



Work instructions

Title: Secretarial tasks for initial preparation and update of veterinary European public assessment reports (EPARs)		
Applies to: Veterinary Medicines		
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1. Changes since last revision

Minor revision to reflect current procedure: additional step in the sign-off procedure and clarification on refusal EPAR.

2. Records

See sections 3.4.2. and 3.7.

3. Procedure

3.1. Related documents

- SOP/V/4037 on Preparation of a European Public Assessment Report (EPAR) for a veterinary medicinal product following positive or negative opinion
- SOP/V/4038 on Updating of the European Public Assessment Report for a veterinary medicinal product
- EPAR templates in SIAMED/cross procedures folder
- EPARs on the EMA website
(http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/vet_epar_search.jsp&mid=WC0b01ac058008d7a8)
- Interinstitutional style guide - language codes (see section 7.2.1)
(<http://publications.europa.eu/code/en/en-370200.htm>)



- Background note EPARs (EMA/130820/2014)
- EPAR translations tracking list (EMA/5118/2014)
- User guide on how to generate PDF versions of the product information – veterinary (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2011/02/WC500101956.pdf)
- The EPAR transmission slips (TS–NEW EPAR-VET, TS-revised EPAR-VET, TS-suspended EPAR, TS-Refusal EPAR and TS-Withdrawn EPAR) can be found in Microsoft Word under File – New – My templates – More – Transmission Slips.
N.B.: *External Web Team no longer requires hard copy of EPARs transmission slips which are submitted electronically via email instead (see section 3.7). Nevertheless, this does not impact on the internal sign-off process in the V-DEM Service where the signature book along with a hard copy of the EPAR transmission slip is still necessary for management review. However for V-ROS procedures, except for major type II variations, the internal sign-off process is now done electronically (see section 3.6).*

3.2. Definitions

AST	Assistant
CCI	Commercially confidential information
CD	Commission Decision
CdT	Centre de Traduction (Translation Centre)
cMF	Core master file
CVMP	Committee for Medicinal Products for Veterinary Use
CVMP AR	CVMP assessment report
DREAM	Document records electronic archive management system
EPAR-SA	EPAR Scientific administrator
EPAR	European public assessment report
EMA	European Medicines Agency
HDep	Head of department
HSer	Service head
MA	Marketing authorisation
MAH	Marketing authorisation holder
PI	Product information
PM	Project manager
QRD	Quality review of documents
REPAR	Refusal EPAR
SIAMED	European Medicines Agency product information and application tracking system

SME	Small and medium-sized enterprise
SOP	Standard operating procedure
SPC	Summary of product characteristics
V-VM-DEM	Development and Evaluation of Veterinary Medicines (Service)
V-VM-ROS	Veterinary Regulatory and Organisational Support (Service)
WEPAR	Withdrawal EPAR

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3.3. Modules of EPARs

3.3.1. Modules of a new EPAR

Name (on web page)	Description	Translated (by whom?)
Authorisation details	Information displayed under the <i>Authorisation details</i> tab and the <i>PI</i> tab on the EPAR website. Template generated from SIAMED.	No
EPAR - Summary for the public	Generated from SIAMED in a question and answer format. Drafted by medical writers (Product-related Information to the Network Service) and reviewed by rapporteurs/MAH/PM.	Yes (EMA/CdT)
EPAR - All authorised presentations	Prepared from Annex A (opinion) (MAH to use templates available from website).	Yes (MAH)
EPAR – Public assessment report	Converted from CVMP AR by applying the standard SIAMED template. Reviewed by MAH. Final decision on CCI is taken by EPAR-SA in consultation with rapporteurs, if required.	No
EPAR - PI	Annexes I (SPC), II (includes conditions of the MA for MAH), IIIA (labelling) and IIIB (package leaflet). Provided by MAH and translations checked by Member States.	Yes (MAH; for SMEs: EMA/CdT)

3.3.2. Modules of an EPAR update

Name (on web page)	Description	Translated (by whom?)
Authorisation details	Information displayed under the <i>Authorisation details</i> tab and the <i>PI</i> tab on the EPAR website. Template generated from SIAMED.	No
EPAR – Summary for the public	Updated by medical writers (Product-related Information to the Network Service) and reviewed by MAH, PM and rapporteurs in a question and answer format.	Yes (EMA/CdT)
EPAR – All authorised presentations	MAH to provide the updated versions.	Yes (MAH)
EPAR – Variation/Extension assessment report	Converted from CVMP AR by applying the standard SIAMED template. Reviewed by MAH. Final decision on CCI is taken by EPAR-SA in consultation with rapporteurs, if required.	No
Procedural steps taken and scientific information after authorisation	Table generated from SIAMED and reviewed by PM.	No
EPAR – PI	Annexes I (SPC), II (includes conditions of the MA for MAH), IIIA (labelling) and IIIB (package leaflet). Updated versions provided by MAH and translations checked by Member States, if required.	Yes (MAH; for SMEs: EMA/CdT)

3.4. Naming and saving of EPARs in DREAM

3.4.1. Naming EPARs

Naming of the different modules of the EPAR is based on the EMA product number, as allocated by SIAMED, and is aligned across all files. This is then followed by the name corresponding to the part of the EPAR and the language code (see section 3.1.). There should not be any spacing between the elements but dash.

Authorisation details (Product overview)	overview
EPAR – Summary for the public	summary
EPAR – All authorised presentations (Annex A)	AA
EPAR – Public assessment report	PAR
EPAR – Product information	PI (or keep the name given by the company)

If a file is created to update an existing published EPAR, the following naming applies in addition to the above:

EPAR – Variation assessment report	VAR followed by the variation in the format e.g. II for type II or X for extension
EPAR – Procedural steps taken and scientific Information after authorisation	steps after

The format for the file name is therefore:

V-<EMA product number>-<name as listed above>-<language code>¹

Examples:

- the file name for the authorisation details in English for Masivet (EMEA/V/C/000128) is:
V-000128-overview-en
- the file name for the EPAR Summary for the public in French for Inlacam (EMEA/V/C/002497) is:
V-002497-summary-fr
- the file name for the EPAR Variation assessment report - extension in English for Draxxin (EMEA/V/C/000077/X/0026) is:
V-000077-VAR-X-en
- the file name for the EPAR Variation assessment report - type II in English for Advocate (EMEA/V/C/000076/II/0022) is:
V-000076-VAR-II-en

¹ The format is temporarily replaced by "<Product name><V>-<EMA product number>-<PAR/VAR>-en" for the purpose of CVMP mailings only (3.5.4).

3.4.2. Saving EPARs

The EPAR folder structure is as follows:

- 0 Product overview
- 1 Summary for the public
- 2 Authorised Presentations
- 6 Scientific discussion²
- 8 Steps taken after authorisation³
- PI

All EPAR modules are saved directly in 07. EPAR sub-folders and updates of these documents are saved as new versions of the current file.

The document category for EPAR documents is “EPAR” with the exception of PI where it is “Product Information”.

3.5. Creating and formatting the EPAR

3.5.1. Authorisation details – Product overview (module 0)

AST generates the template from SIAMED⁴ and saves the document with the correct name (see section 3.4.) in DREAM under the relevant EPAR folder. AST ensures that the file is saved in word format (*.doc – Word 97-2003 Document) and not as Rich Text File (*.rtf).

After finalisation of variation or extension affecting product overview AST sends the DREAM link to PM for review and makes corrections if requested by PM.

3.5.2. EPAR - Summary for the public (module 1)

3.5.2.1. New EPAR

Following the adoption of the opinion by the CVMP the medical writers (Product-related Information to the Network Service) prepare the draft summary for the public using the template generated from SIAMED⁵ and after being reviewed by MAH, PM and rapporteurs, it is saved in the relevant EPAR folder in DREAM.

After receipt of the reviewed EPAR summary for the public from the medical writers (in agreement with rapporteurs, MAH and PM) AST starts internal circulation for final review and sign-off (EN only) before sending it to CdT for translations. AST makes corrections if requested.

Upon finalisation of EPAR summary for the public, AST submits the request for translations to TranslationsRequests@ema.europa.eu (with PM and product mailbox in cc) enclosing the final clean version of the EN EPAR summary for the public for translations to CdT⁶. Make sure to supply the final PI in all languages (in clean Word format if available) as supporting information (zip file) which will be

² Module 6

³ EPAR updates only

⁴ Use SIAMED template “EPAR – module 0” located in the cross procedures folder

⁵ Use SIAMED template “EPAR – summary for the public” located in the cross procedures folder

⁶ Use SIAMED template “EPAR – translation request email” located in the cross procedures folder

used as reference for translations

(http://emeaplus/EMEAPlus_WebsiteNew/Translations/html/EPARSection.htm).

Once the translations have been received from CdT, AST checks quality and formatting of the translations against the original document. They are saved in DREAM with the name given by CdT as a *.zip-file in the 05 Translation folder along with the e-mail received from CdT, and then saved in the relevant EPAR folder using the naming convention detailed above.

The translations are usually provided by the CdT after 2 weeks.

NB: *If the CD is still pending the date is not translated. Remember to add it separately for every language once it is confirmed using the format DD/MM/YYYY with the exception for Hungarian and Lithuanian where the date must be written in full.*

3.5.2.2. EPAR update

Translation requests for EPAR updates need to contain:

- EN final versions of the summary (in track changes and clean).
- Information on the latest CdT translation number for the relevant product, i.e. EMA-2010-0100-00-00, which can be retrieved from the EPAR translations tracking list (see section 3.1.).
- For translation into Croatian (hr), a separate request has to be submitted with clean EN final versions of the summary and final PI (English and Croatian) in Word format.

As previous language versions will no longer need to be provided to the CdT, it is important that:

- Any change in the EN version of the summary (i.e. insertion of the initial CD date or the removal of exceptional circumstances) is shown as track changes in the document.
- Any change in the CdT translations must be reported to translationsrequests@ema.europa.eu (this includes corrections done as a result of incorrect CdT translations, as well as in-house changes).

The translations are usually provided by the CdT after 2 weeks.

3.5.3. All authorised presentations (module 2)

Product AST uses Annex A translations prepared by the MAH in Word format as part of the opinion in all EU languages, ensuring the following:

- There should not be a copyright © symbol in the footer.
- Double check that the header of the table “EMA Procedure number” has been replaced by “EU (MA) Number”.
- Double check that the EMA number has been replaced with EU number (i.e. “EMEA/V/C/000xxx/x” to “EU/2/xx/xxx/xxx”)(the allocated EU numbers can be found in the draft CD)⁷.
- If Annex A has been submitted from the company with a cover page – delete this cover page as only the Annex A table is necessary for publication.
- Save Annex A translations in the following DREAM folder:

⁷ This is only relevant for new EPARs and EPARs with new presentations

- For initial applications: Cabinets/01. Evaluation of Medicines/V - C/2. Active applications/<product name>/01 Pre Authorisation/05 Translation/Day 237 Commission/Annex A
- For extension applications: Cabinets/01. Evaluation of Medicines/V - C/2. Active applications/<product name>/02 Post Authorisation/Post Activities/extension number/10 Translation/Day 237 Commission/Annex A

Annex A translations are then linked by EPAR AST in the relevant EPAR folder.

3.5.4. EPAR – Public assessment report and Variation assessment report (module 6)

This module of the EPAR is prepared by AST on the basis of the final CVMP AR.

- Once the PM has confirmed that the CVMP AR is finalised, AST prepares the module 6 by converting CVMP AR and adding appropriate standard text generated from SIAMED template⁸ making sure to add the appropriate sentence on the first page saying *“Assessment Report as adopted by the CVMP with all information of a commercially confidential nature deleted”* and include in the first page footer the EMA copyright sentence *“© European Medicines Agency, 20XX. Reproduction is authorised provided the source is acknowledged”*.
- AST saves the document in the relevant EPAR folder in DREAM and sends it to MAH via Eudralink⁹ (with rapporteurs and product mailbox in cc.) for identification of CCI. Two weeks deadline are given for comments.
- Once comments have been received from MAH:
 - AST saves the MAH comments as a new version of module 6 and the e-mail received from MAH in the “Post-opinion” folder in DREAM. Then AST sends the DREAM link to the EPAR-SA.
 - EPAR-SA reviews comments and proposals to identify necessary deletion of CCI¹⁰/corrections/editorials and implements them in track changes. Rapporteurs can be consulted in case of any scientific issue. Comments received from rapporteurs are saved by AST as a separate document in the “Post-opinion” folder in DREAM.
- After EPAR-SA finalises proposals, AST starts internal circulation for review and sign-off (latest track changes + semi-clean versions¹¹) before presenting it to CVMP for endorsement (CVMP for endorsement only applicable for initial and extension procedures). It should be noted that all modules 6 shall be included in CVMP agenda for endorsement as standard approach or silent endorsement if there are no substantial changes in the assessment for discussion.
- Before circulation to CVMP: AST renames temporarily module 6 in DREAM for the purpose of CVMP mailings only as follows: <Product name><V>-<EMA product number>-<PAR/VAR>-en and adds the label “For CVMP”. The document will be then renamed before the publication according to the EPAR naming convention by removing the product name in front of the name.

⁸ Use SIAMED template “EPAR – scientific discussion” located in the cross procedures folder

⁹ Use SIAMED template “EPAR – Draft EPAR to MAH” located in the cross procedures folder

¹⁰ For guidance on what is considered confidential information see *“Principles to be applied for the deletion of commercially confidential information for the disclosure of EMA document”* (EMA/45422/2006) and HMA/EMA guidance document on the identification of CCI and personal data

¹¹ Transmission slip signed off by AST, EPAR-SA, (PM), HServ and HDep

- Before the 1st CVMP mailing the EPAR-SA updates the background note in DREAM (EMA/130820/2014), which will be included for information in the CVMP agenda (item 2.5) along with module 6.
- After the CVMP endorses module 6, AST includes it along with the track changes versions in the final sign-off folder containing all EPAR's modules for release for publication.

3.5.5. Procedural steps taken and scientific information after authorisation - only for EPAR updates (module 8)

This document is prepared/updated by AST and approved by the PM. The document is generated from SIAMED¹². As the information which is in SIAMED is only generated once the procedure is closed, the information has to be filled in manually by PM if the procedure is not yet closed (i.e. before the CD date).

The document is saved in DREAM in the relevant EPAR folder with the correct name (see section 3.4.) ensuring that it is saved in word format (*.doc) and not Rich Text File (*.rtf). In order to know after which variation this module was updated when check in the new document in DREAM write under the version label the text 'Updated after <type of variation>-<number>' e.g. Updated after II-0006.

3.5.6. EPAR - Product information (PI)

The translations of the PI are supplied by the MAH, using the standard QRD templates (unless it is an SME, in which case EMA obtains the translations from the CdT). Translations of PI can only be prepared for publication once the post-opinion checking phase is complete (QRD and Standing Committee of the European Commission). If CD is due in 12 months, translations of updated PI can be prepared for publication after the post-opinion checking phase (if required).

The MAH is responsible for providing the final translations of PI in clean PDF format including bookmarks and document properties (see section 3.1.). The product AST should check only three languages including the authentic language (national language of MAH) to make sure they are presentable and without dates under points 10 of SPC and points 14 of package leaflet, without blank pages and without track changes. The font of the PI should be "Times New Roman" and font size 11, with the exception of the footer where a font size 8 should be used instead.

Final translations of the PI for new EPARs, received from MAH, are saved by the product AST under pre-authorisation in the folder "05 Translations". PI translations are then linked by EPAR AST in the relevant EPAR folder.

Final translations for EPAR updates are saved under post-authorisation in the relevant variation/renewal/extension product translation folder. They are then saved as links by the EPAR AST in the relevant EPAR folder, replacing the outdated links (old links are deleted by selecting "delete current link").

EPAR AST ensures that the CD date of the initial MA is always included in all language versions of the PI (specifically in SPC, section 9).

The Norwegian and Icelandic translations of the PI are also published.

¹² Use SIAMED template under EPAR "steps after" tab

3.6. Sign-off procedure

AST prints off the EN version of the affected parts of the EPAR, ensuring that the clean version is attached along with the comments received from EPAR-SA, HSer and rapporteurs, if any, and places them separately in the sign-off folder accompanied by the relevant Transmission Slip (see section 3.1.).

If it is an EPAR update the pages of the PI which have been changed (if any) have to be attached with track changes along with the whole clean PI.

After circulation of the sign-off folder AST implements in DREAM all the changes requested, if any and sends the final complete EPAR (English) to the applicant/MAH for information.

NB: *If the EPAR - summary for the public has already been approved by the HDep and sent for translation, this should be written as a comment on the transmission slip, as it will not need to be approved again (the relevant signed TS can be attached for information).*

In the V-ROS Service the sign-off, except for major type II variations, is done electronically via a general email sent from the AST to the PM and then forwarded to the Head of Service for approval before being sent to the Webteam for publication.

3.7. Finalising the EPAR in G:drive for publication

Once the EPAR is finalised the EPAR modules are saved by AST in the newly created product folder VET EPAR Working area (location: G:\External Information Draft\Vet Working Area) in the following format:

- Module 0: EN Word
- Module 1: EN Word + PDFs in all lang (check bookmarks and document properties)
- Module 2: PDFs in all lang (check document properties)
- Module 6: EN PDF (check bookmarks and document properties)
- Module 8 (only for extensions and annual reassessment): EN PDF (check document properties)
- PI: PDF in all lang (check bookmarks and document properties)

When the final sign-off is complete, the VET EPAR Working folder is copied to the Sign-off folder (location: G:\External Information Draft\SIGN OFF\Veterinary Unit). AST informs the External Web Team via email (webteam@ema.europa.eu) that the content of the EPAR has been checked and verified by the relevant procedure manager and that all modules have been saved on the G-drive for the publication on the EMA public website.

3.8. After publication

3.8.1. Closing down procedure in SIAMED

Upon confirmation of the EPAR publication from the External Web Team, AST archives the transmission slip in the EPAR transmission slip folder along with the confirmation e-mail received from External Web Team. AST then also closes the procedure in SIAMED, only if the status is "completed": under the "view application" tab select "add/edit EPAR details" and then enter the publication date and the revision number. If the EPAR is incorporating other procedures especially after extensions, types II and renewals procedures, tick the appropriate ones. ASTs to make sure that no procedure is left out in the EPAR update. The only exception are type II procedures or transfers with immediate Commission

Decision, where the EPAR can only be updated after the CD, so these can be omitted if the CD has not been adopted yet.

AST notifies Veterinary Medicines Division (with product mailbox in cc) on EPAR publication.

3.8.2. cMF

AST adds the EPAR to cMF by saving the published EPAR documents previously saved in the G: drive as a zip file in DREAM (04 Post-opinion folder)¹³ and then adds the zip folder to cMF.

The EPAR folder in the G: drive can now be deleted.

3.9. Refusal EPAR (negative opinion)

The preparation for a Refusal EPAR (REPAR) is the same as for a normal EPAR after the adoption of the negative opinion by CVMP. However, if there is a request for a re-examination then the process will be deferred to take place after the outcome of the re-examination. The REPAR only has 2 parts which are listed below along with the naming of these parts.

3.9.1. Components of a REPAR

Name (on web page)	Description	Translated?
Refusal Q&A - module 1	Prepared by medical writers and reviewed by PM	Yes (EMA/CdT)
Refusal Assessment Report (RAR) – module 6	Prepared and finalised by PM	No

3.9.2. Naming of REPAs

Refusal Assessment Report: The document is given the name of the DREAM document number e.g. *EMA-CVMP-12345-2011*

3.10. Withdrawal EPAR (WEPAR)

All the steps are described in WIN/V/4031.

¹³ In case of new application