



## Standard operating procedure

Title: Preparation and publication of COMP monthly report		
Status: <b>PUBLIC</b>		Document no.: SOP/H/3018
Lead author	Approver	Effective date: 20-DEC-2011
Name: Agnieszka Wilk-Kachlicka	Name: Jordi Llinares Garcia	Review date: 20-DEC-14
Signature: On file	Signature: On file	Supersedes: SOP/H/3018 (15-OCT-07)
Date: 15-DEC-11	Date: 15-DEC-11	TrackWise record no.: 3396

### 1. Purpose

To describe the procedure for preparing and publishing the Committee for Orphan Medicinal Products monthly report.

### 2. Scope

This SOP applies to the Orphan Medicines Section in the Human Medicines Special Areas Sector and the Communications and Media Team in the Office of the Executive Director.

### 3. Responsibilities

It is the responsibility of each Head of Sector/Section to ensure that this procedure is adhered to within their Sector/Section. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

### 4. Changes since last revision

- Extensive revision to simplify procedure.
- New Template 2 for calculation of percentage values in Annex 1 to the monthly report.
- Deletion of SOP annex.

### 5. Documents needed for this SOP

- Template 1: COMP monthly report template (located at X:\Templates\Others\OD Post COMP)



- Template 2: COMP monthly report annex 1 (located at X:\Templates\Others\OD Post COMP)
- Template 3: TS general content (transmission slip) (located at X:\Templates\File New\More\Transmission Slips)

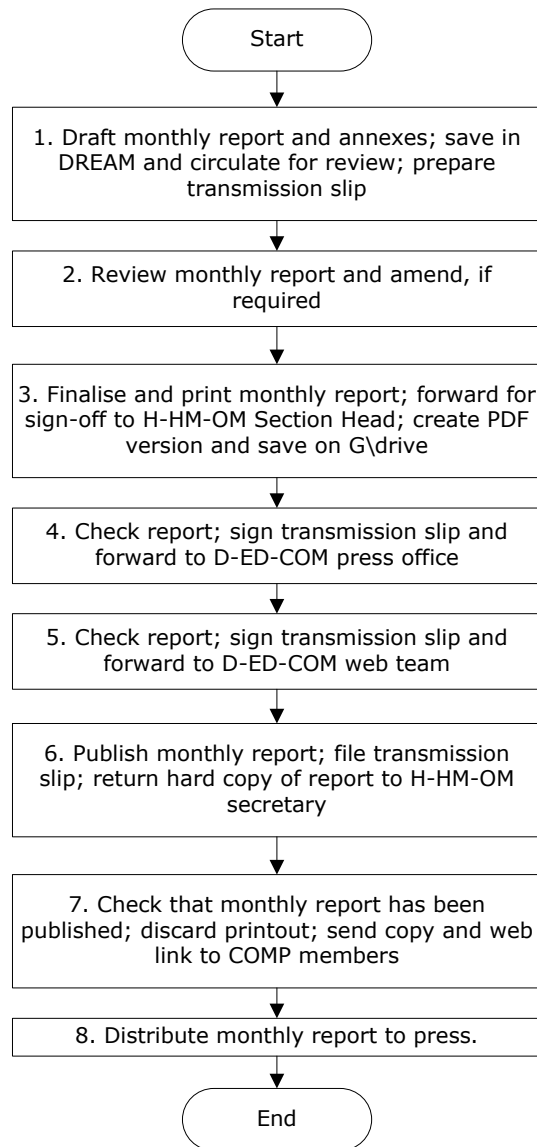
## **6. Related documents**

- COMP opinions
- Commission decisions on Orphan Medicinal Products
- Community Register of designated Orphan Medicinal Products

## **7. Definitions**

COMP:	Committee for Orphan Medicinal Products
D-ED-COM:	Communication and Media Team in the Office of the Executive Director
DREAM:	Document records and electronic archive management system
H-HM-OM:	Orphan Medicines Section
SOP:	Standard Operating Procedure

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



## 9. Procedure

Step	Action	Responsibility
<b>Preparation of monthly report</b>		
1	<p>Draft monthly report and annexes on the last day of the COMP meeting (use Templates 1 and 2).</p> <p>Save draft monthly report and Template 2 in relevant COMP meeting folder in DREAM. Send link by e-mail to H-HM-OM Section Head and copy D-ED-COM press office.</p> <p>Prepare and print transmission slip (Template 3).</p>	H-HM-OM secretary
2	Review draft monthly report and make amendments or insert comments in Word document, if required, by noon of the next day following the end of the COMP meeting.	H-HM-OM Section Head; D-ED-COM press office

<b>Step</b>	<b>Action</b>	<b>Responsibility</b>
<b>Finalisation/sign-off</b>		
3	Finalise and print monthly report. Forward hard copy by hand to H-HM-OM Section Head (followed by D-ED-COM press office) for sign-off according to attached transmission slip.  Create PDF version of monthly report and save in G:\External Information Draft\SIGN OFF\Human Unit\SAOD\COMP for publication on external website.	H-HM-OM secretary
4	Check monthly report. Sign transmission slip and forward report to D-ED-COM press office.	H-HM-OM Section Head
5	Check monthly report. Sign transmission slip and forward to D-ED-COM web team.	D-ED-COM press office
<b>Publication</b>		
6	Publish monthly report on external website.  File transmission slip and return signature folder with hard copy of monthly report to H-HM-OM secretary.	D-ED-COM web team
<b>Distribution</b>		
7	Upon receipt of hard copy of monthly report from web team check that monthly report has been published on external web site. Discard printout.  Send e-mail with monthly report (Word format) and web link to the COMP members.	H-HM-OM secretary
8	Distribute monthly report to press (DREAM link made available in step 1).	D-ED-COM press office

## 10. Records

The final monthly report and all relevant correspondence are stored electronically in the appropriate DREAM folder of the relevant COMP meeting.