Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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POSITION PAPER

ON

CHANGING THE REFERENCE MEMBER STATE

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1. INTRODUCTION

In **exceptional** circumstances, a Marketing Authorisation Holder (MAH) may request a change of the Reference Member State (RMS), for instance when the Marketing Authorisation (MA) is no longer valid in the RMS. This position paper has been agreed by the CMD(v) in order to facilitate this process for the MAH.

It should be noted that:

(i) A request for the change of RMS based on scientific disagreement between the MAH and the current RMS is not acceptable; and
(ii) A change of RMS cannot take place during a pending procedure.

2. LEGAL BASIS AND RELATED DOCUMENTS

Changing the RMS is not regulated in the present pharmaceutical legislation, however it may be necessary to do so during the life-cycle of a veterinary medicinal product (VMP).

- CMD(v) SOP for the Allocation of the Mutual Recognition and Decentralised Application Number (CMD(v)/SOP/018)
- Guidance document for management of e-mail use during procedures and standardisation of subheadings (CMD(v)/GUI/003).

3. PRACTICAL OUTCOMES

Advice to the Marketing Authorisation Holder

If a MAH considers a request for change of RMS, the MAH should approach the current RMS and the chosen future RMS to discuss the situation before any further steps are taken.

It is the responsibility of the MAH to ensure that both the current RMS and the future RMS accept the change of RMS. According to MS interpretation of the present legislation, a withdrawal of the marketing authorisation in the current RMS without appointing a new RMS will have an indirect impact on the granted MA(s) in all CMS(s), as the RMS has the lead position during PSUR-, variation- and renewal procedures. In cases with only one remaining CMS in the MRP or the DCP, the MS concerned will automatically become the new RMS. It is not possible for that MS to refuse to act as the RMS, even if there has not been any prior agreement.

Notification of the change

The original RMS must record the change of the RMS in the CTS database, closing the original procedure.

The new RMS will then create a new procedure for the product; a new procedure number will be given to the VMP.

The MAH should send an official notification of the change, giving a justification, to the outgoing RMS. The current RMS will notify the change of RMS to all CMS, and the Secretariat, via email (mrna mail box), including a copy of the MAH notification, before the change of the RMS takes effect.

The following information should be given:

Name of the VMP : **Name of the MAH :**	
PRESENT	**PROPOSED**
Procedure number : XX/V/AAA/001 RMS : XX CMS : YY, ZZ, WW	Procedure number : YY/V/BBB/001 RMS : YY CMS :ZZ, WW

The new RMS also has the responsibility to ensure that updated information is available in the VMRI- Product Index.

Transfer of Assessment reports and other relevant material to the new RMS

When the change has been agreed between the MAH and the new RMS, it is the responsibility of the MAH to supply to the new RMS if anything is missing or by any reason not already in possession of the new RMS.
It will be the responsibility of the new RMS to store and to make available any documentation relating to that procedure, if requested, e.g. assessment reports, List of Questions etc.

Upon request from the new RMS, it is also an obligation of the previous RMS to assist in providing the relevant information from previous procedure(s).

It has been agreed that the transfer of assessment reports and other relevant material to the new RMS should be sent within 30 days from the request. The new RMS will only be able to start any new procedure when the requested documentation has been received.