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

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Best Practice Guide
For
The Repeat Use Procedure

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CMDv Secretariat:
30 Churchill Place, Canary Wharf, London, E14 5EU, UK
Tel. (44-20) 3660 6000 Fax. (44-20) 3660 5545

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1. Introduction

The Notice to Applicants (Volume 6A – Chapter 2 – section2.2) states that the Mutual Recognition Procedure (MRP) may be used after completion of a first MRP or a Decentralised (DCP) procedure for the recognition of a marketing authorisation by other Member States (MS) for the same veterinary medicinal product. This procedure is known as the 'Repeat Use Procedure', hereafter abbreviated to RUP.

This procedure can be used in Concerned Member States (CMS) which were not included, or where the application was withdrawn, during an earlier procedure

2. Aim and scope

This Best Practice Guide has been prepared in order to define what should be done by the Reference Member State, the CMSs and the Applicant during a RUP.

3. Description of Procedure

3.1 Before submitting the application

3.1.1 Case of withdrawal of the application during an earlier procedure

In the case of withdrawal from CMS during an earlier procedure, the issues concerned may sometimes be resolved by the submission of additional data. The Marketing Authorisation Holder (MAH) may submit new data for addition to its dossier after completion of a previous marketing authorisation procedure by means of a variation in the RMS and existing CMS in preparation for a RUP.

3.1.2 Ongoing and related procedures (e.g. variations, renewals)

These should be completed before the start of the updating of the dossier and the RUP.

However, the RUP can start before all marketing authorisations are issued in the original Member States.

Even if the veterinary medicinal product has been renewed before the RUP was initiated, a further renewal should be conducted in the new CMS. For more information on the renewal procedure, see the Notice to Applicants guideline: "Guideline on the processing of renewals in the mutual recognition and decentralised procedure".

3.1.3. Updating of the dossier

This updating would include any additional information/data to be submitted to meet current marketing authorisation application requirements (for example, ERA, detailed description of the pharmacovigilance system) and the review of the commitments obtained during the original MRP/DCP.

The applicant should discuss the updating of the dossier with the RMS. The RMS will consider if a variation procedure is required to update the dossier prior to the commencement of the RUP Procedure.
A variation is foreseen if new data (new studies or report) are submitted unless there is an agreement from RMS and CMS that there is no variation needed. The RMS may arrange for a confirmatory discussion at the CMDv meeting before the dossier is prepared for the RUP.

The CMDv insists that the dossier is formatted as: the initial dossier submitted as presented in earlier round(s) with additional information/data annexed.
These additional information/data are:

- AR-Resp-LOQs including all appendices;
- Documentation relating to variations and renewals that have taken place after the previous round(s) were completed;
- Commitments that have been fulfilled without a variation procedure;
- New data submitted for which no variation was needed.

These documents should be adequately indexed, dated and referenced to the part of the dossier they complement.

If the application is submitted electronically, the structure should be as defined above.

The Applicant will submit the dossier to the RMS who will update the Assessment Report (AR). The applicant should also provide a statement to the RMS confirming that the original elements of the dossier as submitted for the original procedure remain unchanged.

3.1.4. Updating of the Assessment Report

The RMS will update the AR taking into account the documentation submitted since the original procedure, including the RMS assessment of the applicant's responses to the list of questions from CMS (AR-Resp-LOQ), and any previous RUPs and, if applicable, variations, renewals, commitments and new data.

The updating of the AR will take place within 90 days after receiving the updates to the dossier from the applicant.

Normally the original AR will be revised by adding an addendum to the original AR summarising all variations, renewals and commitments. Reports on all changes and renewals will be included.

3.1.5. Numbering of the Repeat use

The RUP should be entered into the CTS database using the same number as the original procedure but using the extension numbers for the RUP to separate it from the original (see the Best Practice Guide (BPG) for the Allocation of the Mutual Recognition and Decentralised Application Number).

For example, FR/V/105/002 for the original procedure
FR/V/105/002/E/001 for the 1st RUP
FR/V/105/002/E/002 for the 2nd RUP etc

3.2. Submission of the documentation and Assessment Report

The Applicant will submit the original dossier with updates to the CMS involved in the RUP (the “new CMS”).

In case of electronic submissions the “Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product” should be taken into consideration and adapted as mention in 3.1.3.

All the data not previously available to the original CMS will be submitted to them at the same time as the dossier is submitted to the new CMS, together with a table of contents of the dossier. The original dossier need not be resubmitted to the original CMS.

The RMS will send the updated version of the AR to both new CMS and the original CMS, as well as the applicant.

3.3. Validation

The new CMS should validate the application according to the BPG for Automatic Validation of Applications in The Mutual Recognition and Decentralised Procedures.
The original CMS are kept informed only, by the RMS as below.

3.4. Communication during the assessment period

The RMS should copy the original CMS with e-mail communication taking place after day 54 of the RUP including the AR-Resp-LOQ.

3.5 At the CMDv meeting (Day 77)

The RMS will consult CMS in order to agree whether a product discussion by web conference ("Vitero") is necessary the following Monday (i.e. on Day 81).

If there are no issues of potential serious risk to resolve, it is not necessary for the application to be discussed by Vitero unless agreed by the member states concerned.

The RMS will announce this at the CMDv plenary meeting and by e-mail communicate the same information via the List V-CMD, List V-MRNA and CMDv@ema.europa.eu

3.6. Vitero discussion

All new CMS should be involved in the Vitero discussion as described in the BPG on MR procedure. "Old" CMS are encouraged to participate especially where a new CMS proposes to request specific changes to the SPC and/or package leaflet/labelling by way of a commitment from the applicant to submit a subsequent variation. If it is the case, the RMS has to inform and draw the attention of the CMS to the changes requested.

All CMS should be noted on the agenda of the Vitero discussion. The CMS involved in the earlier procedures will be within brackets.

3.7 Outcome of the procedure

New CMSs should accept the Summary of Product Characteristics (SPC), package leaflet and labelling agreed during the earlier procedure **without amendments** in accordance with Volume 6, Chapter 2 of the Notice to Applicants. Minor editorial changes should not be implemented during the RUP, but will be incorporated at the time of renewal or next variation.

If a new CMS is unable to accept the Summary of Product Characteristics (SPC), package leaflet and labelling having identified a potential serious risk(s) for human or animal health or for the environment the matter should be referred to the CMDv at Day 90 in accordance with the relevant SOP. If no agreement can be reached in this group, the matter is referred to CVMP for arbitration.

In the rare situation where a new CMS requires amendment to the SPC, which is not related to potential serious risk concerns this should not prevent a positive conclusion of the RUP. In this exceptional case, the new CMS should accept a commitment from the applicant to submit a Type II variation after the close of the RUP to the RMS and all CMSs (old and new) to implement the requested changes to the SPC and/or product literature[1]. Following a positive outcome of this variation, the marketing

[1] The amendment of the SPC according to the comments made by the new concerned Member State(s) after a repeat use MRP has to be submitted as a variation and classified as type II, C.I.z (according to the CMDv art. 5 tracking table). Changes to the labelling and/or the package leaflet which are not connected with the SPC are classified by Commission Regulation (EC) 1234/2008 as a Type IB C.II.6.

authorisation(s) can then be issued by the new CMS with the product information approved at the end of the RUP.

ANNEX 1

LIST OF RELATED DOCUMENTS

External documents

Directive 2001/82/EC	
EMEA/CVMP/115769/05	Guideline for an Assessor preparing Assessment Reports for Veterinary Medicinal Products
CMDv/GUI/003	Management of e-mail use during procedures and standardisations of subheadings
CMDv/ROP/001	CMDv Rules of Procedure
CMDv/SOP/001	CMDv SOP: Disagreement in procedures – referral to CMDv
CMDv/TEM/006	CMDv Annotated QRD template for MRP and DCP (English and translations)
CMDv/BPG/010	CMDv Best Practice Guide for the Production of Publicly Available Assessment Reports
CMDv/SOP/006	Production and Publication of Public Assessment Reports
CMDv/BPG/008	BPG for Automatic Validation of Applications in the Mutual Recognition / Decentralised Procedures
CMDv/GUI/021	CMDv Guidance on product discussions using Vitero
	Guideline on the specifications for veterinary e-submissions

Internal documents

CMDv/GUI/015	CMDv Guidance for CTS Minimum data input
CMDv/TEM/007	CMDv Template CMS Comments Mutual Recognition /Decentralised Procedure
CMDv/TEM/001	Template for the consolidated List of Questions (LOQ)
CMDv/SOP/003	CMDv SOP for the allocation of the Mutual Recognition/Decentralised Procedure Application Number

ANNEX 2

LIST OF USED ABBREVIATIONS / TERMS

AR	Assessment Report
ASMF	Active Substance Master File
BPG	Best Practice Guide
CMDv	Co-ordination Group for Mutual Recognition and Decentralised Procedures - veterinary
CMS(s)	Concerned Member State(s)
CRD	Common Renewal Date
CTS	Communication Tracking System
CVMP	Committee for Veterinary Medicinal Products
DAR	Draft Assessment Report
DCP	Decentralised Procedure
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
LOQ	List Of Questions
MA	Marketing Authorisation
MRP	Mutual Recognition Procedure
MS	Member State(s)
NtA	Notice to Applicants
PAR	Preliminary Assessment Report
PL	Package leaflet
Product literature	Labelling and package leaflet
Product information	SPC, labelling and package leaflet
PSR	Potential Serious Risk to human or animal health or for the environment
PSUR	Periodic Safety Update Report
Resp	Response
RMS	Reference Member State(s)
RUP	Repeat-use procedure
SPC	Summary of Product Characteristics
Vitero	Virtual team room = a facility to hold virtual meetings online