EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Management of the procedure for assessment of the final report of Post-Authorisation Safety Studies (PASS) for veterinary medicines		
Applies to: Veterinary Medicines		
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1. Changes since last revision

New work instruction (WIN).

2. Records

Electronic copies of all correspondence and documents related to each study are saved in appropriately labelled folders in DREAM.

3. Instructions

3.1. Purpose

This WIN applies to the Pharmacovigilance team in the Animal and Public Health service of the Veterinary Medicines Division responsible for processing the assessment of final study report on post-authorisation safety studies. The WIN aims at providing guidance and giving a detailed overview of individual responsibilities for processing the assessment of the final study report of post authorisation safety studies (PASSs). This WIN does not cover the steps concerning the receipt of the study protocol, appointment of rapporteurs and agreement of the timetable which are carried out similarly to other CVMP procedures.

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3.2. Responsibility

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

3.3. Related documents

- SOP/PDM/1004 on Core Master Files of medicinal products for human and veterinary use following the centralised procedure (the principles concerning PSURs are applied by analogy)
- Style guide for Agency templates (EMA/741370/2009) and Editorial style guide (EMA/560894/2012), Communication guidance microsite http://emeaplus/EMEAPlus_WebsiteNew/Communication/html/Communications_guidance.htm.

3.4. Definitions

AA	Administrative assistant (here: AA in VROS)
APH	Animal and Public Health (in the Veterinary Medicines Division)
AR	Assessment report
AST	Assistant (here: AST allocated to the procedure)
CD	Commission Decision
cMF	Core master file
CVMP	Committee for Medicinal Products for Veterinary Use
DLP	Data lock point
DREAM	Document Records Electronic Archive Management system
HSer	Service Head
MAH	Marketing authorisation Holder
LoQ	List of questions
PASS	Post authorisation safety study
PAM	Post authorisation measure
PhV	Pharmacovigilance (here: veterinary pharmacovigilance)
PhV SA	Scientific administrator in APH responsible for veterinary pharmacovigilance
PhVWP-V	CVMP Pharmacovigilance Working Party
(Co-)Rapporteur	CVMP member and/or alternate responsible for the PASS assessment
SIAMED	Database for tracking applications and procedures
SPC	Summary of product characteristics
VROS	Veterinary Regulatory and Organisational Support Service (in the Veterinary Medicines Division)

3.5. Instructions

3.5.1. General tasks

The procedure should in principle be finalised within three CVMP meetings after receipt of the final study report unless otherwise agreed (justified by complexity, amount of data); if a LoQ to marketing authorisation holder (MAH) is required (i.e. recommendation to amend the product literature or clarification needed with regard to the study report before a final conclusion can be made), a clock stop applies.

The following archiving tasks apply throughout the procedure and should be managed by the AST in liaison with the PhV SA:

- Ensure documents are saved in DREAM, labelled with cMF status following the PSUR cMF checklist by analogy, where appropriate.
- All documents included in the cMF should be labelled as "potential" in the cMF status field until the procedure is finalised (i.e. CVMP adoption), after which the cMF status field should be changed to completed.
- Ensure documents saved in DREAM are named in accordance with the convention detailed in Annex VII and formatted in accordance with the Style guide for Agency templates (EMA/741370/2009) and the Editorial style guide (EMA/560894/2012).
- All SIAMED templates created should be saved in DREAM
- All correspondence is sent electronically. Signed letters should be converted to portable document files (pdf) and saved as the latest/current version in DREAM.
- Vet-phv@ema.europa.eu should be copied in all electronic correspondence.

3.5.2. Final study report for PASS received at the Agency

Step	Action	Responsibility
1	Save the PASS documentation received in EURS, record and start the procedure in SIAMED and inform PhV SA.	AA
2	Send confirmation of receipt of final study report to the MAH informing of the provisionally scheduled adoption at CVMP.	PhV/AST
3	*Receipt and preparation for review* Coordinate with AST the completion of the following tasks: *(actions to be completed if possible **within 3 working days**)* • Save final study report and cover letter in DREAM under document category "PASS" in *DREAM/01 Evaluation of medicines/V – C/Active applications/[Product name]/PhV/Post-authorisation safety study*. Files received might need to be merged if sent in more than one file. Save any additional files/attachments (e.g. study protocol, study raw-data, SPCs)	 PhV SA AST

Step	Action	Responsibility
	sent with the PASS in above folder.	AST
	• Create PASS AR template using SIAMED template *PASS - assessment report.* Naming of the AR should be "product name – Assessment report – PASS".	AST
	• Forward locator to PASS folder to PhV SA for review.	
4	*Review* *(actions to be completed **within 14 calendar days,** if possible)*	
	• Check the content of the PASS final study report (and request additional information from the MAH, as necessary), create the procedure timetable in agreement with the Rapporteur (using template *PASS – timetable*), save the timetable in DREAM (Naming of the timetable should be "product name – timetable – PASS") and review the PASS AR template.	PhV SA
	• Request the rapporteur to give a brief presentation summarising the final study report (3 – 4 slides; no assessment) at the next available CVMP meeting and add the point for information to the CVMP agenda point 05.5 Pharmacovigilance.	PhV SA
	• Request the AST to send the final study report, the timetable and the AR template for the PASS procedure to the rapporteur and co-rapporteur, for assessment. Refer to the agreed timetable for the deadline for submission of the AR.	PhV SA
5	*Request for assessment*	
	• After review by the PhV SA, send the request for assessment to the rapporteur and co-rapporteur (final study report, the timetable and the AR template for the PASS procedure) via Eudralink; cc all CVMP members via LIST-V-CVMP@EUDRA.ORG and the project manager for the initial MA application; save in the PASS folder.	AST
	• If the rapporteur is not able to meet the deadline on the agreed timetable make sure that CVMP is informed. If not done by the rapporteur forward to all CVMP members via LIST-V-CVMP@EUDRA.ORG	PhV SA

3.5.3. Receipt of assessment report (AR) to final study report for PASS

Step	Action	Responsibility
1	On the date indicated in the timetable under "Rapporteurs initial assessment report" check if the AR has been submitted and, if so, save in PASS folder in DREAM and alert the PhV SA.	AST

Step	Action	Responsibility
	If the AR has not been submitted send a reminder to the rapporteur with the template *PASS - AR submission reminder.*	
2	Review the initial AR and request the AST to circulate the initial AR to the co-rapporteur and all CVMP members. If significant changes have been introduced inform the rapporteur.	PhV SA
3	On the date indicated in the time table under "Comments from co-rapporteur and CVMP members": check for comments. If comments on the rapporteurs initial AR are received from CVMP members save in DREAM. Liaise with the PhV SA to send a request to the rapporteur to revise, as necessary, the rapporteur's AR according to the time table (10 days after end of period for comments). If no comments on the rapporteur's initial AR are received, create CVMP AR draft 1. Review the formatting and update the table of contents etc., as necessary.	AST
4	Does the AR contain questions to the MAH or recommendations to amend the SPC? If yes, go to 5. If no, go to 13.	
5	Recommendations made by the rapporteur to amend the SPC should be formulated as questions to the MAH and sent as LoQ for comment to the MAH before a final conclusion can be drawn by CVMP to recommend amendments to the SPC. Liaise with the rapporteur if changes have to be made to the AR e.g. wording of the questions to be forwarded to the MAH. Make sure that SIAMED is updated with the LoQ. Table the draft CVMP AR for endorsement at the next CVMP meeting (agenda point 5.5 Pharmacovigilance). Create the letter, as necessary, with list of questions to be sent with the draft CVMP AR (labelled as "draft" in DREAM). The letter is to be sent via Eudralink to the MAH using template *PASS - LoQ to MAH letter*.	PhV SA AST
6	After endorsement of the AR by CVMP, review the letter containing the list of questions and set a deadline for response (usually 2 weeks are sufficient, reconsider on a case by case basis, as necessary). Review the draft CVMP AR and notify AST when the documents are ready for sending. Send LoQ letter to the MAH and cc the rapporteur and co-rapporteur and save the signed and scanned version in DREAM, labelled "signed".	PhV SA AST

Step	Action	Responsibility
7	Check that the responses are submitted before the deadline given to the MAH in the letter.	AST
	If no response is submitted one day after the deadline has passed, prepare a reminder to be sent to the MAH using template *PASS - LoQ responses submission reminder.*	AST
	Review the reminder to be sent to the MAH and ask AST to send via e-mail to contact point for the PASS procedure.	PhV SA
	Send the reminder to the MAH and cc to rapporteur, co-rapporteur and save in DREAM.	PhV SA
8	Once responses are received prepare request to revise the draft CVMP AR using template *PASS - AR revision after LoQ;* to be sent to the rapporteur, cc co-rapporteur and attach the responses submitted by the MAH and the draft CVMP AR to the request.	AST
9	Check the responses to LoQ submitted by the MAH and, provided the information requested by CVMP is included, review the request to revise the draft CVMP AR prepared by the AST, and set a deadline (usually within 7 to 10 days, consider if this is sufficient and adjust the deadline on a case by case basis) and notify AST when ready for sending to the rapporteur.	PhV SA
10	Send the request for revision of the draft CVMP AR, via Eudralink to the rapporteur, cc co-rapporteur, attach the responses submitted by the MAH and the draft CVMP AR to the request; and save in DREAM.	AST
	On the date indicated in the time table under “Rapporteur’s revised “CVMP draft 2” assessment report” check for receipt of the revised AR. Save in DREAM and alert the PhV SA.	
	Check if the revised CVMP AR draft 2 has been sent by the rapporteur to all CVMP members. If not, forward to all CVMP members as soon as possible.	
12	Review the revised CVMP AR draft 2 and amend, according to current terminology/agreed internal standards, in track changes and if necessary (comments or amendments to the scientific and/or regulatory recommendations) send to rapporteur for approval.	PhV SA
	Once the CVMP AR is thoroughly reviewed request the AST to table it for adoption on the main CVMP agenda (point 05.5 Pharmacovigilance) of the next available CVMP meeting. This should be done for the first mailing preferably, although it could be added to the second mailing if the HSer agrees. If the item can’t be added to the second mailing, it should be included in the first mailing of the following CVMP meeting.	

Step	Action	Responsibility
	Expected outcome to be recorded in SIAMED ("Record outcome" and "Edit PAM" in the section "Reporting").	
13	Table the CVMP AR for adoption on the main CVMP agenda (under point 05.5 Pharmacovigilance), and include the final study report, the initial rapporteurs AR, any additional information received from the MAH and/or comments received from CVMP members, under background information. Prepare outcome letter to be sent to the MAH using *PASS - CVMP outcome*, to be dated last day of the CVMP meeting.	AST
14	Review the CVMP agenda before the mailing (1st or 2nd mailing). Update, as necessary, the annotated agenda (before the CVMP meeting). Update the draft press release (according to the deadline specified). Review the outcome letter.	PhV SA

3.5.4. During and after CVMP

Step	Action	Responsibility
1	Check with the PhV SA if any amendments to the CVMP AR, impacting the outcome letter, have been made.	AST
2	Update the CVMP AR, outcome letter and press release, as necessary, and notify AST when ready for processing.	PhV SA
3	Print final CVMP AR and outcome letter. If necessary, finalise the CVMP AR by accepting all track changes, deleting any yellow text box and labelling the AR as "final" in DREAM. Pass to PhV SA for review and signature, then to HSer for approval (no later than the last day of CVMP at noon).	AST
4	Send signed outcome letter together with the final CVMP AR (clean version, labelled "final") to the MAH, cc rapporteur and co-rapporteur, and save signed version in DREAM, labelled "signed".	AST
5	Update CVMP minutes and other relevant CVMP documents e.g. press release, as required.	PhV SA
	End of procedure	