EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Handling of withdrawals of applications for marketing authorisation of veterinary medicines		
Applies to: Veterinary Medicines Division		
Status: **PUBLIC**		Document no.: WIN/V/4031
Lead Author	Approver	Effective Date: 15-MAY-14
Name: Barbara Cyrus	Name: Fia Westerholm	Review Date: 15-MAY-17
Signature: on file	Signature: on file	Supersedes: n/a
Date: 05-MAY-14	Date: 05-MAY-14	TrackWise record no.: 4032

1. Changes since last revision

New WIN.

2. Records

The original, signed hard copy of the withdrawal letter is filed in the master file. Electronic copies of all major correspondence are saved in the relevant product folder in DREAM (*Cabinet 01. Evaluation of Medicines/V-C/[…]*).

SIAMED should be updated accordingly.

Renaming and moving the product folders

Folders for products (initial) or procedures (post-authorisation) should be re-named by adding "withdrawn", the (step in) procedure, and the date of withdrawal. Following withdrawals of an initial application the relevant folder should also be moved from *Cabinet 01. Evaluation of medicines/V-C/2. active* to *Cabinet 01. Evaluation of medicines/V-C/3. withdrawn*.

Naming convention for folders:

- Initial applications:
  <Product name> <No.>-withdrawn-D120-<date>; OR
  <Product name> <No.>-withdrawn-presubmission<-date>;
- Post-authorisation (extensions and major type II variations only):
  YYYY-MM-DD-<product name><proc. No.>-withdrawn

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

3.1. Documents related to this procedure

- CVMP reflection paper on publication of withdrawals of marketing authorisation applications for veterinary medicinal products (EMEA/CVMP/425558/2006-Rev.1; http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500005259.pdf);
- Table of centralised procedures (EMA/265910/2014; unpublished CVMP document listing rapporteurs and peer reviewers)
- SOP/V/4037 on Preparation of the EPAR for a veterinary medicine
- SOP/V/4038 on Updating of the EPAR for a veterinary medicine
- WIN/V/4035 on Secretarial tasks for processing veterinary EPARs

3.2. Definitions & abbreviations

AA	Administrative assistant (here: administrative assistant in vet.applications team)
AR	Assessment report
AST	Assistant (here: product assistant in DEM or VROS)
CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	Document Records Electronic Archive Management
EPAR	European Public Assessment Report
HSer	Head of service (here: Head of V-VM-DEM service)
HDep	Head of department (here: Head of V-VM department)
PM	Project manager (here: scientific administrator responsible for product/procedure)
Product shared mailbox	Agency mailbox to collect product-specific electronic correspondence; the email addresses are based on the product name and EMA number (e. g. Kexxtone-2235@ema.europa.eu)
SOBRA	Scientific overview and benefit-risk assessment
V-VM-DEM	Development and Evaluation of Veterinary Medicines service
V-VM	Veterinary medicines department
WEPAR	Withdrawal EPAR

3.3. Scope

Applications for a marketing authorisation can be withdrawn at different stages in the initial application or post-authorisation procedure (i. e. during pre-submission, validation or evaluation phases).

“Pre-submission” covers any period between the receipt of a letter of intent and validation of the application.

“Withdrawals during evaluation” concern a validated dossier and include any withdrawal from the start of the assessment (Day 1) until adoption of an opinion (i.e. before opinion). For withdrawals prior to the adoption of a list of questions (i. e. between day 1 and day 120) no withdrawal assessment report is published; only a statement summarising the circumstances of the withdrawal is prepared for publication on the EMA website.

Post-authorisation withdrawals (for the purposes of this WIN) only affect applications for major changes, i. e. extensions and “major” Type II variations (for example new indications or changes/ additions of a non-food target species). *This WIN does not deal with the withdrawal of a marketing authorisation or the post-authorisation withdrawal of certain presentations (e.g. certain pack sizes, or pharmaceutical forms).*

3.4. Instructions

Step		Action	Responsibility
1		**Intent to withdraw**	
	1.1	Once notified about the intention to withdraw an application, advise the applicant to submit a formal letter of withdrawal. The letter should be addressed to the project manager, and provided electronically to vet.applications@ema.europa.eu, with a copy to the product shared mailbox. *NB: It is recommended to use the template letter published in the annex to the CVMP reflection paper.* Proceed to 2.	All
2		**Receipt of letter of withdrawal**	
	2.1	Forward letter to relevant colleagues in the service (PM, AST, and HSer; also HDep, if applicable, and/or vet.applications@ema.europa.eu, if received elsewhere).	AA (PM/AST)
	2.2	Save letter in DREAM in the appropriate product/procedure folder for the current step in the procedure (e.g. if it arrived between Day 120 and Day 180, it should be saved in this subfolder). Indicate in product (sub-) folder name that the application has been withdrawn.	AST
	2.3	Update SIAMED. Highlight the relevant procedure and choose “Withdrawal request” from the scrolling list of options. Enter the date of receipt of the withdrawal letter/email and record the justification in “Comments”.	AA

Step	Action	Responsibility
2.4	Does the withdrawal notification concern a post-authorisation procedure? If yes, go to 2.5 If no, go to 2.7	
2.5	Does the post-authorisation withdrawal notification concern an extension or "major" Type II variation? If yes, go to 2.7 If no, go to 2.6	
2.6	Update EPAR module 8 ("steps taken") accordingly. Proceed to 7 (*End of procedure*)	AST
2.7	Notify rapporteurs, peer reviewers and CVMP via CNA (for initial applications) or CVE (for post-authorisation applications) mailbox, copy product shared mailbox. Inform any other groups involved in the assessment (e.g. CVMP working party or scientific advisory group) and SME office, where relevant.	PM PM
2.8	Add letter and last adopted version of the SOBRA or draft CVMP AR (as appropriate/available) to the mailing for the next CVMP meeting for information. *NB: PM will indicate in case CVMP discussion is required exceptionally.*	AST
2.9	Was the withdrawal notification submitted prior evaluation (i.e. in the pre-submission phase and/or before validation)? If yes, go to 3 If no (i. e. withdrawal during evaluation phase), go to 4	
3	**Withdrawal during pre-submission/validation phase**	
3.1	For withdrawals prior to evaluation, remove rapporteurs and peer reviewers of the withdrawn application from table listing rapporteurships and peer reviewers.	AA
3.2	Rename (see *Heading 2. "Records"*) and, if applicable move, product/procedure folders in DREAM: • for <u>new products</u> withdrawn prior to submission should be moved from "intended" to "withdrawn" applications; • for <u>major post-authorisation changes</u>, folder remains in the post-authorisation folder, but the word "withdrawn" and the date of withdrawal should be added to the folder name.	AA
3.3	Update SIAMED. Proceed to 7 (*End of procedure*)	AA

Step		Action	Responsibility
4		**Withdrawal during evaluation phase**	
	4.1	Insert information about the withdrawal in the (draft) press release, as appropriate (use the standard wording as in the reflection paper on publication of withdrawals).	PM
	4.2	Was the withdrawal notification submitted prior to the adoption of a list of questions (i.e. between day 1 and day 120)? If yes, go to 4.3 If no (withdrawal after day 120), go to 5	PM
	4.3	Prepare "withdrawal statement" document (introductory summary for Webteam) and initiate sign-off for publication. Proceed to 6	PM
5		**Preparation of Withdrawal EPAR (WEPAR)**	
	5.1	*Within 1-2 weeks following letter of withdrawal:* Follow WIN/V/4035 for the preparation of the withdrawal EPAR (WEPAR). Set up template from SIAMED, and copy text of last adopted version of the SOBRA or draft CVMP AR, as appropriate. Send template for completion to PM.	AST
	5.2	*Within 2-3 weeks following receipt of templates*: Prepare draft WEPAR in style of CVMP AR based on relevant text, shortening details and/or stating open conclusions as appropriate, and delete confidential information. Initiate internal review in line with current internal review procedure for assessments. *NB: The introduction text should be suitable for extraction to be published separately (see below).*	PM AST
	5.3	*Within 2 weeks following drafting of WEPAR*: Follow-up and/or monitor internal review of WEPAR draft 1 (review includes HSer, HDep, project team members, any other colleagues involved.	PM
	5.4	*Within 1-2 weeks following internal review*: Finalise draft WEPAR (draft 2) and send to rapporteurs for review (indicating 2 week deadline).	PM/AST
	5.5	*Within 2-3 weeks following receipt of rapporteurs comments:* Finalise WEPAR (initiating a further round of internal review, in case of major changes).	PM
	5.6	Add WEPAR for endorsement to mailing for next CVMP meeting.	AST
	5.7	*Within 1 week following CVMP approval*: Send draft WEPAR to applicant for review (with 2 week deadline) to identify commercially confidential information.	PM

Step		Action	Responsibility
	5.8	*Within 1-2 weeks following receipt of comments from applicant:* Finalise WEPAR by deleting commercially confidential information and make necessary corrections (initiate another round of internal review and/or liaise with rapporteurs in case of major changes).	PM
		Send final WEPAR to rapporteurs for information.	AST
	5.9	Copy introduction text from WEPAR into new document "withdrawal statement" (*NB: This document is used by the Webteam to summarise the procedure*.)	AST
		Initiate sign-off, using EPAR transmission slip (*see WIN/V/4035*), to be signed-off by PM, HSer and HDep.	AST
		Proceed to 6.	
6		**Publication**	
	6.1	Following sign-off, forward letter of withdrawal (pdf), WEPAR (if applicable) and withdrawal statement to web publishing services for publication.	AST
		In case of post-authorisation application withdrawals: Update EPAR module 8 ("steps taken") accordingly.	
	6.2	Rename (see *Heading 2. "Records"*) and, if applicable move, product/procedure folders in DREAM: • for <u>new products</u> folders should be moved from "active" to "withdrawn" applications; • for <u>major post-authorisation changes</u>, folder remains in the post-authorisation folder, but the word "withdrawn" and the date of withdrawal should be added to the folder name.	AST
	6.3	Update SIAMED: Update timetable with the date of the draft WEPAR sent to the Applicant and the date of the Applicant's response.	AA
		Proceed to 7.	
7		**End of procedure**	