EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Preparation and updates of EPAR summaries by Product-related Information to the Network Service		
Status: **Public**		Document no.: SOP/H/3131
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Signature: on file	Signature: on file	Supersedes: SOP/H/3131 (23-SEP-10)
Date: 10-Mar-2014	Date: 28-Mar-2014	TrackWise record no.: 3783

1. Purpose

The purpose of this standard operating procedure (SOP) is to detail the process for preparing European public assessment report (EPAR) summaries for human medicines when first authorised, and for the subsequent updating of the EPAR summaries in the post-authorisation phase. EPAR summaries correspond to the requirements of Regulation EC 726/2004, article 13, § 3:

"The European Public Assessment Report (EPAR) shall include a summary written in a manner that is understandable to the public. The summary shall contain in particular a section relating to the conditions of use of the medicinal product."

2. Scope

This SOP applies to the medical writers (MedWs) in Product-related Information to the Network Service (S-CO-PIN), and assistants and Administrators responsible for liaison with patients' and consumers' organisations (PCOs) in the Patients and Healthcare Professionals Department (S-PHP). It is only relevant for EPAR summaries. Some activities also involve product team leaders (PTLs) and PTL assistants in the Human Medicines Evaluation Division (E).

3. Responsibilities

It is the responsibility of staff in S-CO-PIN to identify the need for an EPAR summary or an EPAR summary update.

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It is the responsibility of the MedWs in S-CO-PIN to provide the EPAR summary or the update of the EPAR summary within the timelines laid down in this SOP or as agreed with the PTL.

Each Head of Division, Head of Department and Service Head under the responsibility of the Executive Director must ensure that this procedure is adhered to within their own division, department or service. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedures**.

4. Changes since last revision

Minor amendments have been carried out to reflect the updated guidance and template for EPAR summaries and the new organisational names in the Agency, and to amend reference to DREAM rather than EDMS.

5. Documents needed for this SOP

- Internal guidance for writing EPAR summaries (EMA/688762/2012 – internal working document)
- Internal glossary of medical terminology expressed in lay language (EMA/261764/2006 – internal working document)
- EPAR summary template (EMA/688155/2012)
- Table of standard text translated into all official European Union (EU) languages (EMA/354937/2008)

Templates can be found on the X: drive: X:\Templates\Others\H - Q&A documents.

6. Related documents

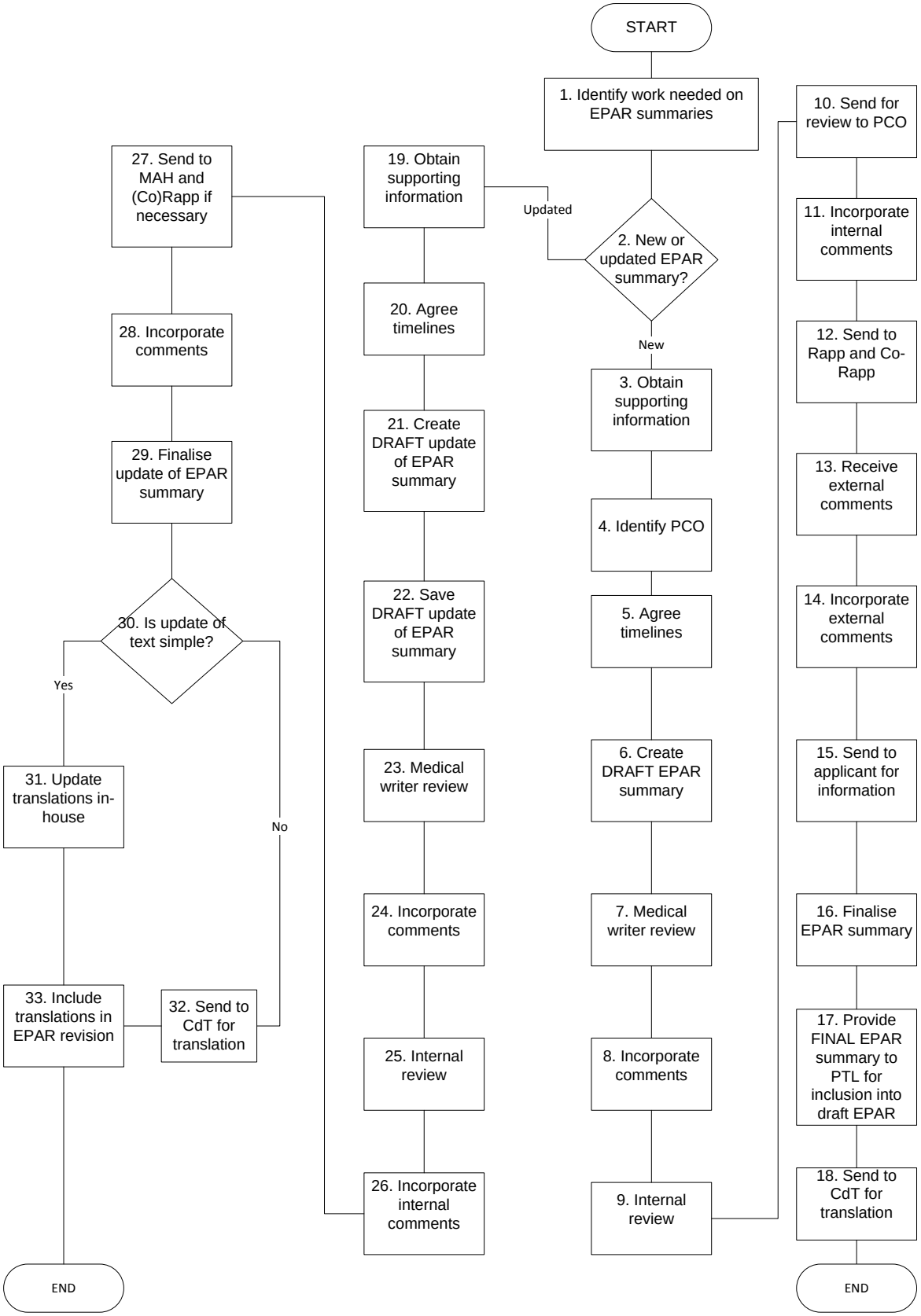
- Procedure for review of information on products by patients'/consumers' Organisations (EMA/174255/2010)
- SOP/PDM/1400: Translation workflow of EMA documents
- SOP/H/3003: Preparation of a European Public Assessment Report (EPAR) for a medicinal product following positive or negative opinion
- SOP/H/3012: Updating of the European Public Assessment Report for a medicinal product

7. Definitions

CdT	Centre de Traduction (Translation Centre)
CHMP	Committee for Medicinal Products for Human Use
DREAM	Document Records Electronic Archive Management
EPAR	European public assessment report
EPAR summary	Summary of the EPAR written in a manner that is understandable to the public (Regulation EC 726/2004, article 13, § 3).

EU	European Union
E Division	Human Medicines Evaluation Division
Lay language	Language understandable by someone not an expert in the field.
MAH	Marketing authorisation holder
MedW	Medical writer (specialist staff in S-CO-PIN whose main task is to write documents in lay language)
PCO	Patients'/Consumers' Organisation
PCOAd	Administrator in S-PHP responsible for liaison with PCOs
PTL	Product team leader
PTM	Product team member
S-CO-PIN	Product-related Information to the Network Service
SOP	Standard operating procedure
S-PHP	Patients and Healthcare Professionals Department

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



9. Procedure

Step	Action	Responsibility
1	**Identify work needed on EPAR summaries** At the time of CHMP opinion (Friday after CHMP plenary meeting - day 1), use the CHMP documents (e.g. table of decisions) and databases (e.g. SIAMED) to identify any new EPAR summaries that need writing and any EPAR summaries that need updating following post-authorisation procedures. EPAR summary updates are triggered by those variations that have an impact on the text of the EPAR summary, such as: • Extensions or restrictions of indication, including new contra-indications; • Additions of new strengths or pharmaceutical forms (annex II opinions); • Change of product name. Any EPAR summaries that have not been updated for over two years should also be updated.	MedW
2	**Does the MedW need to write a new EPAR summary or update an existing EPAR summary?** If NEW, go to **step 3.** If UPDATE, go to **step 19.**	MedW
	NEW EPAR SUMMARY	
3	**Obtain information to create EPAR summary** Obtain the adopted CHMP assessment report and product information from DREAM. Identify the PTL, relevant PTM, Rapporteur, Co-Rapporteur and contact person for the applicant (using the Product Overview and SIAMED databases).	MedW
4	**Identify PCO** Identify the PCO that will be consulted.	PCOAd

Step	Action	Responsibility
5	**Agree timelines with PTL** Agree with the PTL the timelines for the circulation and finalisation of the summary. Ensure that enough time is available for the entire review process to be finalised before the post-mail of the following CHMP meeting. If no timelines are agreed the default timelines described in this SOP apply[1].	MedW
6	**Create DRAFT EPAR summary (by day 4, or as agreed with PTL)** Using the 'Internal guidance for writing EPAR summaries' and the 'Glossary of medical terminology expressed in lay language', create the DRAFT EPAR summary according to the EPAR summary template. The EPAR summary is written in English. Save the summary in the appropriate folder in DREAM (4 Post Opinion/EPAR preparation/summary).	MedW
7	**Review of DRAFT EPAR summary by MedWs (by day 4, or as agreed with PTL)** Send a locator to the new DRAFT EPAR summary to all other MedWs in S-CO-PIN, asking for feedback within three working days.	MedW
8	**Incorporate MedWs' comments** Update draft, taking MedWs' comments into account to create DRAFT I EPAR summary. Save as the next integer version in DREAM.	MedW
9	**Internal review of DRAFT I EPAR summary (by day 8, or as agreed with PTL)** Send a locator to DRAFT I EPAR summary to the PTL and the relevant PTM, asking for feedback within three working days.	MedW
10	**Send DRAFT I EPAR for review to PCO (by day 11, or as agreed with PTL)[2]** Send the DRAFT I EPAR summary to the representative of the appropriate PCO using EudraLink, giving a deadline for comments of 10 calendar days. See 'Procedure for review of information on product by Patients'/Consumers' Organisations' (EMA/279083/2006).	PCOAd

[1] The timelines in this SOP apply when there are four weeks between the CHMP meeting when the medicinal product receives a positive Opinion and the subsequent CHMP meeting. Whenever there is more or less time, timelines need to be adjusted accordingly.
[2] For generic, biosimilar or informed-consent medicinal products, this step can be omitted.

Step	Action	Responsibility
11	**Incorporate internal comments**	
	Update draft, taking internal comments into account to create DRAFT II EPAR summary.	MedW
	Save as the next integer version in DREAM.	
12	**Send DRAFT II EPAR summary for review to Rapporteur and Co-Rapporteur (by day 14, or as agreed with PTL)[3]**	
	Send the DRAFT II EPAR summary to the Rapporteur and Co-Rapporteur, asking for comments within five working days. Copy PTL in email.	MedW
13	**Receive external comments (by day 21, or as agreed with PTL)**	
	Receive comments directly from Rapporteur and Co-Rapporteur.	MedW
	Receive comments from PCO via PCOAd.	
14	**Incorporate external comments**	
	Update draft, taking external comments into account to create DRAFT III EPAR summary. If comments have been extensive, recirculate to PTL or PTM for brief feedback.	MedW
	Save as the next integer version in DREAM.	
15	**Send DRAFT III EPAR summary for information to applicant (by day 22, or as agreed with PTL)**	
	Send the DRAFT III EPAR summary to the contact person for the applicant using EudraLink, copying the PTL. Obtain email address from SIAMED, checking with PTL if necessary. Inform the contact person that any comments the MAH wishes to make should be received within five working days.	MedW
	If relevant comments are received from the applicant, incorporate them into the text, liaising with PTL or PTM if necessary. Record outcome of the review as a new version in DREAM.	
16	**Finalise EPAR summary**	
	Accept all changes and remove all comments to create FINAL EPAR summary for adoption. Save as the next integer version in DREAM.	MedW

[3] For generic, biosimilar or informed-consent medicinal products, this step can be combined with step 15.

Step	Action	Responsibility
17	**Provide FINAL EPAR summary to PTL for inclusion in draft EPAR (by day 32, or as agreed with PTL)**	
	Forward the FINAL EPAR summary to the PTL for inclusion in the draft EPAR in time for the CHMP post-mail.	MedW
	Inform applicant that EPAR summary has been finalised and provide feedback on comments if appropriate.	MedW
	Prepare version of summary including feedback on PCO comments.	MedW
	Feed back to PCO on comments received.	PCOAd
18	**Translation of EPAR summary**	
	Provide PTL assistant with FINAL EPAR summary.	PTL
	Send request for translation to translationsrequests@ema.europa.eu including: • FINAL clean EPAR summary (in English); • product information in all official EU languages in clean format and in a zip file (IS and NO not needed)[4].	PTL assistant
	Refer to SOP/PDM/1400.	
	Receive translated EPAR summaries from translationsrequests@ema.europa.eu on agreed date prior to publication.	
	Refer to SOP/H/3003.	
	UPDATED EPAR SUMMARY	
19	**Obtain information to create update of EPAR summary**	
	Obtain the adopted CHMP assessment report and the revision–marked product information for the procedures to be included in the update from DREAM.	MedW
	Check for any other procedures finalised since the last update of the EPAR summary using DREAM or SIAMED. Include these procedures in the current update as necessary.	
20	**Agree timelines with PTL**	
	Agree with the PTL the timelines for the circulation and finalisation of the summary.	MedW
	Ensure that enough time is available for the entire review process to be finalised before the expected date of the Commission decision, if applicable[5].	

[4] For further information, please see http://emeaplus/EMEAPlus_WebsiteNew/Translations/html/EPARSection.htm (internal access only).
[5] EPAR updates need to be published within 15 calendar days of the Commission decision and for those procedures with no Commission Decision within two months of the CHMP opinion or the positive notification (see SOP/H/3012). Since translation of EPAR summary updates takes up to 10 working days, finalising the English version by the expected date of

Step	Action	Responsibility
21	**Create DRAFT update of EPAR summary (by day 6, or as agreed with PTL)**	
	Locate the latest English version of the EPAR summary in DREAM.	MedW
	Using the 'Internal guidance for writing EPAR summaries' and the 'Glossary of medical terminology expressed in lay language', update the EPAR summary as appropriate according to the changes in the product information. Only the English version is updated at this stage.	
22	**Save DRAFT update of EPAR summary**	
	Create a new folder under '05 Post Authorisation/EPAR/EPAR summary working area' in DREAM. Indicate the variation number in the folder name, e.g. 'xx Update for II-41'.	MedW
	Save DRAFT update of EPAR summary in folder.	
23	**Review of DRAFT update of EPAR summary by MedWs (by day 6, or as agreed with PTL)**	
	Send a locator to the DRAFT EPAR summary to all other MedWs in S-CO-PIN, asking for feedback within three working days.	MedW
24	**Incorporate MedWs' comments**	
	Update draft, taking MedWs' comments into account to create DRAFT I update of EPAR summary.	MedW
	Save as the next integer version in DREAM.	
25	**Internal review of DRAFT I update of EPAR summary (by day 12, or as agreed with PTL)**	
	Send a locator to DRAFT I update of EPAR summary to the PTL. Copy the assistant responsible for the product in the email. Ask for feedback within five working days.	MedW
26	**Incorporate internal comments**	
	Update draft, taking internal comments into account to create DRAFT II update of EPAR summary.	MedW
	Save as the next integer version in DREAM.	

the Commission decision will allow translations to be returned in time for the publication deadline. For this SOP, a target of 29 days is used, which will allow 80% of EPAR summary updates to be completed prior to the Commission decision. This is calculated from EPAR summary updates completed between August 2008 and July 2010.

Step	Action	Responsibility
27	**Send DRAFT II update of EPAR summary to MAH (by day 20, or as agreed with PTL)**	
	Send DRAFT II update of EPAR summary to MAH for information[6]. Copy PTL and the assistant responsible for the product in the email. Give a deadline of five working days. Also send to (Co-)Rapporteur if their input is considered necessary, e.g. for extensions of indication or extensive changes to the text.	MedW
28	**Incorporate comments on DRAFT II update of EPAR summary**	
	Receive comments from MAH and (Co-)Rapporteur and incorporate them if relevant. Liaise with PTL as necessary. Record outcome of the review as a new version in DREAM.	MedW
29	**Finalise update of EPAR summary (by day 28, or as agreed with PTL)**	
	Remove all comments and finalise update of EPAR summary. Save FINAL update of EPAR summary as next integer version in DREAM. Do not remove tracked changes.	MedW
	Provide FINAL update of EPAR summary to the assistant responsible for the product in E division. Copy the PTL responsible for the product.	
	If the MAH provided comments, inform MAH that EPAR summary update has been finalised and provide feedback.	
30	**Update translations of EPAR summary**	
	Is the update of the EPAR summary text simple (i.e. deletion of entire bullet points, sentences or sections)?	
	If YES, go to **step 31**.	
	If NO, go to **step 32**.	
31	**Update translations of EPAR summary in-house (by day 43)**	
	Update all language versions of the EPAR summary in line with the changes made to the English version. Use the text from the 'Table of standard text translated into all official European Union (EU) languages' if appropriate.	PTL assistant
	Notify translationsrequests@ema.europa.eu of the in-house update and provide updated translations in clean Word format.	
	Go to **step 33**.	

[6] If the MedW and PTL agree, this step can be omitted for minor updates or for updates bringing summaries for generic medicinal products in line with the reference medicinal product(s).

Step	Action	Responsibility
32	**Send updated EPAR summary for translation (by day 29)**	
	Send request for update of translation to translationsrequests@ema.europa.eu including: • finalised update of the EPAR summary with tracked changes (in English); • finalised update of the EPAR summary in clean format (in English); • Quote of the latest CdT translation number, which can be found in the EPAR tracking spreadsheet[7]. Refer to SOP/PDM/1400.	PTL assistant
33	**Include updated EPAR summaries in EPAR revision (by day 44)**	
	Receive translated EPAR summaries from translationsrequests@ema.europa.eu on agreed date. Publish as part of the EPAR revision. **Refer to SOP/H/3012.**	PTL assistant

10. Records

EPAR summaries and all correspondence relating to them are part of the master file and should be kept accordingly.

[7] For further information, please see http://emeaplus/EMEAPlus_WebsiteNew/Translations/html/EPARSection.htm (internal access only).