

CMDv/GUI/006
GUIDANCE
for
Exchange of documentation relating to a RVMP between MS

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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

GUIDANCE For exchange of documentation relating to a RVMP between MS	CMDv/GUI/006
	Ed.: 02
	Page 2 of 6

Index

1. Introduction
 2. Aim and Scope
 3. Reference documents and/or related documents
 4. Documentation to be submitted
 - 4.1 Documentation
 - 4.2 Procedure
- Annex 1: Standard format for RVMP information

GUIDANCE For exchange of documentation relating to a RVMP between MS	CMDv/GUI/006
	Ed.: 02
	Page 3 of 6

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.

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.

GUIDANCE For exchange of documentation relating to a RVMP between MS	CMDv/GUI/006
	Ed.: 02
	Page 4 of 6

When the RVMP is currently authorised in the EU, current documentation 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 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. 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 (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)

While it is acknowledged that these might not always be available or retrievable in the defined 30 day time frame, the MS should make every effort to provide the information in due course.

4.2. Procedure

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

If the SPC and related documentation are not available in English the applicant may be responsible for any expenses related to the translation.

The RMS will make the information available to all CMS.

GUIDANCE For exchange of documentation relating to a RVMP between MS	CMDv/GUI/006
	Ed.: 02
	Page 5 of 6

ANNEX 1 **Standard format for RVMP information**

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	
Date of request	
MS providing the documentation	
MS seeking documentation Email Fax number	
Other MS where application is submitted (CMS)	
Date of initial authorisation and any renewals	
Is Authorisation current? If not, expiry date	Yes/No
Reason for withdrawal of authorisation, if applicable	

GUIDANCE For exchange of documentation relating to a RVMP between MS	CMDv/GUI/006
	Ed.: 02
	Page 6 of 6

Check list for the responding Member State

The following documentation relating to the RVMP is provided:	YES	NO
Composition	<input type="checkbox"/>	<input type="checkbox"/>
FPS (release and shelf life)	<input type="checkbox"/>	<input type="checkbox"/>
SPC in English	<input type="checkbox"/>	<input type="checkbox"/>
Post marketing safety information (e.g. latest PSUR)	<input type="checkbox"/>	<input type="checkbox"/>
Assessment report (if available)	<input type="checkbox"/>	<input type="checkbox"/>

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

A written explanation detailing how the user warnings were agreed	<input type="checkbox"/>	<input type="checkbox"/>
A written explanation of how the withdrawal period was set (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>