EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Management of periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products		
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1. Purpose

To enable a transparent procedure for the management of periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products following the granting of a central marketing authorisation by the European Commission and to ensure timely submission and assessment of the PSURs as well as the follow-up of the conclusions and recommendations of the Committee for Medicinal Products for Veterinary Use (CVMP).

2. Scope

This standard operating procedure (SOP) applies to CVMP members and alternates, CVMP Pharmacovigilance Working Party members and the European Medicines Agency (EMA) staff of the Veterinary Medicines Division.

3. Responsibilities

It is the responsibility of the Head of Veterinary Medicine Department (delegated to the APH Service Head) to ensure that this SOP is adhered to. The responsibility for the execution of each particular step of this procedure is identified in the right-hand column of section 9 of this SOP.

4. Changes since last revision

Update to reflect new Agency structure and contact details. Update of internal EMA working document to support SOP (checklist to replace former working instruction).

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5. Documents needed for this SOP

Models as identified by the Checklist for processing of PSURs for centrally authorised veterinary medicinal products (EMA/190856/2015).

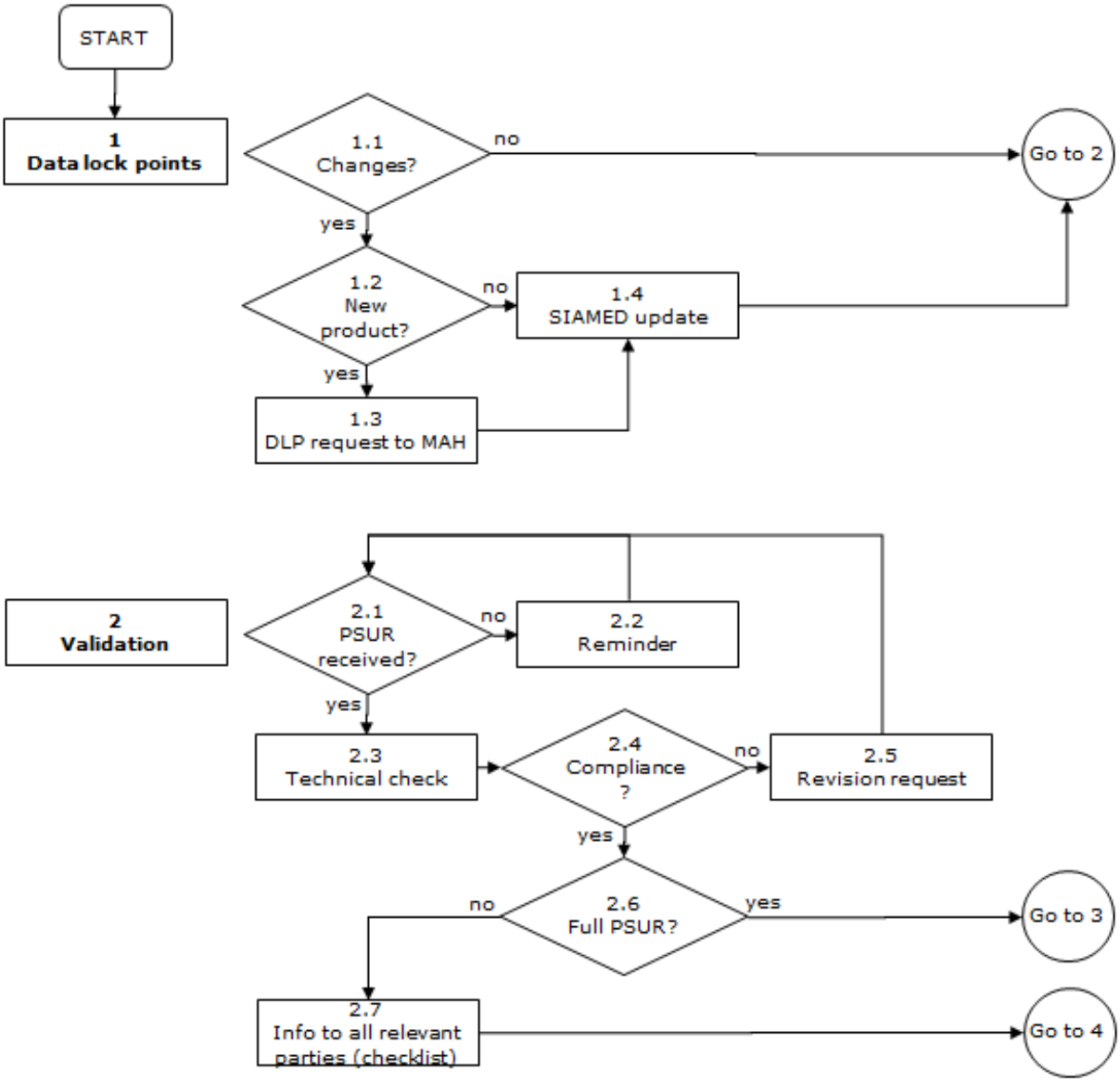
6. Related documents

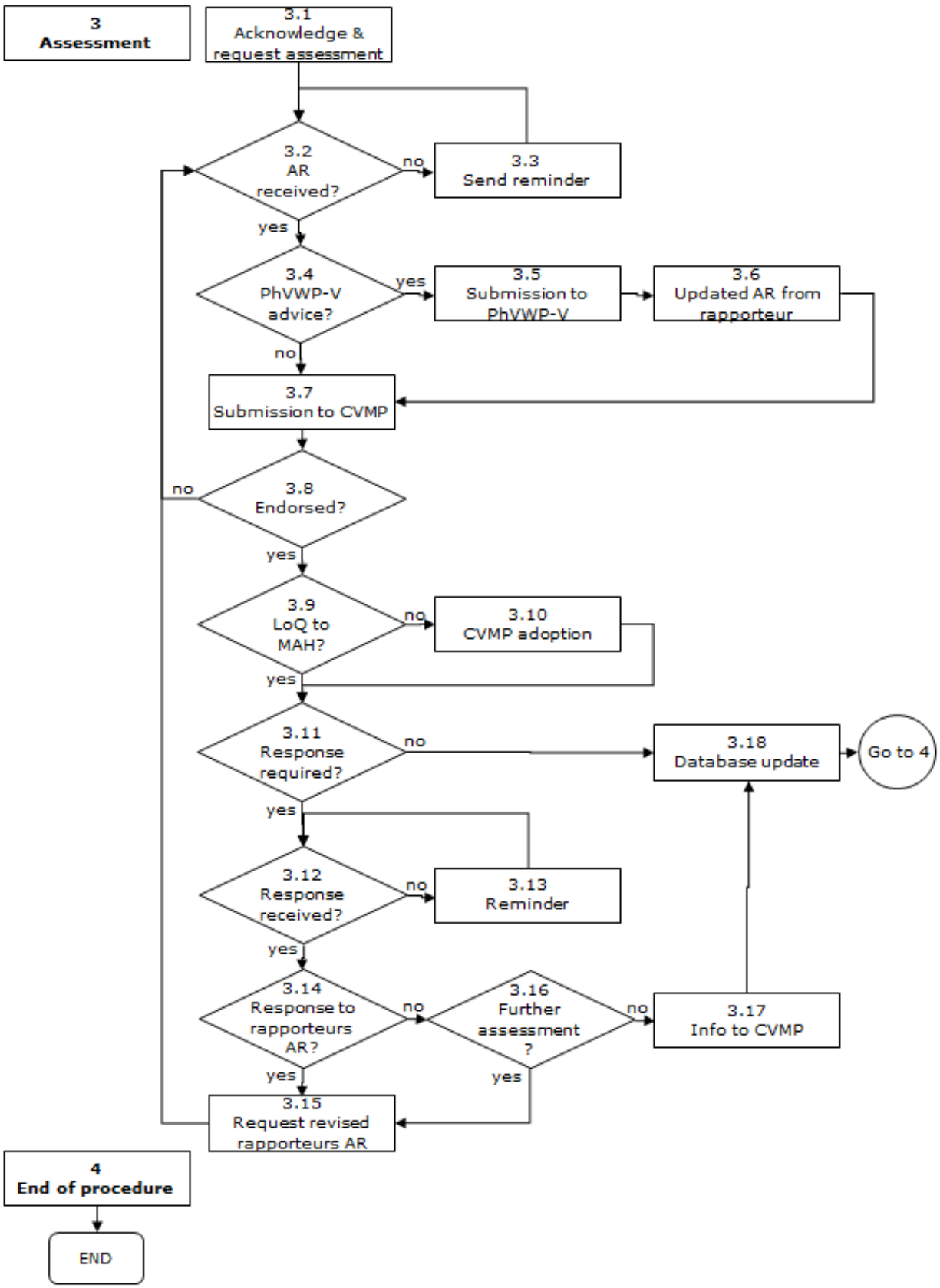
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
- Regulation (EC) No. 726/2004 of 31 March 2004
- Commission Regulation (EC) No. 540/95 of 10 March 1995
- Volume 9B of The rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use
- Procedure on PSUR submission and evaluation for non-marketed products (EMEA/CVMP/227/01-Rev.1)
- Recommendation on management and assessment of periodic safety update reports (PSURs) of veterinary medicinal products (EMEA/CVMP/PhVWP/4550/2006)
- Checklist for processing of PSURs for centrally authorised veterinary medicinal products (EMA/190856/2015)
- SOP/PDM/1004 on Core Master Files of medicinal products for human and veterinary use following the centralised procedure.

7. Definitions

AA	Administrative assistant
Abridged PSUR	PSUR in accordance with CVMP procedure for non-marketed products (EMEA/CVMP/227/01-Rev.1)
Checklist	EMA internal checklist (here: specific reference to EMA/190856/2015)
CVMP	Committee for Medicinal Products for Veterinary Use
Data lock point (DLP)	Designated cut-off date for data to be included in a PSUR
Full PSUR	PSUR in accordance with Volume 9B of The rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use Part I 6.3.1
MAH	Marketing authorisation holder
PhV SA	Veterinary pharmacovigilance scientific administrator
PhVWP-V	CVMP Pharmacovigilance Working Party
PSUR	Periodic safety update report provided by the MAH in accordance with Art. 49(3) of Regulation (EC) No. 726/2004
Rapporteur	CVMP member or alternate responsible for the product

8. Process map(s) / flow chart(s)




3
Assessment
3.1
Acknowledge &
request assessment
3.2
AR
received?
no
3.3
Send reminder
yes
3.4
PhVWP-V
advice?
yes
3.5
Submission to
PhVWP-V
3.6
Updated AR from
rapporteur
no
3.7
Submission to CVMP
no
3.8
Endorsed?
yes
3.9
LoQ to
MAH?
no
3.10
CVMP adoption
yes
3.11
Response
required?
no
3.18
Database update
Go to 4
yes
3.12
Response
received?
no
3.13
Reminder
yes
3.14
Response to
rapporteurs
AR?
no
3.16
Further
assessment
?
no
3.17
Info to CVMP
yes
yes
3.15
Request revised
rapporteurs AR
4
End of procedure
END

9. Procedure

Step	Action	Responsibility
1.0	**Determination and update of data lock points**	
1.1	Upon receipt of Commission Decision for granting, renewal or variation of a marketing authorisation or after adoption of final CVMP PSUR assessment report, check whether introduction or amendment for the PSUR cycle for the product is required. If yes, go to 1.2 If no, go to 2.0	PhV SA
1.2	For setting of DLPs for a new product, go to 1.3 For amendment of PSUR cycle, go to 1.4	
1.3	Request clarification of data lock point from MAH in accordance with the checklist.	PhV SA
1.4	Update[1] SIAMED in accordance with the checklist. Proceed to 2.0	AA
2.0	**Submission and validation**	
2.1	Track submission of due PSURs and/or responses using SIAMED in accordance with the checklist. Was (revised) PSUR received on or before the due date? If yes, go to 2.3 If no, go to 2.2	AST
2.2	Send reminder to MAH. Proceed to 2.1	PhV SA
2.3	Considering whether it is a full or an abridged PSUR, start internal technical validation on format and content of PSURs against Volume 9B in accordance with checklist. Pass validation documents to PhV SA.	AST
2.4	Check content for regulatory compliance and consideration of previous requests. Is the (revised) PSUR in compliance? If yes, go to 2.6 If no, go to 2.5	PhV SA
2.5	Request revision of PSUR from MAH. Go to 2.1	PhV SA
2.6	If full PSUR, go to 3.0 If abridged PSUR, go to 2.7	
2.7	Send the abridged PSUR to the rapporteur for information and forwarding to PhVWP-V member. Inform CVMP in accordance with checklist. Send letter to MAH acknowledging receipt of valid abridged PSUR in accordance with checklist. Proceed to 4.0	PhV SA

[1] Note: If the MAH does not respond to the DLP request letter, the PSUR cycle is based on the EU Birth Date (date of Commission Decision).

3.0	**Assessment and CVMP endorsement**	
3.1	Send the PSUR and prefilled assessment report template to rapporteur, requesting assessment (which should indicate if advice from PhVWP-V or clarification from the MAH is required) with proposed timetable for evaluation. Send letter to MAH acknowledging receipt of valid PSUR and informing of evaluation period in accordance with checklist.	PhV SA
3.2	Was rapporteur's (revised) assessment report received before or on due date? If yes, go to 3.4 If no, go to 3.3	
3.3	Send reminder to rapporteur. Proceed to 3.2	PhV SA
3.4	Is advice from PhVWP-V required? If yes, go to 3.5 If no, go to 3.7	
3.5	Submit PSUR assessment report and request for advice to PhVWP-V.	PhV SA
3.6	Upon receipt of advice from PhVWP-V, ensure updated rapporteur's assessment report is received in accordance with timetable.	PhV SA
3.7	Circulate rapporteur's assessment to CVMP for endorsement.	PhV SA
3.8	*CVMP comments on rapporteur's assessment in case of disagreement.* Was the rapporteur's assessment endorsed by CVMP? If yes (or unknown), go to 3.9 If no, go to 3.2	
3.9	Are questions to be addressed to MAH? If yes, go to 3.11 If no, go to 3.10	
3.10	Circulate PSUR and assessment for the next CVMP meeting for adoption in accordance with checklist.	PhV SA
3.11	Inform MAH of outcome of (current step of) assessment, indicating any outstanding questions. Is a response required? If yes, go to 3.12 If no, go to 3.18	PhV SA
3.12	Was MAH response received before on on due date? If yes, go to 3.14 If no, go to 3.13	PhV SA
3.13	Remind MAH to send response to LoQ, indicating new due date. Proceed to 3.12	PhV SA
3.14	If response to rapporteur's assessment, go to 3.15 If response to CVMP assessment, go to 3.16	PhV SA
3.15	Submit response to rapporteur for preparation of revised assessment report. Proceed to 3.2	PhV SA
3.16	Is response requiring further assessment by rapporteur and/or CVMP? If yes, go to 3.15 If no, go to 3.17	PhV SA
3.17	Circulate MAH response to CVMP for information at next meeting.	PhV SA
3.18	Update databases in accordance with checklist.	AST/AA
4.0	**End of procedure**	

10. Records

Electronic copies of all correspondence and documents received are saved in the appropriately labelled folder in DREAM and core master file, as necessary.

A record of the status of the PSURs for centrally authorised products is produced on a monthly basis from SIAMED and circulated to CVMP for information in accordance with the internal checklist on PSURs.

Annex I

Contact details of national competent authorities for submission of PSURs for centrally authorised veterinary medicinal products; published on the EMA website.