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

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GUIDANCE

for

Exchange of documentation relating to a RVMP between MS

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EDITION	DATE	PAGE/S	REASON FOR CHANGE
01	4 Apr 2006	All	The title of the document has been modified so that it reflects the contents of the document better.
02	11 Dec 2008	All	Update following publication of GUI-014
03	15 Sept 2014	All	Scope opened to National procedure Timing of providing MIRP Revision MIRP template

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1. Introduction

The new legislation does not require that the Reference Veterinary Medicinal Product (RVMP) be currently authorised in any Member State, when a generic application is submitted.

Directive 2004/28 Article 13 states:

"1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 5 for not less than eight years in a Member State or the Community.

The first subparagraph shall also apply when the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit, within a period of one month, confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation."

2. Aim and Scope

This Guidance document aims to give guidance on what should be included in this "Other relevant information" needed by the Member State/s (MS) where the application has been submitted, and how the requests should be handled.

This document is relevant to all MS taking part in the mutual recognition or decentralised procedure, and should be used to exchange information related to RVMP in any national procedure.

3. Reference documents and/or related documents

Directive 2001/82/EC as amended by Directive 2004/28/EC
Best Practice Guide for the Veterinary Mutual Recognition Procedure
Best Practice Guide for the Reference Member State
Best Practice Guide for the Veterinary Decentralised Procedure
CMD(v)/GUI/014 Guidance for the processing of generic applications through MRP/DCP

4. Documentation to be submitted

4.1 Documentation

In order to ensure that the documentation concerning the RVMP passed from one MS to another is sufficient for assessing a generic application, the CMD(v) has agreed the documentation to be passed by the competent authority of the MS where the RVMP is (or

has been) authorised, to the competent authority of the RMS and/or CMS. For more detail on the principle of data exchange between MS, see CMD(v)/GUI/014.

When the RVMP is currently authorised in the EU, the minimum information on the reference product (MIRP) should be readily available to the MS. In cases where the Marketing Authorisation (MA) for the RVMP has expired or has been withdrawn, the most recent documentation is required.

The information to be provided on the RVMP in that MS is:

- Confirmation of current or past authorisation of the RVMP:
    - Date of first authorisation
    - Legal basis of the initial application for a marketing authorisation
    - Date of expiry, withdrawal of the authorisation by the Marketing Authorisation Holder (MAH), or withdrawal by the MS
    - If the authorisation has expired or been withdrawn in the MS (and/or, if the information is available, in any other MS), date of termination and where this was not for commercial reasons, an explanation of why this was necessary

- Full qualitative and quantitative composition of the RVMP
- Finished product specifications (release and shelf-life)
- The latest Summary of Product Characteristics (SPC) in English (if available). Where necessary, translation should preferably be approved by the competent authority passing the information
- Post-marketing safety information, either
    - The latest Periodic Safety Update Report (PSUR) or
    - Confirmation that the MA of the RVMP has not been withdrawn or lapsed due to safety reasons in the MS and/or, if the information is available, in any other MS
- Assessment report in English (if available). In the absence of an assessment report, every effort should be made to provide the following information:
    - A written explanation detailing how the user warnings were agreed
    - A written explanation of how the withdrawal period was set (if applicable)

4.2. Procedure

The RMS/CMS should send the request electronically in the format as shown in Annex 1. The responding MS should return the completed format and attachments electronically, to the requesting MS and the RMS (if different).

In the framework of MRP/DCP, the RMS will make the information available to all CMS using the MRNA mailbox. During a national procedure, the NCAs will communicate on an individual basis.

4.3. Timing

It is acknowledged that the requested documentation might not always be available or retrievable in a short time frame. However the MS providing the information should make every effort to provide the information in due course.

During a national procedure and in the MRP, the MIRP should be made available within 30 days following the Day 0 (start date of the procedure).
During the DCP, the documentation and relevant information should circulate at latest by Day 70 (coinciding with the RMS's preliminary assessment report).

ANNEX 1 Standard format for the MIRP

Standard form for MS to provide information on the Reference Veterinary Medicinal Product if the product is not authorised in the Member State where the application is submitted.

RVMP documentation will be submitted together with this form.

RVMP name and reference number in MS providing the documentation	
MAH of RVMP	
MS providing MIRP in the framework of procedure	<two country lettercode > <procedurenumber>
Date of initial authorisation Legal basis of initial application for MA Status of renewal(s)	<dd/mm/yyyy> Last renewal date <dd/mm/yyyy> <indefinite>
Is the authorisation current? If not, expiry date	Yes/No <dd/mm/yyyy>
Reason for withdrawal of authorisation, *if applicable*	

Check list for the responding Member State

The following documentation relating to the RVMP is provided:	**YES**	**NO**
Qualitative and quantitative composition	☐	☐
FPS (release and shelf life)	☐	☐
SPC in English (if available)	☐	☐
Post marketing safety information (e.g. latest PSUR)	☐	☐
Assessment report in English (if available)	☐	☐

In the absence of an assessment report, the following should be provided:

A written explanation detailing how the user warnings were agreed	☐	☐
A written explanation of how the withdrawal period was set (if applicable)	☐	☐