EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Preparation of an initial European Public Assessment Report (EPAR) for a veterinary medicinal product following positive or negative opinion		
Status: **PUBLIC**		Document no.: SOP/V/4037
Lead author	Approver	Effective date: 10-JUN-15
Name: Karen Quigley	Name: Kornelia Grein	Review date: 10-JUN-18
Signature: on file	Signature: on file	Supersedes: SOP/V/4037 (01-OCT-07)
Date: 08-JUN-15	Date: 08-JUN-15	TrackWise record no.: 3134

1. Purpose

The purpose of this SOP is to provide the project managers (PM) and assistants (AST) in the Veterinary Medicines department with guidance on the procedure for the preparation of the initial European Public Assessment Report (EPAR) from the adopted Committee for Medicinal Products for Veterinary Use (CVMP) Assessment Report (AR) following initial marketing authorisation applications with a positive or a negative opinion (refusal of marketing authorisation).

It does not cover the preparation of an EPAR following the withdrawal of an application.

2. Scope

This SOP applies to staff in the Veterinary Medicines department and specifically the Development and Evaluation of Medicines service.

3. Responsibilities

It is the responsibility of the Head of Veterinary Medicines (HDep) (delegated to Head of Service (Hser) for Development and Evaluation of Veterinary Medicines) to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

4. Changes since last revision

Rebranding and business review following the new corporate identity of the Agency. Update to reflect current practice/terminology in preparation of EPARs. Steps taken for assessment (previously module 7) are no longer executed. Publication of divergent position(s) has been included.

5. Documents needed for this SOP

Template 1	Communication to the applicant asking for comments/proposals on deletion of commercially confidential information in the public assessment report
Template 2	Email requesting translation of summary for the public
Template 3	Letter to applicant with final EPAR
Template 4	EPAR publication transmission slip – positive opinion
Template 5	EPAR publication transmission slip – negative (refusal) opinion

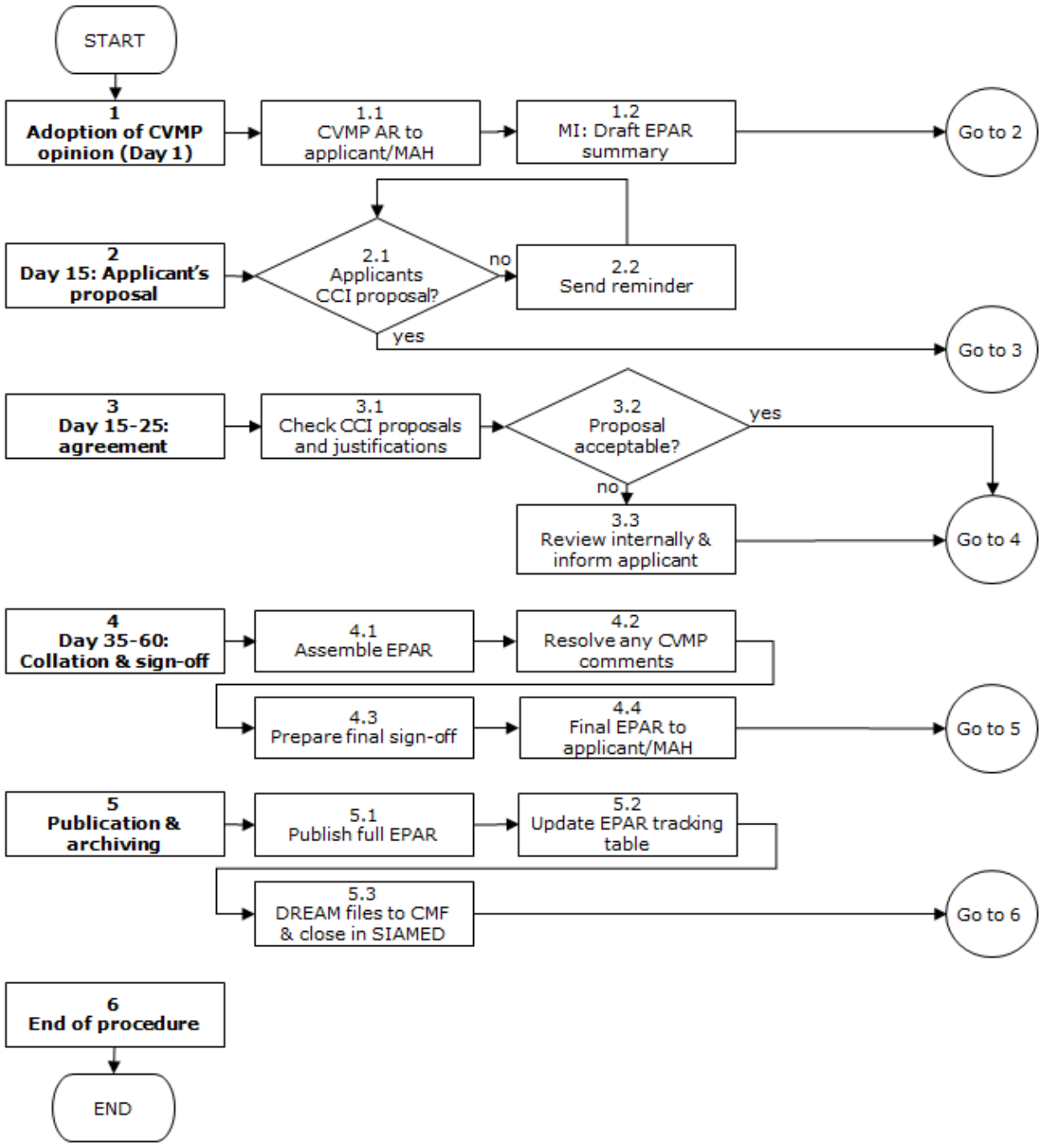
6. Related documents

- WIN/V/4035 – Secretarial tasks for preparation of veterinary European public assessment reports (EPARs)
- EMEA/45422/2006 - Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents
- SOP/H/3131 – Preparation and updates of EPAR summaries by Medical Information
- SOP/V/4038 – Updating of the European Public Assessment Report for a veterinary medicinal product
- EMEA/CVMP/459912/2006 - Reflection paper on the publication of the CVMP's negative opinion and refusal to recommend the granting of a marketing authorisation for veterinary medicinal products

7. 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
ECO	EPAR module 6 co-ordinator (PM responsible for CCI coordination for all vet EPARs)
EPAR	European public assessment report
EMA	European Medicines Agency
HDep	Head of department
HSer	Service head
MA	Marketing authorisation
MAH	Marketing authorisation holder
MI	Medical information (service)
PAR	Public assessment report
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)

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



9. Procedure

Step	Action	Responsibility
1.0	**Adoption of the opinion by CVMP (Day 1)**	
1.1	Send out CVMP AR to the applicant/MAH AST to send the adopted CVMP AR (which should include as an appendix the divergent position(s), if any, copied and pasted without signatures from the opinion) by Eudralink, requesting the applicant/MAH to identify those issues that are considered to be commercially confidential information (CCI) and to make a proposal including justifications for any deletions/alternative wording, within 15 calendar days (*Template 1*). In case of a refusal (negative opinion), the timing for sending this depends on whether the applicant/MAH asks for a re-examination: • if the applicant/MAH decides not to ask for re-examination: send the adopted CVMP AR to the applicant/MAH; • if a re-examination has been/will be requested: send the CVMP AR on the day after adoption of the CVMP opinion for the re-examination procedure.	AST
1.2	Draft summary for the public For positive opinions: the draft EPAR summary is prepared by Medical Information as outlined in *SOP/H/3131*, reviewed by PM and then sent to the rapporteurs for review. The summary is sent to the MAH for information. The final version to be prepared by day 35 after adoption of the opinion is then signed off by the HSer/HDep and sent to the Translation requests email box for translation into all EU languages by CdT (*Template 2*). Proceed to step 2	MI/PM/AST
2.0	**Day 15: applicant's proposal**	
2.1	On day 15: Applicant's proposal received? If yes, go to step 3 If no, go to Step 2.2	
2.2	Send e-mail reminder(s). Go to step 2.1	AST
3.0	**Day 15-25: Agreement**	
3.1	Day 15-22: Check the acceptability of the proposals and justifications for deletion of CCI with:	ECO

Step	Action	Responsibility
	• PMs/HSer/similar products, • Rapporteurs/CVMP, only if the proposals for deletion impact on the scientific integrity of the CVMP report. Only confidential information, factual errors and grammar mistakes should be amended.	
3.2	Is applicant's proposal acceptable? If yes, go to step 4 If no, go to step 3.3	
3.3	Day 22-25: Reach agreement on applicant's proposals. Questions regarding proposals from the applicant need to be discussed with ECO/HSer/responsible PM. Involvement of the Legal service may be sought at this stage. Organise internal meeting, record outcome in DREAM and inform applicant of outcome. ECO to ensure that all confidentiality issues have been resolved. Consult rapporteurs if needed. Proceed to step 4	ECO
4.0	**Day 35-60: Assembling EPAR & sign-off**	
4.1	Day 35-45: Assemble EPAR.	
	AST to format and name files in line with *WIN/V/4035*.	AST
	a. Complete product overview Create product overview from SIAMED, in EN only (*not applicable for REPAR*). For refusal EPAR provide a link to the CVMP press release in EN only.	AST
	b. EPAR summary for public from CdT AST to save all EU languages to DREAM *product name* EPAR 07 folder and format and name documents (*not applicable for REPAR*).	AST
	c. All authorised presentations Annex A is received from applicant in all EU languages including EU numbers (*not applicable for REPAR*).	AST
	d. Prepare PAR AST to format and name the document. Table PAR with changes visible for next CVMP meeting for endorsement.	ECO/AST
	e. Product information The adopted product information is received from applicant as bookmarked pdf-file in all EU languages (*not applicable for REPAR*).	AST
4.2	Check if comments have been received on PAR from CVMP	ECO/AST

Step	Action	Responsibility
	members and discuss any comments received with the CVMP member and the rapporteur to resolve. Delete all comments to prepare a clean final version.	
4.3	Day 45-60: Agency sign-off	
	Prepare the final sign-off folder of all modules and circulate to (ECO/PM/HSer/HDep) for approval with the transmission slip for publication within 30 days of the Commission Decision (CD) being issued.	AST
	The EU numbers are included in Annex A by the MAH. AST to check prior to publication.	AST
4.4	Send final complete EPAR (English) to applicant/MAH for information (*Template 3*).	AST
5.0	**Publication of EPAR & archive**	
5.1	Commission Decision date +30 days	
	The documents signed off at step 4.3, as well as all the documents and translations processed are sent off for web publication using template email (*Template 4/5*).	AST
	NB: Publication can only take place once the CD has been issued, and should be published within 30 days of the issue of the CD.	
5.2	The EPAR tracking table is updated with the new EPAR details and date of publication. Notify Veterinary Medicines Division (with product mailbox in cc) of EPAR publication.	AST
5.3	Commit to Core Master File (cMF) all final files in DREAM. Close the application in SIAMED.	AST
6.0	**End of procedure**	

10. Records

EPARs are part of the cMF and should be archived according to *SOP/PDM/1004*.

Electronic documents are saved in the appropriately labelled product folder (07 EPAR) in DREAM.