CMDv/BPG/021

BEST PRACTICE GUIDE
for
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(MAH) may request a change of the Reference Member State (RMS), for instance when the Marketing Authorisation (MA) is no longer valid in the RMS.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 best practice guide has been agreed by the CMDv 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.

Due to resource implications, it is recommended only to have one RMS for a medicinal product, as the same variations often are foreseen for different pharmaceutical form(s)/strength(s) of a medicinal product.

2. LEGAL BASIS AND RELATED DOCUMENTS

Changing the RMS is not regulated in the Directive 2001/82/EC as amended on the Community code relating to veterinary medicinal products; however it may be necessary to do so during the life-cycle of a veterinary medicinal product (VMP).

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

3. PRACTICAL OUTCOMES

3.1. 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 new 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 new 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 CMSs, as the RMS has the lead position in post-authorisation procedures (such as PSUR assessment, variation and renewal applications). 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.

3.2. Notification of the change

The MAH should send an official notification of the change, giving a justification, to the current RMS and inform on the preferred new RMS. In addition, the MAH should inform the new RMS of his choice and ask for agreement.
Before the RMS change is initiated, it is highly recommended that all possible withdrawals from CMSs have been finalised. The current RMS will update CTS to this regard before the change is initiated.

The current RMS must record the change of the RMS in the CTS database according to the procedure described in the CTS manual. The new RMS will inform the current RMS of the procedure number foreseen for the product together with the site to be stated in CTS without creating a new procedure in CTS. This is very important because creating new MAA procedures for RMS transfers would falsify procedure statistics and could impact data quality negatively. The current RMS will initiate the change in CTS by opening the product sheet in question and selecting the menu File and RMS change. The details provided by the new RMS will be entered here and saved. The current RMS will inform the new RMS that the change has been initiated in CTS. The new RMS will access CTS and chose the menu Reports – RMS changes to accept and accept the change, which concludes the RMS change. After the change has been completed in CTS the old product sheet will be deleted and be replaced with a new product sheet under the new RMS.

The current RMS will notify the change of RMS to all CMS, and the CMDv Secretariat, via email (mrna mail box), including a copy of the MAH’s notification.

The following information should be given:

<table>
<thead>
<tr>
<th>Current</th>
<th>New</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the VMP:</td>
<td>Name of the VMP:</td>
</tr>
<tr>
<td>Name of the MAH:</td>
<td>Name of the MAH:</td>
</tr>
<tr>
<td>Procedure number : XX/V/AAA/001</td>
<td>Procedure number : YY/V/BBB/001</td>
</tr>
<tr>
<td>RMS : XX</td>
<td>RMS : YY</td>
</tr>
<tr>
<td>CMS : YY, ZZ, WW</td>
<td>CMS : ZZ, WW</td>
</tr>
</tbody>
</table>

Although the procedure number will change due to the RMS transfer the numbering of subsequently submitted notifications/variations/extensions/repeat use procedures/renewals will be continued from the last chronological number.

The current RMS has the responsibility to ensure that all provided documentation is up to date and that the current SPC and PuAR are stored in CTS. The new RMS also has the responsibility to ensure that updated information is available in CTS respectively in the VMRI-Product Index.

3.3. 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 current RMS 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 current RMS to assist in providing the relevant information from previous procedure(s).
It has been agreed that the transfer of assessment reports, public 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.
ANNEX 1

LIST OF RELATED DOCUMENTS

CMDv/SOP/018  CMDv SOP for the Allocation of the Mutual Recognition and Decentralised Application Number

CMDv/GUI/003  Guidance document for management of e-mail use during procedures and standardisation of subheadings
ANNEX 2

LIST OF USED ABBREVIATIONS / TERMS

CMS  Concerned Member State
CMDv  Co-ordination Group for Mutual Recognition and Decentralised Procedures - veterinary
CTS  Communication Tracking System
DCP  Decentralised Procedure
MA  Marketing Authorisation
MAH  Marketing Authorisation Holder
MRP  Mutual Recognition Procedure
MS  Member State
PSUR  Periodic Safety Update Report
PuAR  Public Assessment Report
RMS  Reference Member State
SPC  Summary of Product Characteristics
VMP  veterinary Medicinal Product
VMRI-Product Index  European Veterinary Product Index