



## Work instructions

Title: Scientific Advice/Protocol Assistance peer review		
Applies to: Scientific Advice Section in Human Medicines Special Areas Sector		
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### 1. Changes since last revision

A CHMP lead peer reviewer has been introduced.

A table with the products to be discussed by the CHMP has been introduced (step 4).

### 2. Records

Correspondence is saved in the appropriately labelled product folder in DREAM.

### 3. Definitions

AA:	Administrative assistant
CHMP:	Committee for Medicinal Products for Human Use
FAL:	Final advice letter
JR:	Joint report
PA:	Protocol assistance
SA:	Scientific advice
SAA:	Scientific advice administrator
SAWP SAA:	Scientific advice administrator responsible for SAWP secretariat
SAWP:	Scientific Advice Working Party
Sec:	Secretary



## 4. Documents needed for these WIN

- Peer Review tracking list (located in Cabinets\02b. Administration of Scientific Meeting\WPs SAGs DGs and other WGs\ CHMP – SAWP\ 1. Governance\ 02. Rules of procedure\ Peer review)

CHMP Peer review groups (located in Cabinets\02b. Administration of Scientific Meeting\WPs SAGs DGs and other WGs\ CHMP – SAWP\ 1. Governance\ 02. Rules of procedure\ Peer review

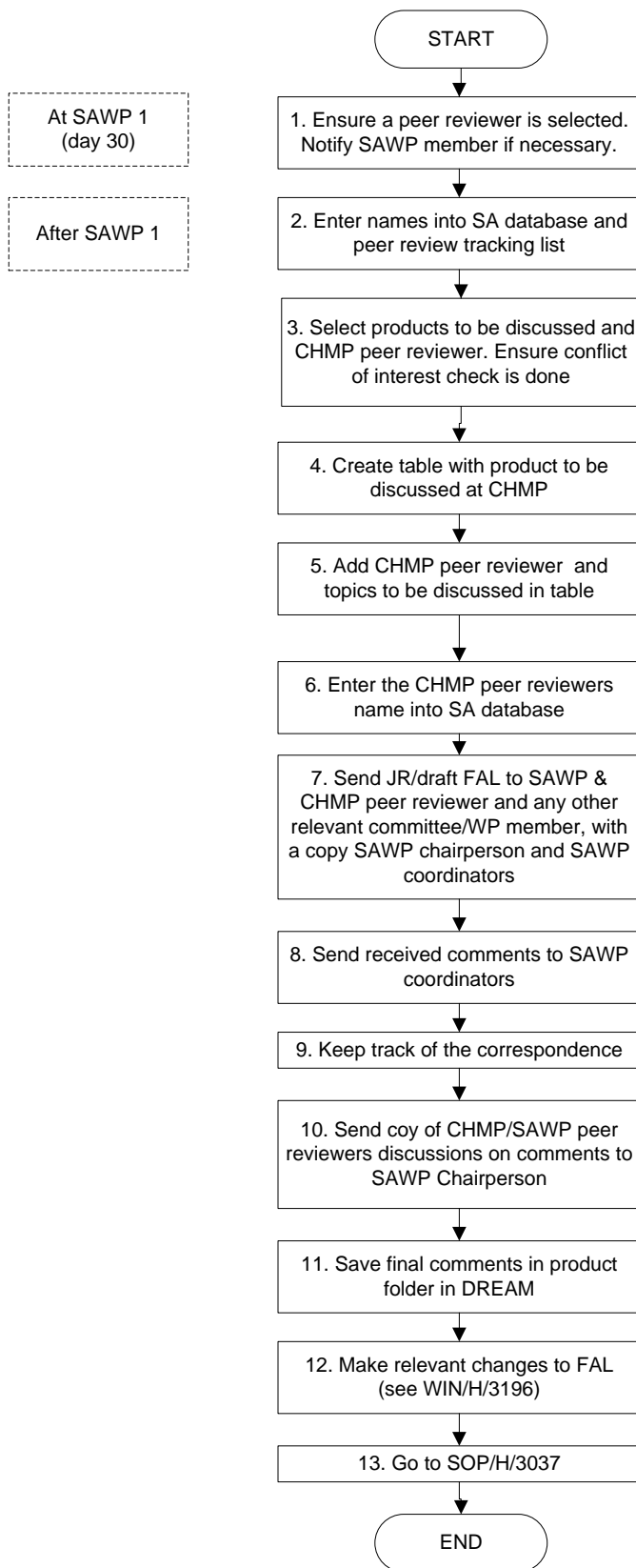
The following templates are located at X: Templates/Others/H-Scientific advice

- Template 1: Email to SAWP peer reviewer
- Template 2: Email to CHMP peer reviewer

## 5. Related documents

- SOP/H/3037: Scientific Advice and Protocol Assistance procedure
- WIN/H/3195: Organisation of Scientific Advice Working Party meetings
- WIN/H/3196: Finalisation of Scientific Advice and Protocol Assistance letters

## 6. Flow chart



## 7. Instructions

*Note: All SA FALs are peer reviewed by at least one SAWP member and when needed, one member of the committee or working parties involved in the advice.*

*The CHMP peer review the SA procedures selected for discussion at the CHMP meeting; these are, in most cases, the products for which there has been a discussion meeting. On a case by case basis products not being discussed at the CHMP plenary may also be selected for the CHMP peer review.*

*For each individual discussion at the CHMP one CHMP member is selected to lead the discussion.*

Step	Action	Responsibility
<b>At SAWP 1 (day 30)</b>		
1	Ensure a peer reviewer is selected at SAWP meeting after discussion of the first reports of the product. If the peer reviewer is selected by SAWP Chairperson, notify the SAWP member via email (Template 1).	SAWP SAA
<b>After SAWP 1 (for SAWP peer reviewer) or SAWP 2 (for CHMP peer review group)</b>		
2	Enter names of the selected SAWP members into the SA database and peer review tracking list.	AA/SAWP SAA
3	In liaison with SAWP Chairperson select the products to be discussed at the CHMP meeting and for each product select a CHMP member who will peer review. Ensure that the check of conflict of interest is done.	SAA
4	Create a table with all the products to be discussed at the CHMP.	Sec
5	Add the CHMP peer reviewer and the topics to be discussed in the table.	SAA
6	Enter the CHMP peer reviewers' names into the SA database.	AA/SAA
7	Send the JR or draft FAL to the SAWP peer reviewer, to the relevant other Committees/working parties members and when applicable, to the CHMP peer reviewer via Eudralink as soon as the JR is available. The template 2 text can be used (but not mandatory). Copy the SAWP Chairperson as well as the coordinators.	SAA
8	On receipt of comments from SAWP peer reviewers and from lead CHMP peer reviewer (should be sent at the latest 2 working days before the 1 <sup>st</sup> day of CHMP), ensure that SAWP coordinators receive copy.	SAA
9	Keep track of the email correspondence and responses from peer reviewer and coordinators.	SAA
10	On receipt of correspondence via email/Eudralink on discussions taking place between CHMP peer reviewer and SAWP peer reviewers on the comments, ensure that SAWP Chairperson receives a copy.	SAA
11	Save final relevant comments in product folder in DREAM.	SAA/(or if delegated) product Sec
12	Make relevant changes to the FAL (see WIN/H/3196).	SAA
13	Go to SOP/H/3037.	Sec