EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Preparation of a Withdrawal Assessment Report – Orphan Maintenance following the request of withdrawal of an orphan designation after COMP review at time of Marketing Authorisation or Extension of Indication		
Applies to: D-DS-OME / E-PM / S-CO-OLD		
Status: **PUBLIC**		Document no.: WIN/H/3530
Lead Author	Approver	Effective Date: 30/05/2018
Name: Cinzia N'Diamoi	Name: Kristina Larsson	Review Date: 30/05/2021
Signature: ON FILE	Signature: ON FILE	Supersedes: Not applicable
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1. Changes since last revision

New WIN.

2. Records

The templates needed for these WIN can be found in the following folder on the X drive: Templates\Others\H - Orphan Medicines\Review of designation and market exclusivity.

Records produced from this procedure are stored in accordance with WIN/H/3047.

Review reports are versioned and labelled for tracking procedural steps and electronic verification process. Opinions are labelled for recording final version and possible corrections, revisions and corrigenda as applicable. Detailed labelling and versioning instructions are available in Cabinets/14. Working areas/14.01 D-Division/02. D-DS Activities/D-DS-OME Activities/Section activities/Templates and DREAM labels.

3. Instructions

Related documents

Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents (EMA/45422/2006)
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004043.pdf

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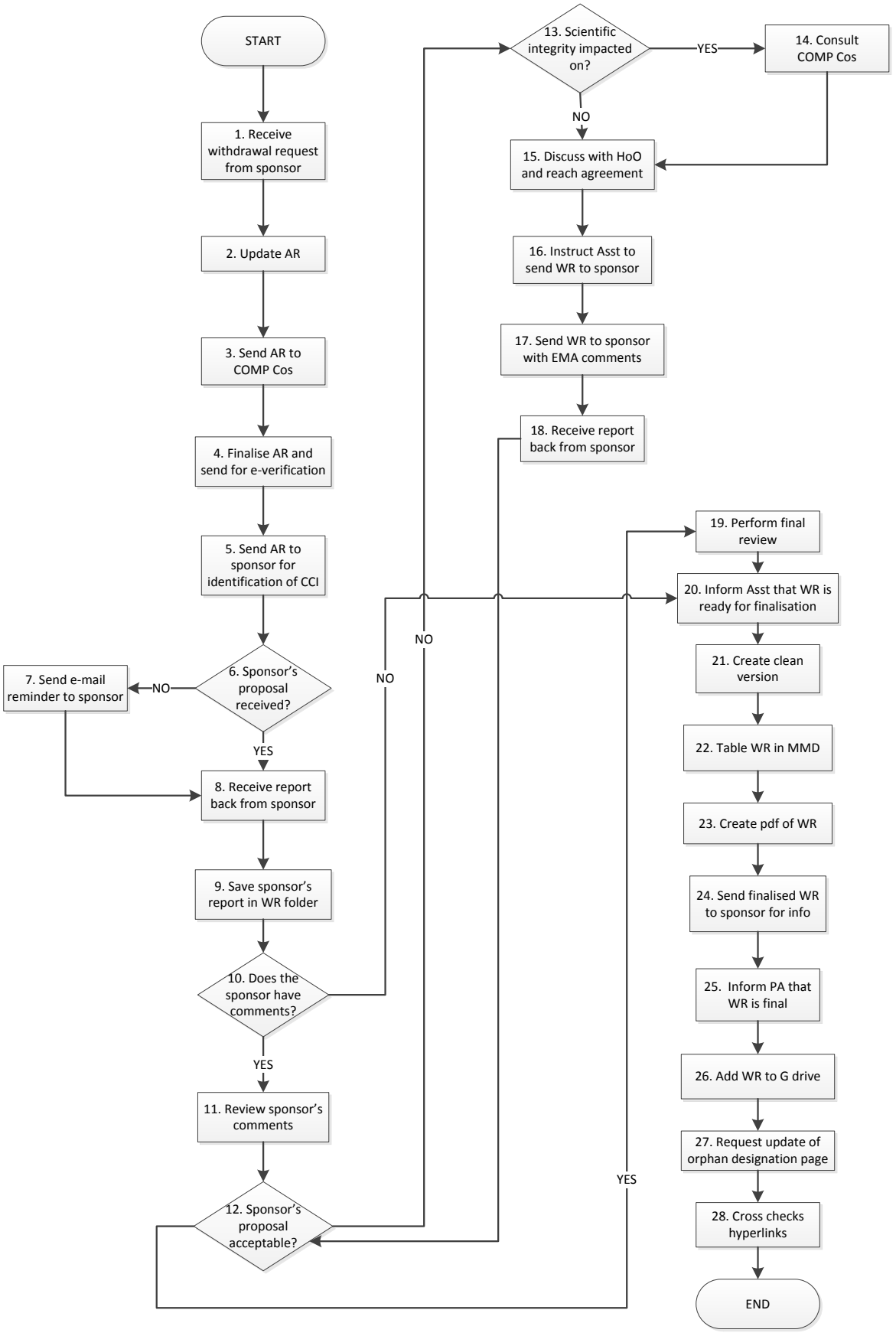
Definitions

AR	Assessment Report
Asst	Assistant
CCI	Commercially confidential information
COMP	Committee for Orphan Medicinal Products
COMP Cos	COMP coordinators
DREAM	Document records electronic archive management system
EMA	European Medicines Agency
EMA Co	European Medicines Agency coordinator
EPAR	European Public Assessment Report
E-PM	Procedure Management in Human Medicines Evaluation
Eudralink	The European medicines regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
HoO	Head of Office
MMD	Managing Meeting Document system
OME	Orphan Medicines office
OME Asst	Assistant in Orphan Medicines Office
OME Co	Co-ordinator (Scientific Officer in Orphan Medicines Office)
WR	Withdrawal report (Withdrawal Assessment Report – Orphan Maintenance)

Process map / flow chart



Procedure

Notes:

- All messages containing confidential information must be sent via Eudralink.
- Assistant in charge of saving AR versions received from COMP Co and sponsor.
- OME Co correspondence exchanges to be saved by relevant OME Co.

Step	Action	Responsibility
	Follows on from step 56 of SOP/H/3190 (Review of orphan designation at the time of granting/varying a marketing authorisation)	
1	Receive and save sponsor's request of withdrawal of the orphan designation from the Community Register of Orphan Medicinal Products.	OME Asst
2	Update AR: • document date: a) withdrawal request date or if already available b) withdrawal date as per EC notification; • after the Product and administative information table please add the following sentence: "Following communication of the outcome of the discussion, the sponsor formally requested the withdrawal of the orphan designation on <date>, prior to final opinion; • after the subtitle "Comments on sponsor's response to the COMP list of issues" please add in highlighted yellow "(to be deleted following consultation with the COMP before being sent to the company for review)".	OME Asst
3	Share the AR with the COMP Cos in charge of the procedure (with copy to all COMP members) giving 5 days to return comments. (template 1).	OME Co
4	Taking into account the comments received, if any, finalise the AR (remove all text following and including "Comments on sponsor's response to the COMP list of issues") and send to HoO for e-verification.	OME Co
5	Send the AR (in Pdf and Word format) by Eudralink to the sponsor, asking them to identify those issues that are considered to be commercially confidential and to make proposal including justifications for deletions/alternative wording within 7 calendar days (template 2). • *Rename pdf copy <product> - Withdrawl Assessment Report* • *Rename word copy <product> - Withdrawl Assessment Report – FOR DELETION OF CCI* • *Remove **all** supporting documents on 1st page of the Word document before sending*	OME Asst
6	If the sponsor's proposal has been received go to step 8. If the sponsor's proposal has not been received go to step 7.	OME Asst
7	Send e-mail reminder(s) to sponsor (template 3)	OME Asst
8	Receive report back from sponsor.	OME Asst

Step	Action	Responsibility
9	Create a subfolder in DREAM and save the version of the report received from the sponsor in this folder as a new document. *Name: "<Product> - Withdrawal Assessment Report - Orphan Maintenance"* *Document category: Assessement report* *Internal / external: EMA* *Responsible body: leave blank*	OME Asst
10	If the sponsor has no comments, go to step 20. If the sponsor has comments, go to step 11.	OME Asst
11	Review sponsor's comments within 3 working days and assess the acceptabily of the sponsor's proposal. *Note: only confidential information, factual errors and grammar mistakes should be amended.* *The document should show clearly in track changes and with the use of comments if the amendments/deletions are acceptable or, if not, provide reasons for their refusal.*	OME Co
12	If the sponsor's proposal is acceptable, label "WR agreement" and go to step 19. If the sponsor's proposal needs to be discussed further label "WR comments" and go to step 13.	OME Co
13	If the proposal for deletion of CCI impacts on the scientific integrity of the report go to step 14. If not go to step 15	OME Co
14	Consult COMP Cos on the sponsor's proposal(s) for deletion giving 5 working days to return comments. Then proceed to step 15.	OME Co
15	If needed, discuss sponsor's proposal with HoO and reach agreement (taking into account COMP Cos comments if any). *Involvement of the Legal Department and Regulatory Affairs can be sought at this stage if needed.*	OME Co
16	Inform Asst that the report is ready to be sent back to the sponsor.	OME Co
17	Send report with EMA comments to sponsor. Give sponsor 3 days to react to EMA comments. (template 4)	OME Asst
18	Receive report from sponsor and go back to step 12.	OME Asst
19	Perform final review: accept all track changes and delete any comments.	OME Co
20	Inform Asst that the report is ready to be finalised.	OME Co
21	Create clean version of the report: • insert date of withdrawal if not previously available; • delete "CONFIDENTIAL" and "Committee for Orphan Medicinal Products" from document properties; • change title to "Withdrawal Assessment Report - Orphan Maintenance"; • insert following text: **Note** Assessment report as adopted by the COMP with all information	OME Asst

Step	Action	Responsibility
	of a commercially confidential nature deleted. • Delete document label from footer. • insert publication disclaimer in first page footnote; "© European Medicines Agency, <year>. Reproduction is authorised provided the source is acknowledged." • Delete "CONFIDENTIAL" from the footer on subsequent pages; • remove EMA Co from "Product and administrative information" table; • remove Expert from "Product and administrative information" table where applicable; • in the "Product and administrative information" table under "Therapeutic indication" add link to relevant EPAR as follows: Further information on <product> can be found in the European public assessment report (EPAR) on the Agency's website ema.europa.eu/Find medicine/Human medicines/European public assessment reports. (insert link to EPAR page from "CHMP_details_master_list" EMA/243248/2013 https://docs.eudra.org/webtop/drl/objectId/090142b283cc8fec) • re-run table of contents; • save and check in.	
22	Table finalised report in MMD in the upcoming plenary folder for information.	OME Asst
23	Create pdf version of the withdrawal report and save in DREAM alongside Word version. Assign the following properties to the pdf document: • Title: Withdrawal Assessment Report - Orphan Maintenance - <product> • Author: European Medicines Agency Keywords: Withdrawal Assessment Report - Orphan Maintenance - <product>	OME Asst
24	Send finalised report to sponsor for information (template 5)	OME Asst
25	Inform the PA in E-PM that the withdrawal report is final and provide text for EPAR inclusion (template 6).	OME Asst
26	Upon notification by Procedure Assistance in E-PM to Webteam requesting the publication of the relevant EPAR, add the withdrawal report to the relevant External Information Draft sign off folder on the G drive. (G:\External Information Draft\SIGN OFF\Human Unit\Product name)	OME Asst
27	Request update of orphan designation page (orphan designation and review of designation tabs) (template 7)	OME Asst
28	Ensure all relevant hyperlinks are working.	OME Asst