GL14

GUIDELINE FOR PROCESSING VARIATIONS TO MARKETING AUTHORISATIONS FOR VETERINARY MEDICINAL PRODUCTS APPROVED THROUGH EAC MUTUAL RECOGNITION PROCEDURES

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INTRODUCTION

The Mutual Recognition Procedure (MRP) for registering veterinary medicinal products through a harmonised process in East African Community (EAC) Partner States (PSs) was developed in 2015 and introduced in 2016 in accordance with the direction from the EAC Council of Ministers on 26 September 2016 for National Regulatory Authorities (NRAs) of the EAC Partner States to implement MRP (**EAC/CM34/Decision 35**).

Following the issue of a Marketing Authorisation (MA), the Applicant may wish to make changes or improvements to the way that a veterinary medicine is manufactured or sold. Such changes are known as Variations. Any Variations to a Marketing Authorisaton must be notified to the relevant National Regulatory Authority (NRA) and in some cases they must be reviewed and approved before the change can be introduced.

Guideline 9; Guideline for Variations to Marketing Authorisations for registered Immunological Veterinary Products approved through a Mutual Recognition Procedure (EAC: PSS/1/1/21/87), was issued in February 2019 to provide guidance to applicants on the conditions to be fulfilled and the type of documentation to be submitted before a Variation can be approved by an NRA. GL15; Guideline for Variations to Marketing Authorisations for registered Pharmaceutical Veterinary Products approved through a Mutual Recognition Procedure (EAC: PSS/1/1/21/104) will be available at a future date.

Four categories of changes that require an application for variations are provided in that guideline. These include notifications, minor changes, major changes and changes that mean an application for a new Veterinary Medicinal Product (VMP) must be applied for. Changes are classified as major only in those instances where the level of risk is considered to be high and it is deemed necessary to provide NRAs with adequate time for an assessment of the supporting documentation.

The present guideline, GL14; Guideline for Processing Variations to Marketing Authorisations for Veterinary Medicinal Products approved through EAC, describes the process by which NRAs receive, review and approve Variations to products that were registered through MRPs. As with the progression of applications for MRPs, the progress of MRP Variation applications runs to a fixed timetable ensuring that the harmonisation of the product in the Reference Country (RC) and the Concerned Countries (CCs) remains intact.

CATEGORIES OF CHANGES REQUIRING VARIATIONS

1. NOTIFICATIONS (N)
2. MINOR (Min)
3. MAJOR (Maj)

MRP Variation Procedure:

When Marketing Authorisation holders of veterinary medicines registered through EAC MRPs want to make a change to the information that was provided to obtain the authorisation they should consult Guideline 9 and Guideline 15 to identify the implications of that change and prepare the required supporting documentation.

Since some very minor changes are classified as "Notifications" which may be introduced without waiting for an approval, these will be processed by a simplified version of the steps described below for Minor and Major Variations.

PROCESSING STEPS FOR MINOR AND MAJOR VARIATIONS:

1. The MA holder contacts the Reference Country (RC) for the MRP product and informs them that they want to introduce the change.
2. The Applicant completes the appropriate form:
    a. F3: Application for a Variation to a registered Immunological Veterinary Product (EAC: PSS/1/1/21/94).
    or
    b. F8: Application for a Variation to a registered Pharmaceutical Veterinary Product (EAC: PSS/1/1/21/101)
3. The Applicant sends the completed form, the fees and the required supporting data as indicated in GL9 and GL 15 to the RC who screens the application for completeness.
4. Once the RC confirms that a positive screening has been carried out they inform the MR-C and the CCs.
5. The Applicant sends the application form, supporting documents and National variation fees to the CCs, informing the MR-C of the submission dates.
6. The CCs notify the MR-C as soon as they have received the application, documentation and fees. The MR-C starts the clock at Day 0.

7. The RC reviews the application and sends their Assessment Report and recommendations to the CCs within the timeline shown in Table 1.
8. If the RC had decided that the documentation provided in support of the Variation application was inadequate they inform the applicant who should aim to provide the requested information within 30 days. In these circumstances that RC revises the Assessment Report with their new recommendations following receipt of the required documentation and sends this report to the CCs, notifying the MR-C.
9. The CCs send their acceptance or rejection of the RC's recommendation within the timeline shown in Table 1.
10. If the Variation is approved, the Applicant is notified within the timeline shown in Table 1.

Table 1. Timeline for different categories of MRP Variations

Category of Variation	Notification	Minor	Major
Start Date: Day 0			
RC reviews the application, sends Assessment Report to CCs	Not applicable	20 days	90 days
If RC requests more documentation, Applicant responds before process continues			
CCs respond to RC	Not applicable	10 days	10 days
If Variation is approved, RC notifies Applicant	Not applicable	10 days	10 days

Notifications should be sent, with the completed appropriate application form, to the RC and CCs simultaneously confirming that identical information has been provided to each relevant NRA.