



REPEAT-USE MUTUAL RECOGNITION PROCEDURES

IN THE EAST AFRICAN REGION

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Repeat-use 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 was created. When an applicant wishes to have a Marketing Authorisation (MA) granted in more than one Partner State, then the Applicant uses 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. However once a veterinary medicinal product has been registered through a MRP, it will be possible to extend that MRP to include other markets in the EAC through a Repeat-Use Mutual Recognition Procedure (RUP)

An RUP can be used in the following situations:

- either by application to new Concerned Countries (CCs) not involved in the first MRP
- or by reapplication to CCs withdrawn from the first procedure.

In cases where the applicant withdraws its application for marketing authorisation during a MRP this does not prevent an Applicant initiating a Repeat Use Procedure for that/those PSs at a later stage.

This document describes the procedure to be adopted for “Repeat Use MRP”.

Aim and Scope

This Guideline 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 and expand the availability of good quality, safe and efficacious veterinary medicines into more Partner States of the EAC.

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Acronyms

AR: Assessment Report

CC: Concerned Country

CGMR: Coordination Group for Mutual Recognition

EAC: East African Community

GMP: Good Manufacturing Practice

MA: Marketing Authorisation

MR: Mutual Recognition

MR-C: Mutual Recognition Coordinator

MRP: Mutual Recognition Procedure

PL: Package Leaflet

RC: Reference Country

RUP: Repeat-Use Mutual Recognition Procedure

SPC: Summary of Product Characteristics

TWG: Technical Working Group

1. Description of the initial Mutual Recognition Procedure

Once an Applicant or Marketing Authorisation Holder (MAH) decides that they wish to register a veterinary medicinal product through the Mutual Recognition Procedure they prepare a registration dossier for the product in accordance with the relevant EAC guidelines, e.g.:

- Registration Dossier Structure for an Immunological Veterinary Product: EAC/PSS/AGRI-LIV/IVP-REG DS/GL1
- Guideline on the Technical Documentation required to be included in a Registration Dossier for an Immunological Veterinary Product: EAC/PSS/AGRI-LIV/IVP-REG/GL2

or equivalent harmonised guidelines for veterinary pharmaceuticals.

The initial Mutual Recognition Procedure takes place as described in the document “Best Practice Guide for Mutual Recognition Procedures for the registration of immunological veterinary product(s) in the East African region”:

EAC/PSS/AGRI-LIV/IVP-REG/BPG-MRP PSM/GL5

2. Description of a Repeat-Use Mutual Recognition Procedure

After completing a MRP, the Applicant may wish to extend the number of Marketing Authorisations issued through the first MRP to include other existing Partner State’s markets or countries that have recently acceded to the EAC.

2.1 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 and RU-MRPs.

The Reference Country will be represented by their national member of the Coordination Group for Mutual Recognition (CGMR). 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.

2.2 Pre-procedural phase:

2.2.1 Discussion with the RC

A Pre-Submission meeting for an RUP may be requested by the Applicant. The Pre-Submission Meeting Request Form, available in GL6, "Pre-submission meeting advice", should be completed and submitted to the same Reference Country that was used for the initial MRP, indicating the new CC(s) where Marketing Authorisation(s) will be sought. The Reference Country will advise the Applicant if their application is eligible for a Repeat Use MRP and will inform the MR-Coordinator (MR-C) that the request has been made for an RUP. The MR-C will inform the relevant new CCs that an RUP involving them will take place.

If, during the discussion, it transpires that the Applicant's manufacturer does not have a valid GMP Certificate, a GMP inspection will be arranged. The applicant should submit an application for a GMP inspection and pay the fees. The date of the GMP inspection will subsequently be notified to the Applicant.

The RC will discuss with the applicant whether the dossier needs updating with any amendments or Variations granted prior to initiating the clock start of the RUP.

The dossier updates to be included are:

- Responses to previous procedures; variations/renewals.
- Commitments fulfilled without a variation procedure.
- Additional data to comply with any recent changes to regulatory requirements.

These additional documents may either be presented sequentially in an Annex to the dossier, or inserted as appropriate into the original dossier, thus bringing it up to date.

If necessary, the MR-C can advise the Applicant which documents are required because they were placed in the EAC archive by the MR-C. Any on-going procedures such as Variations and Renewals must have been completed prior to starting a RU-MRP.

Once the RC is satisfied that the dossier meets the current requirements and that it has been satisfactorily updated, if necessary, to include data supporting any Variations granted since the initial MRP, the RC informs the MR-C that the RUP application is valid. The MR-C informs the CGMR members of the new CCs that the RUP is about to begin.

3.0 The Timetable for RUP

3.1 Day -30 Updating the Assessment Report

Once the RC has agreed to start an RUP they have between 30 and 60 days to update the Assessment Report to reflect any changes made to the updated dossier, including references to the responses to questions in the original MRP and any subsequent Variations of renewals that

have taken place. If the initial MRP was completed within the previous 12 months it is expected that the updated Assessment Report will be completed in less than 30 days.

The MR-C will further notify CGMR member(s) in the new CC(s) of the proposed application and the timetable.

3.2 Day -7 Submission of dossier 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 new 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 the MR-C 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 MR-C for onward submission to the RC. The MR-C will note the dates of receipt of the screening report from each CCs participating in the MRP and forward them to the RC.

Day -7: The RC sends the revised Assessment Report to the new CCs.

3.3 The RUP starts

Step 1, Day 0: The <CLOCK STARTS>

The CCs review the updated Assessment Report and may review the updated dossier. If they have any questions they send these to the MR-C, via their CGMR member, within 30 days. It should be noted that any concerns raised and dealt with in a previous MRP should not be raised again in any subsequent repeat use procedure except for justified reasons. If no questions are raised by the new CCs, the clock stops and the procedure ends with the granting of Marketing Authorisations by the new CCs.

Step 2, Day 30: Response to questions

If questions were raised, the Applicant has 30 days to respond to them.

Step 3, Day 60: Acceptance of responses

By day 60 the CCs inform the MR-C and RC that they accept the responses.

The <CLOCK STOPS>

The new CCs must recognise the MA of the product with the same, identical SPC, labelling and package leaflet that were approved in the earlier MRP.

Step 4, Day 90: Marketing Authorisations issued

By day 90 of the procedure the new CCs must have issued Marketing Authorisations for the product.

4. Rules for RUPs

4.1 SPC and Labelling

If a new CC is not able to recognise the product with its current SPC, labelling and package leaflet because the CC considers that the product will cause a potential serious risk to public health, the procedure will be referred to the TWG for discussion and resolution.

4.2 Variations

Any additional changes to the dossier requiring a Mutual Recognition variation should be completed before the start of the Repeat Use procedure. The first MRP needs to be completed before submitting such a variation.

4.3 Questions raised during previous MRP

Any concerns raised and dealt with in a previous MRP should not be raised again in any subsequent RUP except for justified reasons.

4.4 In case of withdrawal of the application during an earlier procedure

If an application was withdrawn from a CC during the first MRP or an earlier Repeat Use Procedure, the Applicant may have included that CC again in the new RUP. That CC should note that the Applicant may have added new data to the dossier in preparation for this Repeat Use Procedure.

4.5 Number of Repeat Use MRPs

There is no limit to the number of Repeat Use Procedure(s) until all Partner States are involved in the MRP.

4.6 Harmonising old Marketing Authorisations

If an Applicant holds one or more non-MRP MAs for a veterinary medicinal product which were granted in one or more other Partner States (e.g. B and/or C), apart from the RC and before MRP was initiated, the Applicant may wish to harmonise those MAs with the MAs granted through an MRP. This will reduce the administrative burden for both the Applicant and the relevant NRA(s). To achieve this, the Applicant should discuss the proposal with the NRA(s) that granted the non-MRP MA(s) and with the Reference Country. If the SPC(s) authorised by NRA(s) B and/or C is/are identical to that authorised through an MRP, the MR-C and RC should be notified. The MR-C will issue the MRP authorisation number to the product(s) in B and/or C and record that those MAs have become part of the MRP and will be administered as MRP products in future.

If the SPC of the product authorised in B and/or C, before MRPs were initiated, differs from the harmonised SPC authorised through an MRP, the Applicant may ask for a RUP to bring those Marketing Authorisations into alignment with the ones issued through MRP. This can be achieved simply by sending the Assessment Report and the SPC authorised through MRP to the NRA(s) that approved the product through National process(es). If it/they agree to upgrade the Applicant's SPC(s) to harmonise it/them with the SPC authorised through MRP, the MR-C will issue the MRP authorisation number to the products in B and/or C and record that those MAs have become part of the MRP and will be administered as MRP products in future.