 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 in order to facilitate the smooth running of the entire procedure.

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ACRONYMS

AR: Assessment Report

CC: Concerned Country

CGMR: Coordination Group for Mutual Recognition

EAC: East African Community

MA: Marketing Authorization

MR: Mutual Recognition

MRC: Mutual Recognition Coordinator

MRP: Mutual Recognition Procedure

PL: Package Leaflet

RC: Reference Country

SPC: Summary of Product Characteristics

TWG: Technical Working Group

1.0 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:

- Registration Dossier Structure for an Immunological Veterinary Product: EAC/PSS/AGRI-LIV/IVP-REG DS
- Guideline on the Technical Documentation required to be included in a Registration Dossier for an Immunological Veterinary Product: EAC/PSS/AGRI-LIV/IVP-REG

or equivalent harmonised guidelines for veterinary pharmaceuticals.

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 in order 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 how the CC needs to receive the 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. If, during the discussion, it transpires that the Applicant's manufacturer does not have a valid GMP Certificate, a GMP inspection will be organised. 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 also 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 MRC that the MRP clock may start. The MRC informs the Applicant that they may submit their application form and dossier.

1.2.2 The Application dossier

The 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 CCs have up to 7 working days to screen the application dossier and send their screening reports to the MRC for onward submission to the RC. The MRC will note the dates of receipt of the screening report from each CCs participating in the MRP and forward them to the RC.

The MR-C prepares a timetable for the MRP. The timetable gives the calendar dates for days 0, 90, 120. The MRC 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 MRC will issue the calendar dates of the other critical procedure days.

During the same period, the MRC creates the procedure in the EAC Tracking System (ETS) by allocating an Application Number to the MRP application according the numbering system prescribed by the EAC. CCs will use the EAC Application Number allocated to the MRP application by the MRC. 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

2.3 Step 1

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 writes 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 as a consequence 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.

2.4 Step 2

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 working days within which to comment on the Assessment Report and send their comments to the RC through the MRC. The CGMR members may either review the AR themselves, if deemed suitable for this by their NRAs, or they may forward the AR to another member of the NRA for review as appropriate.

2.5 Step 3

Day 120

Assessment Report Review Phase

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 also communicate any queries on the Assessment Report to the Reference Country through the MR Coordinator.

If the Concerned Countries raise no objections other than changes to the SPC and packaging text by Day 120, the MR procedure moves to Step 5; i.e. the applicant is given 20 working days within which to send their final (or revised) labels and SPC to the RC and CCs for approval, bringing the procedure to Day 140.

At this stage, if the SPC and labelling has been approved by the RC and all CCs, the CLOCK STOPS, the MRC then informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorisations within 30 working days =170 days.

However, if no changes to the SPC and packaging were requested, the CLOCK STOPS at Day 120 of the MRP procedure, the MRC informs the Applicant of a Positive Opinion and asks the RC and CCs to issue National Marketing Authorisations within 30 working days =150 days.

2.6 Step 4:

If the CCs raise questions on the Assessment Report they must send them to the MRC 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, which, if unresolved, would lead to an appeal should be communicated at this stage.

Such concerns would include major issues regarding the Assessment Report on the quality, safety or efficacy of the product or Summary of Product Characteristics (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 MRC. The MRC 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.

The Reference Country and the Applicant try to resolve them between Days 120-180 in which case the procedure will end at Day 230.

Between Day 120 and Day 180 the Applicant sends their responses to the consolidated list of questions to the RC. The RC evaluates the responses given by the applicant to the issues raised by the CCs and communicates this evaluation in writing to the MRC who will forward it to all CCs and to the applicant by Day 180 at the latest. If the CCs agree with the RC's evaluation, the procedure moves to **Step 5**. If they do not agree, an APPEAL may be triggered*

2.7 Step 5

Day 180 (or earlier if no questions raised on SPC or labeling by CCs)

All required changes (final or revised) made by the Applicant to the SPC, Package leaflet, and labelling must be done using the 'track changes' tool and sent to the RC, CCs and MRC by Day 200.

2.8 Step 6

Day 200; CLOCK STOPS

The MRC informs the CGMR, the RC, the CCs and the Applicant that Marketing Authorisations will be granted within 30 working days thereby ending the procedure on Day 230.

National MAs are then issued to the Applicant (by Day 230)

3.0 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 120. 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 180 clearly stating that they agree to meet the time limits set for the submission of the outstanding data.

4.0 APPEAL PROCESS.

Day 180

4.1 If no agreement has been reached by Day 180, an APPEAL may be triggered. However if the RC and CCs feel they could reach a positive opinion if given more time, a further 20 days may be taken to reach a decision (Day 200). If that decision is positive, the Applicants send (revised) SPC and packaging to the RC and CCs for approval (20 days) and the clock stops on Day 220. In such cases, Marketing Authorisations are issued by Day 250.

4.2 If, by Day 200, no agreement has been reached, the Applicant has the opportunity to generate more data and ask for hearing by the TWG and appropriate technical experts.

By Day 200 all CCs must send any remaining issues to the RC, the other CCs and the applicant (via the MR-C), in order for the RC to prepare the TWG and/or appropriate technical experts for the discussion necessary for the procedure to be accepted by all CCs.

The APPEAL procedure is held between Days 200 – 240. The **TWG takes the final decision by Day 240.**

If the decision is positive, the following steps are taken;

4.3 Applicant sends their final (or revised) labels and SPC to the RC and CCs for approval by Day 260. After this, the clock stops and the National MAs are issued by Day 290.

On Day 290, 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 common renewal date
- the final SPC, PL and labelling
- the finished product specification
- any agreed commitments

5.0 CONCLUSION OF THE MRP

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

6.0 POST-PROCEDURAL ACTIVITIES

6.1 Within 60 working days after the procedure has been completed, it is recommended that the applicant files hard copies of all documentation sent electronically in a binder and sends it to all CCs and RC as an annex to the dossier, to ensure that the information with regard to the application is the same in all Partner States and to facilitate any repeat use procedures.

6.2 Documentation from the applicant relating to completion of 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.

6.3 Duration of validity of the MA

Marketing Authorisations granted through MRP are valid for 5 years. The harmonised date is allocated by the MRC. The renewal application is progressed by the RC and the renewed MA issued simultaneously in the RC and CCs.

7.0 RULES FOR PROGRESSING MRPS

7.1 Absence of CGMR representative

If a member of the CGMR 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.

7.2 Failure by CGMR to communicate

Failure by the CGMR 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.

7.3 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 MRC.

7.4 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.

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

If the authorized immunological veterinary 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 IVP is registered.

If the authorised immunological veterinary product has been found to cause adverse reactions in the field or has failed to protect against the disease according to the SPC claim the Partner State may suspend the Marketing Authorisation and may alert the other Partner States in which the IVP is registered.

7.6 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 Decentraised Procedure (DCP), Edition Number:05; 7 November 2013; Co-ordination Group for Mutual Recognition and Decentralised Procedures-Veterinary