EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Processing pharmacovigilance data in renewal procedures for centrally authorised medicinal products for veterinary use		
Applies to: Veterinary Medicines (APH and VROS)		
Status: **PUBLIC**		Document no.: WIN/V/4048
Lead Author	Approver	Effective Date: 30-AUG-13
Name: Raquel Gopal	Name: Isaura Duarte	Review Date: 30-AUG-16
Signature: on file	Signature: on file	Supersedes: WIN/V/4048 (05-FEB-09)
Date: 09-AUG-13	Date: 09-AUG-13	TrackWise record no.: 3504

1. Changes since last revision

WIN reviewed to reflect changes following restructuring of the Agency and implementation of Volume 9B of The rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use.

2. Records

The periodic safety update report (PSUR) submission cycle is managed in SIAMED. SIAMED also includes information on the time-frame and the type of pharmacovigilance data to be submitted with the renewal application.

The template for renewal assessment reports is managed by the Veterinary Regulatory and Organisational Support section (VROS) of the Veterinary Medicines sector and renewal assessment reports for each application are created, managed and circulated by the VROS section.

The template for the preparation of a PSUR assessment report, if necessary for preparation of Annex IV of the renewal assessment report, is available as a SIAMED template (*PSUR 17 - Assessment report)*.

The formats for a PSUR, PSUR addendum report and a PSUR summary bridging report are described in Volume 9B of *The rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use* (http://ec.europa.eu/health/files/eudralex/vol-9/vol_9b_2011-10.pdf).

The PSUR assessment report, as included as Annex IV of the renewal assessment report, is available in the safety file and core master file of the relevant product.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

3. Instructions

Abbreviations and definitions

AA	Administrative assistant in the Veterinary Regulatory and Organisation Support section of the Veterinary Medicines sector
DLP	Data lock point
MAH	Marketing authorisation holder
PAM	Post-authorisation measure
PhV SA	Scientific administrator for pharmacovigilance in the Animal and Public Health section of the Veterinary Medicines sector
PM	Project manager in the Veterinary Regulatory and Organisation Support section of the Veterinary Medicines sector
PSUR	Periodic safety update report
SIAMED	Database for the tracking of procedures for centrally authorised products

Instructions

Pre-submission

The information on the pharmacovigilance data required for the renewal application is to be included in the renewal reminder letter sent to the MAH and may also be given at a pre-submission meeting with the MAH which the PhV SA should be invited to attend, where necessary.

PM

- Three months before the renewal application is due, request AA to prepare a renewal reminder letter to be sent to the MAH following receipt of input from PhV SA on pharmacovigilance data to be included in renewal application.
- If a pre-submission meeting takes place with the MAH, invite PhV SA to attend to provide details of the pharmacovigilance data for inclusion in the renewal application.

AA

- Three months before the renewal application is due, upon request from PM, prepare a renewal reminder letter to send to the MAH, liaising with PhV SA for completion of the details of the pharmacovigilance data for inclusion in the renewal application, as detailed below

AA
in liaison with PhV SA

- Retrieve the time-period to be covered by the pharmacovigilance data for submission with the renewal application from SIAMED. Depending on the situation the following pharmacovigilance data are necessary:

    1. A PSUR or a PSUR addendum report:

        a. If the renewal submission date corresponds with the routine PSUR submission date and the DLP is approximately 60 days prior to the submission date, a PSUR should be submitted with

the renewal application.

b. If renewal submission date is more than 60 days after the last DLP, a PSUR addendum report covering the period from the last DLP and approximately 60 days prior to the renewal submission date should be included.

2. A PSUR summary bridging report is usually required unless a PSUR is included in the renewal application that covers the period since authorisation or last renewal; or if only one PSUR has been submitted to the Agency since the last renewal.

AA

- Ensure SIAMED includes the PAM for the PSUR or PSUR addendum report, if applicable, and the PSUR DLP and submission dates specified in the renewal reminder letter.

Validation and assessment

Upon receipt of renewal application from PM:

AA

- Agree on the time available for pharmacovigilance data validation with PM. Inform PhV SA of receipt of renewal application and deadline for validation of pharmacovigilance data (usually within 5 working days). Update the PSUR section of the renewal assessment report template to indicate which documents are included in the renewal application. If a full PSUR is to be provided prepare a PSUR assessment report template (using SIAMED template *PSUR 17 - Assessment report)* for inclusion in Annex IV of the renewal assessment report template. If a PSUR addendum is provided, delete Annex IV from the renewal assessment report template.

PhV SA

- Review the pharmacovigilance data in the renewal application for compliance with the renewal reminder letter, Volume 9B and any previous recommendations from CVMP PSUR assessment reports, if applicable (see WIN/V/4028 for further instructions on PSUR validation). Inform PM of outcome of validation. If necessary, forward request for missing data to PM for communication to the MAH, indicating whether the deficiencies would prevent validation of the application.

PM

- If applicable, communicate request for additional data to MAH, as indicated by PhV SA. Upon receipt of response from MAH, forward to PhV SA for review.

PhV SA

- If additonal data is requested from the MAH, upon receipt of response from PM, review data and inform PM of outcome of validation.

During assessment

AA

- Upon receipt of (co-)rapporteur's renewal assessment report from PM, forward to PhV SA for review. Forward any comments received from PhV SA to rapporteur for consideration.
- Include PSUR data in PAM module in SIAMED to reflect conclusions and administrative information relevant to the pharmacovigilance

	recommendations in (co)-rapporteur's assessment report and update, as required, in light of any changes to the rapporteurs final assessment report agreed.
PhV SA	• Upon receipt of the (co)-rapporteur's renewal assessment report from PM, review report (section on pharmacovigilance data and Annex IV, if applicable), in particular, for the following: ▪ regulatory consistency; ▪ conclusions in light of the pharmacovigilance data assessed - ensure these are justified clearly in the assessment report; ▪ any request for one additional renewal - check that the proposal is in line with the *Reflection paper - Criteria for requiring one additional five-year renewal of the marketing authorisation on basis of Pharmacovigilance grounds* (EMEA/CVMP/430630/2006-Rev.1; Revision 14 May 2008); ▪ any other pharmacovigilance recommendations e.g. re-starting of the PSUR cycle, requests for specific monitoring etc.. Ensure recommendations are appropriately substantiated. • If applicable, prepare and send comments to PM for communication to the rapporteur within 10 calendar days (by day 55 of the renewal procedure). Review updated rapporteur's assessment report when received from PM. • If an additional renewal or PSUR cycle re-start are recommended email AA to request SIAMED to be updated accordingly following adoption of opinion. • If applicable, forward comments from PhV SA on (co)-rapporteur's assessment report to rapporteur. When received, forward updated rapporteur's renewal assessement report to PhV SA for review, before inclusion in CVMP mailing.
PM	• After drafting CVMP assessment report, forward to PhV SA for review. • If one additional renewal or re-start of PSUR cycle have been recommended forward draft CVMP opinion to PhV SA for review of standard text included in Annex II of opinion.
PhV SA	• Upon receipt of the CVMP assessment report and opinion from the PM, review the documents for editorial consistency (e.g. ensure terminology is consistent with Volume 9B) and, if applicable, ensure standard text concerning pharmacovigilance requirements is included in Annex II of the opinion and consistent with the CVMP assessment report. Amend assessment report and opinion as necessary, informing PM whether any changes were made.

Post opinion

Following publication of the Commission Decision:

AA	• Update PSUR data in PAM module in SIAMED with any changes to PSUR submission cycle, additional requirements concerning future PSURs or new PSUR procedure if one additional renewal has been requested.