EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Preparation of the public summary of opinion for orphan medicinal product designation		
Status: **PUBLIC**		Document no.: SOP/H/3046
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Signature: On file	Signature: On file	Supersedes: SOP/H/3046 (11-JUN-07)
Date: 30-AUG-11	Date: 01-SEP-11	TrackWise record no.: 2304

1. Purpose

This SOP describes the preparation and publication of public summaries of opinion following positive and negative opinions by the Committee for Orphan Medicinal Products on applications for orphan designation.

The source document for preparation of PSOs is the EMA/COMP Summary Report as adopted by the COMP. Information contained in the PSO represents a summary of knowledge on the medical condition and the medicinal product at the time of opinion. PSOs should be short factual documents written in a language style aimed at patients.

2. Scope

This SOP applies to the Public Information and Stakeholder Networking Section in the Medical Information Sector, the Orphan Medicines Section in the Human Medicines Special Areas Sector, and the Web Team in the Office of the Executive Director.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their sectors. The responsibility for the execution of each step of this procedure is identified under section 9.

4. Changes since last revision

- MedW in P-MI-PIN to draft PSOs and deal with internal (MedWs, E-Co) and external (sponsor and patients' organisations) comments (steps 1 to 14).
- SH in H-HM-OM to review PSO before publication (step 15).

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- MedW to implement SH in H-HM-OM changes as necessary (step 16).

5. Documents needed for this SOP

- Template 1: Positive Public Summary of Opinion (located at X:/Templates/Others/OD Post COMP/Positive Public Summary of Opinion)
- Template 2: Negative Public Summary of Opinion (located at X:/Templates/Others/OD Post COMP/Negative Public Summary of Opinion)
- Template 3: E-mail to sponsor to review draft PSO (located at X:/Templates/Others/OD Post COMP/ Public Summary of Opinion to sponsor via Eudralink)
- Guidelines for completing Public Summaries of Opinions for orphan designation (located at Cabinets/Old EDMS Structure/Operational Units/Human/Pre/H-HM/Orphan Drugs/Line Listings/Public Summary of Opinions \smop¯R¯Guidelines to template Public Summaries of Opinions¯EMEA-17061-02)

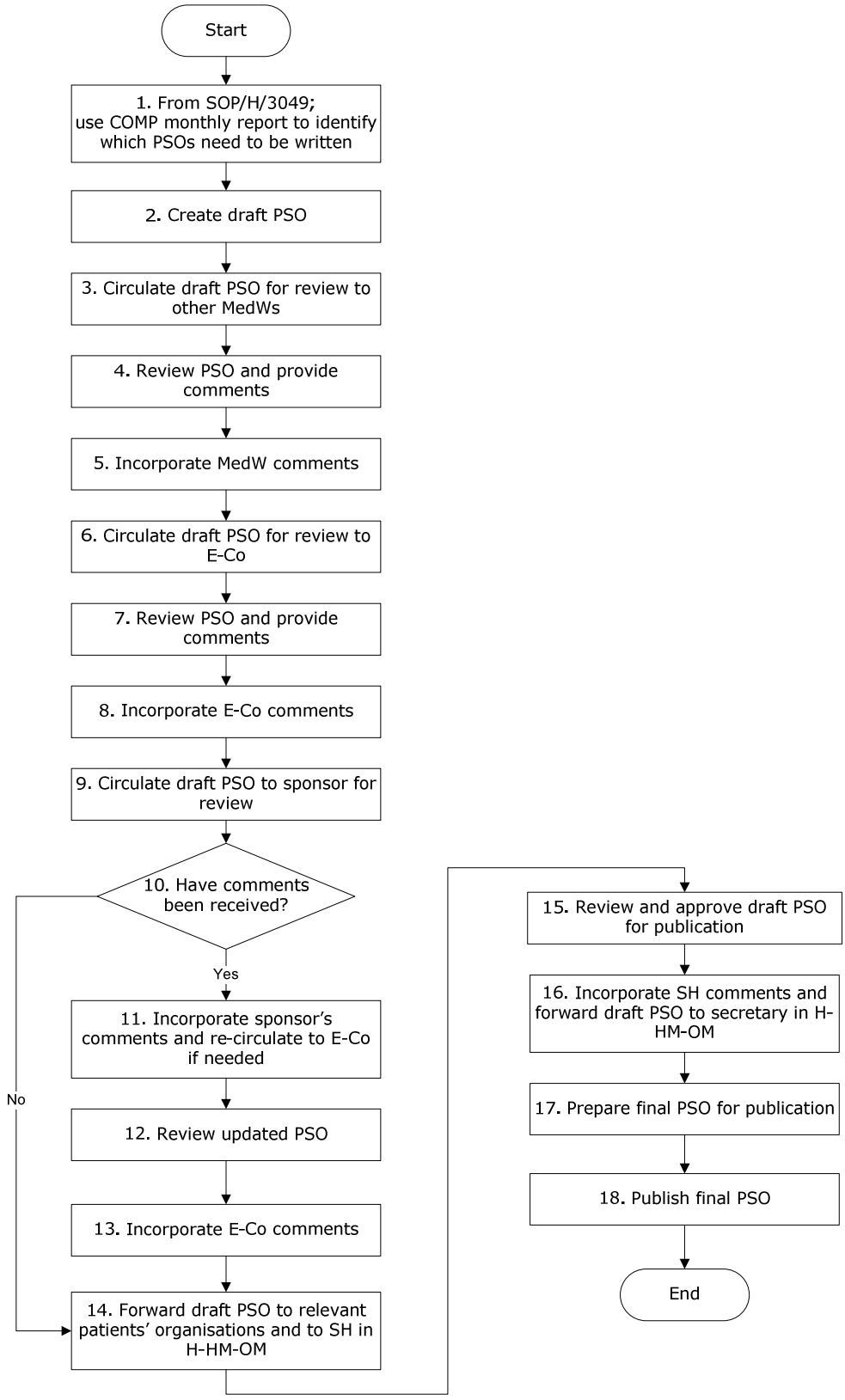
6. Related documents

- SOP/H/3049 on Orphan Medicinal Product Designation

7. Definitions

COMP:	Committee for Orphan Medicinal Products
E-Co:	EMA coordinator for the product
H-HM:	Human Medicines Special Areas Sector
H-HM-OM:	Orphan Medicines Section
MedW:	Medical writer
P-MI-PIN:	Public Information and Stakeholder Networking Section
PSO:	Public summary of opinion
SH:	Section Head

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



9. Procedure

Step	Action	Responsibility
	Drafting of PSO	
1.	From SOP/H/3049 At the time of the COMP opinion, refer to the COMP Monthly Report to identify the positive and negative opinions for which the PSOs are to be written.	MedW
2.	Write a first draft of the PSO, using Template 1 or 2, and the most recently published PSO for the same condition and/or medicinal product. Finalise this first draft within two weeks of the COMP opinion.	MedW
	Review of PSO	
3.	Send locator for the draft PSO to the other MedWs, requesting comments within three working days.	MedW
4.	Review draft PSO and send comments to MedW within three working days.	MedW (reviewers)
5.	On receipt of comments, incorporate as appropriate in the draft PSO within two working days.	MedW
6.	Circulate the draft PSO to E-Co responsible for the product, requesting comments within three working days.	MedW
7.	Review draft PSO and send comments to MedW within three working days.	E-Co
8.	On receipt of comments, incorporate as appropriate in the draft PSO within two working days.	MedW
9.	Provided the EMA/COMP Summary Report has been finalised, transmit the draft PSO (by Eudralink) to the appropriate sponsor for review (use Template 3 and contact details from Orphan Drug database). Give a deadline of five working days (approximately five weeks after COMP opinion).	MedW
10.	If comments are received, go to step 11. If no comments are received by the deadline, go to step 14.	MedW
11.	Save sponsor's feedback in DREAM. Implement comments, if appropriate, in the draft PSO within two working days. In case of major changes, re-circulate the draft PSO to the E-Co requesting comments within one day.	MedW
12.	If needed, review draft PSO and send comments to MedW within one working day.	E-Co
13.	Include comments from E-Co in PSO as appropriate.	MedW

Step	Action	Responsibility
14.	Forward the draft PSOs to the relevant patients' organisations for information and to SH in H-HM-OM for review (any comments to be provided within 5 working days). If major comments are received re-circulate PSO to E-Co.	MedW
15.	Review the draft PSOs and send any comments to MedW, approving PSO for publication subject to implementation of any requested changes.	SH in H-HM-OM
16.	Implement SH's comments within one working day as necessary, and forward draft PSO to secretary in H-HM-OM (approximately 6 weeks after COMP opinion).	MedW
	Finalisation of PSO	
17.	Upon receipt of EC decision, prepare final PSOs as follows: • Copy the PSOs and paste them in a folder on the local drive (not in DREAM). • Print all PSOs to be published and place them in a signature book in alphabetical order. • Create pdf versions of the PSOs. • Save the revised pdf documents in the SIGN OFF folder (G:\External Information Draft\SIGN OFF\Human Unit\SAOD\PSOs). Prepare transmission slip and transmit final PSOs for sign-off by SH or deputy within two working days. Transmit final PSOs to webteam.	Secretary in H-HM-OM
18.	Publish final PSO.	Webteam

10. Records

All documents, including correspondence, are filed in the electronic product file (specific "Public Summary of Opinion" folder in "Post-Opinion" folder).