Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products

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BEST PRACTICE GUIDE

For

The Subsequent Recognition Procedure (SRP)

CMDv Secretariat: European Medicines Agency
Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Email: CMDv@ema.europa.eu

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1. Introduction

According to Article 53 §1 of the Regulation (EU) 2019/6, a Subsequent Recognition Procedure (SRP) may be used after completion of a first Mutual Recognition Procedure (MRP) or a Decentralised Procedure (DCP) for the recognition of a marketing authorisation by additional Member States (MS) for the same veterinary medicinal product.

This procedure can also be referred to as the Repeat-Use Procedure (RUP), which was the common term previously used in national databases and official documents, before implementation of Regulation (EU) 2019/6.

The SRP can be used in Member States, which were not included in the original marketing authorisation procedure or in Concerned Member States (CMS) where the application was withdrawn, during an earlier procedure.

Terminology:

- “old” CMS are member states in which the authorisation has already been granted
- “new” CMS are member states involved in the application for the SRP.

2. Aim and scope

This Best Practice Guide (BPG) has been prepared in order to define, what are the roles of the Reference Member State (RMS), the CMS and the Applicant during an SRP.

At the end of a successful SRP, the “new” CMS will either recognise the marketing authorisation of the product with the same SPC, labelling and package leaflet that were approved in the earlier MRP or DCP, or a new variation will be introduced in the “old” CMS to implement any requested changes linked to Potential Serious Risk (PSR) concerns. Minor editorial changes can be submitted with the first variation involving a change to product information.

3. Description of Procedure

3.1 Before submitting the application

3.1.1 Ongoing and related procedures

Any ongoing procedure should be completed before the start of the updating of the dossier and the SRP. However, the SRP can start before all marketing authorisations are issued in the “old” CMS.

3.1.2 Numbering of the Subsequent Recognition procedure and setting the start date

After the Applicant notifies his intent of submitting an SRP, the RMS creates the procedure in the Communication Tracking System (CTS) by allocating the same procedure number as the original procedure but using the qualifier numbers for the SRP to separate it from the original (see the SOP 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 SRP,
FR/V/105/002/E/002 for the 2nd SRP,
etc.

The start date for the procedure should, after agreement with the Applicant, be set according to the agreed list of start dates.

3.1.3 Information of new CMS

To make the RMS aware that some new CMSs may require MIRP, the applicant needs to identify MSs that do not have the RP authorised and inform the RMS accordingly. The applicant may use the Applicant's template for request to Member States to act as RMS in MRP, SRP or DCP to provide this information to the RMS.

The RMS will inform the CMS of the proposed start date and timetable one month before the start of the validation. In this e-mail the RMS should also highlight/indicate new CMSs identified by the applicant not to have the RP authorised, so that these MSs can already consider if a request for MIRP would be needed/required.

CMS should request MIRP as soon as possible if needed.

3.1.4 Updating of the dossier

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

The update would include any additional information/data to be submitted to meet current marketing authorisation application requirements (for example environmental risk assessment, …) 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 requiring assessment procedure is required to update the dossier prior to the commencement of the SRP.

A variation requiring assessment is foreseen when new data (new studies or report) are submitted unless there is an agreement from RMS and CMS that there is no variation with assessment needed (post-approval commitments). The RMS may arrange for a confirmatory discussion at the CMDv meeting before the dossier is prepared for the SRP.

Normally, the dossier should be formatted as the initial dossier submitted (updated in case of a prior part II update), as presented in earlier round(s) with additional information/data annexed.

These additional information/data are:

(a) A list of all decisions granting, suspending or revoking marketing authorisations which concern the veterinary medicinal product (VMP)

(b) Information on the changes introduced by post-approval procedures, such as:
- AR-Resp-LOQs including all appendices;
- Documentation relating to variations and renewals[1] 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.

(c) A summary report on pharmacovigilance data should include information on any "open" signal, ongoing post-authorisation safety studies and a declaration that the benefit-risk balance for the product remained unchanged. Additionally, the MAH should ensure that the summary of the PSMF covering the product is up to date and submitted in the dossier.

These documents should be adequately indexed, dated and referenced to the part of the dossier they complement. Hyperlinks should be used to link to the relevant parts of the dossier.

For all submissions, the "Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product" should be followed: http://esubmission.ema.europa.eu/tiges/vetesub.htm.

For cases where a full part II update has been performed prior to the SRP submission, an updated dossier could be used for the SRP. In such cases, the Applicant should provide a statement to the RMS mentioning the use of an updated dossier in accordance with the previously approved part II update.

If no update of part II is used, then, the Applicant should provide a statement confirming that the original elements of the dossier as submitted for the initial marketing authorisation procedure remain unchanged. Based on this information, the RMS will update the Assessment Report (AR).

3.1.5 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 SRPs and, if applicable, variations, renewals, commitments and new data.

The updating of the AR will take place within 60 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.

3.2 Submission of the documentation and Assessment Report

[1] According to Directive 2001/82 and submitted before implementation of the New Veterinary Regulation 2019/06.

After the update of the assessment report, the Applicant will submit the original dossier with updates to the RMS

Upon confirmation of the RMS, the applicant should submit the dossier, together with a table of contents, to the “old” and “new” CMS involved in the SRP well before the start of the validation phase. The “old” and “new” CMS should be appropriately identified and only the “new” CMS should get actively involved unless PSRs are raised. The RMS should provide the updated AR for Day 0 or earlier if available.

The RMS will start the validation period by indicating a proposed timetable for the procedure.
In case a risk assessment to make recommendations for post-marketing surveillance testing has been completed in the original MRP or DCP, this document will be also sent by the RMS at this stage. Information regarding the risk assessment template is confidential and should not be disclosed to the Applicant.

3.3 Validation

Validation of the procedure should take 15 days. For details on how to proceed during this phase, please refer to the Best Practise Guide on Validation.

The “new” CMS have the duty to update the status of the CTS record continuously to reflect the current (validation) status.
For generics, new CMS that need MIRP is strongly recommended to make the request at D-15 or before to the RMS.

The “old” CMS will be kept informed by the RMS as described below.

3.4 Assessment phase

First phase **(D0-D30)**:

For generics, at D15, the RMS should circulate the MIRP if requested.
However if the legal deadline has not yet elapsed and the MIRP are still in preparation, the RMS will provide the MIRP 30 days after the request has been received. In that case the procedure may automatically reach the second phase unless the MIRP are received in time for the CMS.

The RMS should copy the mrna-list with all e-mail communication taking place during the SRP. In the event PSRs are raised during the procedure the CMDv should additionally be informed via a specific email according to the guidance on the management of e-mail use during procedures and standardisation of subheadings.

All “new” CMS should participate in the SRP. In case of PSRs, the RMS has the duty to inform and draw the attention of the “old” CMS to the fact that PSRs are raised. The “old” CMS will then participate in the future procedure.

If the RMS has sent a risk assessment document, CMS may comment on this document in this phase. Information regarding the risk assessment template is confidential and should not be disclosed to the Applicant.

Any non-confidential CMS comments on the procedure should be sent directly to the Applicant with the RMS and mrna-list in copy on **day 30**. The comments should clearly indicate if they include PSRs. For cases when the step date is on a week-end, the comments should be sent by midday on the next work day at the latest.

Also on **day 30**, where applicable, documents containing confidential comments (regarding the restricted part of the ASMF and/or the reference product) should be sent directly (and separately) to the RMS with the mrna-list in copy. Both e-mail and documents should be clearly labelled as being confidential in nature. The RMS is responsible for forwarding questions on the restricted part of the ASMF to the respective ASMF holder.

If no CMS comments have been received by **day 30**, the RMS can close the procedure and the national phase starts. Otherwise, the procedure will continue as follows:

Second phase (**D30-D60**):

If comments were received, by **day 33**, the RMS will provide a list of the confidential questions to the new CMS and to the ASMF-Holder, if applicable.

The Applicant will prepare the list of questions (LOQ) and send this to the RMS and CMSs via CESP by **day 35** of the procedure. All questions from CMS should be included in the LOQ using CMDv/TEM/xxx(001).

The Applicant should note that whilst the CMSs may check at this stage that their questions have been included, the Applicant is responsible for ensuring that questions are not omitted

If PSRs have been raised, the RMS should, additionally to the mrna-list, also forward the LOQ to the CMDv mailbox for “old” CMS to be notified using the following subject heading : <Attention Old CMS <xx xx xx> SRP <Product name> PSR concerns.

The applicant’s responses are required by **day 40** and the RMS assessment of the applicant’s responses by **day 46** (if applicable, the RMS should then also provide assessment of response by ASMF-holder and/or answers to confidential LOQs on the reference product).

Resulting CMS comments should be circulated by **day 50** to the Applicant, the RMS and all CMS. In case there are no more comments or only minor comments at this time, an agreement can be reached between the RMS, the CMS and the Applicant in order to end the procedure on **day 60** and start the national phase (see section 3.6).

Further procedure in case of PSR concerns after day 50:

If there is still one or more unresolved PSRs, by **day 53**, the RMS will provide a list of the confidential questions to the new CMS and to the ASMF-Holder, if applicable.

The Applicant will prepare the new list of questions (LOQ) and send this to the RMS and CMSs via CESP by **day 55** of the procedure. All questions from CMS should be included in the LOQ using CMDv/TEM/xxx(001).

Again, while the CMSs may check at this stage that their questions have been included, the Applicant is responsible for ensuring that questions are not omitted.

The Applicant should then provide responses together with updated SPC, labelling and product leaflet before **day 60**.

Third phase **(D60-D90)**:

By **day 65**, the RMS circulates their assessment of the responses to the LOQ to the Applicant and the CMSs.

By **day 70**, CMS should send their pre-CMDv comments to the RMS, applicant and all CMS, which should be answered by the Applicant by **day 75**. The answer should include the updated SPC, labelling and product leaflet.

In the event of remaining issues of PSR, along with any issues concerning the AR, SPC, PL and labelling, the need for virtual discussion should be decided on **day 77** and scheduled on **day 81/82** of the procedure. If requested by the Applicant, an oral hearing will be organised by the RMS.

During the virtual discussion, CMS (including "old" CMS) present their positions and comments on the latest provided SPC, PL and labelling (>**day 75**) and possible requests for commitments should be presented and discussed.

All issues should be resolved as far as possible during the virtual product discussion and the Applicant should be informed of the outcome of the discussions by the RMS. A summary of the discussions should also be prepared by the RMS and sent to the CMS. The CMS should send their remaining (written) comments on the SPC, labelling and leaflet (also requests for commitments) on the next day (**day 82/83**). (See also Guidance on virtual CMDv product discussions)

The Applicant will provide the final drafts of the SPC, labelling and leaflets on **day 84**, which can be commented by CMS until **day 85**.

The remaining days should be used by the Applicant to reach an agreement with all CMS ("old" and "new") and provide a final modification of the SPC, PL and labelling if necessary. On **day 89**, the CMS should notify the RMS and the Applicant of their final position.

On **Day 90**, the procedure is closed preferably at 13:00 CET. If needed, the RMS will update in the CTS client the risk assessment document to make recommendations for post-marketing surveillance testing. Also in case of disagreement, the RMS will circulate an e-mail to all CMS and the applicant indicating the final outcome of the procedure.

The flowchart of procedure is included in Annex III.

3.5 Outcome of the procedure

3.5.1 Positive outcome

In the absence of PSRs, "new" CMS should recognise the AR and accept the Summary of Product Characteristics (SPC), package leaflet and labelling agreed during the earlier procedure **without amendments**. Minor editorial changes should not be implemented during the SRP, but will be incorporated at the time of next variation affecting the SPC, Labelling and/or Package Leaflet as part of a commitment. The SPC, labelling and package leaflet are updated at the end of the Subsequent Recognition procedure to include the product names in the "new" CMS.

3.5.2 Positive outcome followed by variation (exceptional)

In the situation where a "new" CMS requires amendment to the SPC linked to PSRs, this should not prevent a positive conclusion of the SRP if agreement on the change is reached between the Applicant, RMS, "old" and "new" CMS. In this exceptional case, the procedure should be closed with the amended SPC. The Applicant should provide a commitment to submit a variation with

assessment after the closing of the SRP to the RMS and “old” CMS to implement the agreed changes to the SPC and/or product literature[2].

3.5.3 Withdrawal of a CMS

The applicant can withdraw the application from a CMS at any stage of the procedure.
If a CMS is withdrawn this will be stated in the PuAR together with the reason for the withdrawal/ the MS(s) position at time of withdrawal.
If applicable/requested, further information considered relevant to the withdrawal and provided by the competent authority of the withdrawn MS(s) to the RMS and other CMSs, will also be included in the PuAR

The applicant should note that whilst an application for a MA may be withdrawn by the applicant from a CMS at any time during the SRP, his may not prevent any raised potential serious risk concern being taken forward by the withdrawn CMS in a union interest referral.

3.5.4 No agreement reached on day 90

If the RMS has not been able to find an agreement with all “old” and “new” CMS at the latest within 60 days from the date on which the PSRs were raised, the matter should be referred to the CMDv on day 90 in accordance with review procedure detailed in the relevant SOP for the review procedure. If no agreement can be reached in this group, the CMDv shall provide the Commission with the AR, together with the points of disagreement at the latest within 90 days from the date on which the matter was referred to the CMDv.

3.6 National Step – granting of the Marketing Authorisation in "new" CMS

If agreement is reached at the conclusion of the procedure (Day 90), the applicant will send high-quality national translations of final SPC, PL and labelling to all "new" MS concerned.
The granting of the MA is linked with the reception of high-quality translations. Please refer to the BPG on submission of high-quality national translations for veterinary medicines.
Please also refer to the BPG for the processing of SPC, Labelling and Package leaflet & the preparation of Multilingual/-country Packaging provided in support of MRP/DCP/SRP and Variations

QRD templates for product information have been published in all languages on the HMA/CMDv website and must be respected.

If the applicant fails to provide a complete translation of the required documentation to the CMS within a period of six months after the end of the procedure, the application shall be considered to have been withdrawn in that specific MS.

Competent authorities should ensure that authorisations are granted within 30 days after complete and high quality national translations are submitted (i.e. correct translation of the SPC, PL and labelling in the language(s) of the respective MS and also mock-ups, as required).

The approved national translations of the common English SPC, labelling and package leaflet should be uploaded into the UPD by the Competent authorities.

3.7 Public assessment report (PuAR)

[2] The amendment of the SPC according to the comments made by concerned Member State(s) after a Subsequent Recognition Procedure has to be submitted as a variation requiring assessment type GI17b.

The RMS should also update the publicly available assessment report in accordance with the SOP for the production and publication of Public Assessment Reports.

3.8 Commitments

In principle, commitments should not be requested of the applicant by competent authorities during the assessment of the application. Any post procedure commitment, which will be binding for all involved Member States, should be exceptional and must be requested by the RMS on behalf of the CMS. CMS who request such a commitment should provide full justification to the RMS.

Commitments should be provided in a written format as an official signed letter (using template CMDv-TEM-029) from the applicant, clearly stating the time limits for the submission of data. Documentation from the applicant relating to completion of commitments must be sent to the RMS and all CMS simultaneously.

The RMS assessment of information to fulfil any commitments will be circulated to the CMSs with details of a timeline for comments. Should the RMS consider that a subsequent variation is required, following the review of commitment data, this will be notified accordingly. In any case, the applicant will be informed on the outcome of the commitment assessment.

If time limits are exceeded or data are insufficient, the matter will be brought back to CMDv for discussion.

ANNEX 1

LIST OF RELATED DOCUMENTS

External documents

Regulation (EU) 2019/6	
EMEA/CVMP/115769/05	Guideline for an assessor preparing Assessment Reports for Veterinary Medicinal Products
	Guideline on e-submission for Veterinary Products
	Guidance on the management of e-mail use during procedures and standardisation of subheadings
	BPG for Veterinary Mutual Recognition Procedure (MRP)
	BPG for validation of applications
	CMDv Annotated QRD template for MRP and DCP (English and translations)
	SOP for the production and publication of Public Assessment Reports
	SOP for the review procedure
	BPG for the submission of high quality national translations for veterinary medicines
	BPG for the processing of SPC, Labelling and Package leaflet & the preparation of Multilingual/-country Packaging provided in support of MRP/DCP/SRP and Variations
	CMDv Guidance on product discussions

Internal documents

	Guidance for CTS minimum data input
	CMDv Template CMS comments Mutual Recognition /Decentralised Procedure
	Template for the consolidated List of Questions (LOQ)
	SOP for the allocation of the Mutual Recognition/Decentralised Procedure Application Number

ANNEX 2

LIST OF USED ABBREVIATIONS / TERMS

AR	Assessment Report
BPG	Best Practice Guide
CMDv	Co-ordination Group for Mutual Recognition and Decentralised Procedures - veterinary
CMS	Concerned Member State(s)
CTS	Communication Tracking System
CVMP	Committee for Veterinary Medicinal Products
DCP	Decentralised Procedure
EMA	European Medicines Agency
EOP	End of procedure
LOQ	List Of Questions
MA	Marketing Authorisation
MRP	Mutual Recognition Procedure
MAH	Marketing Authorisation Holder
MS	Member State(s)
PL	Package leaflet
Product literature	Labelling and package leaflet
Product information	SPC, labelling and package leaflet
PSMF	Pharmacovigilance System Master File
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 (Subsequent recognition procedure)
SPC	Summary of Product Characteristics
SRP	Subsequent recognition procedure (Repeat-use procedure)
VMP	Veterinary Medicinal Product

ANNEX 3

FLOW CHART FOR SUBSEQUENT RECOGNITION PROCEDURE (SRP)

Pre-Procedural Step	
Before Day -15	Applicant discusses the application with RMS. The RMS will: - Create procedure in CTS and allocate procedure number - Inform CMS and Applicant of proposed start date, procedure number and reference product if applicable - Update the assessment report. New CMS will indicate that the RP is not authorised in their territory and that MIRP is required.
	The Applicant submits the dossier in all CMS and RMS The validation phase starts. D-15 : New CMS makes the MIRP request as necessary
Assessment step	
Day 0	Start of the procedure The RMS will: • Send the official updated AR • Email timetable to CMS and applicant • Update CTS with the start date
Day 15	RMS circulates the MIRP
Day 30	- The CMS send their comments, including all PSRs, to the Applicant, the RMS and all "new" CMS. (with the confidential comments sent to RMS/CMS) or - If there are no CMS comments, the procedure ends and proceeds to the national phase → **EoP = day 30**
Day 33	If applicable, RMS sends a confidential LOQs on the reference product to the CMS and ASMF-holder (and/or restricted part of the ASMF).
Day 35	LOQ circulated by the applicant to RMS and all CMS. In case of PSR(s), the RMS should forward the comments to the "old" CMS.
Day 40	Applicant sends response to LOQ.
Day 46	RMS circulates assessment of response to LOQ to Applicant and CMS. If applicable the RMS should also provide assessment of the confidential LOQ on the reference product (and/or restricted part of the ASMF).
Day 50	CMS send comments to the Applicant, the RMS and all "new" CMS.(Confidential comments sent to RMS/CMS)
Day 53	If applicable, RMS sends a confidential LOQs on the restricted part of the ASMF to the CMS and ASMF holder.
Day 55	In case of PSRs: Applicant circulates the LOQ and RMS circulates the confidential LOQ on the reference product to the CMS (and/or restricted part of the ASMF). Or

	If only minor comments were notified: Applicant provides the final answer and documents
(Day 55-59)	*If only minor comments were notified: Resolve the last issues with the applicant.*
Day 60	- Applicant sends response document to PSR or - if an agreement is reached or if there is no PSR, the procedure ends and proceeds to the national phase → **EoP = day 60**
Day 65	RMS circulates assessment of response to LOQ to Applicant and CMS. (If applicable the RMS should also provide answers to confidential LOQ on the reference product)
Day 70	CMS send pre-CMDv comments to RMS and Applicant (including possible comments from "old" CMS).
Day 75	Applicant sends pre-CMDv response (including updated PI).
Day 77	RMS and CMS (including "old" CMS) should agree whether a virtual product discussion is necessary (and/or an oral hearing if requested by Applicant)
Day 81/82	CMDv virtual product discussion and/or oral hearing if required. RMS informs Applicant of outcome of discussions immediately after the meeting and sends summary note to CMSs.
Day 82/83	CMS (including "old" CMS) send comments on SPC, PL and labelling, including requests for commitments, within one day after the virtual discussion/oral hearing.
Day 84	Applicant provides the final (new) drafts of SPC, PL and labelling.
Day 85	CMS send any remaining comments to RMS, CMS, and Applicant.
Day 85-89	The remaining days should be used by the Applicant to reach an agreement and provide new PI if necessary.
Day 89	CMS notify RMS and Applicant of final position (and in case of negative position also the CMDv secretariat of the EMA).
Day 90	**EoP = Day 90** - If consensus is reached, the RMS closes the procedure. or - If consensus is not reached, the points for disagreement submitted by CMS are referred to CMDv for the review procedure.

National Step	
Within 6 months following the EoP	The Applicant provides the national translations or the procedure is withdrawn or the application shall be considered to have been withdrawn in that specific country
Within 30 days of the receipt of national translations from the Applicant	The MA is issued by the national authorities