



Work instructions

Title: Scientific Advice and Protocol Assistance post-advice procedure (medicines for human use)		
Applies to: Scientific Advice Section, Scientific Advice Working Party		
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1. Changes since last revision

New WIN.

2. Records

All documents are saved electronically in the product folder\post advice:

documentum\Docbases\EDMS\Products\SA\HPA or SA\Post advice

Paper copies (including coordinators' final reports and all comments) are kept in the master file.

At the end of the procedure, the original, signed hard copy of the clarification letter\final advice letter corrigendum is placed in the master file.

3. Definitions

CHMP	:	Committee for Medicinal Products for Human Use
COMP	:	Committee for Orphan Medicinal Products
FAL	:	Final advice letter
MMD	:	Managing meeting documents
PA	:	Protocol assistance
SA	:	Scientific advice
SAA	:	Scientific advice administrator



SAWP : Scientific Advice Working Party
Sec : Secretary in Scientific Advice Section
WP : Working party

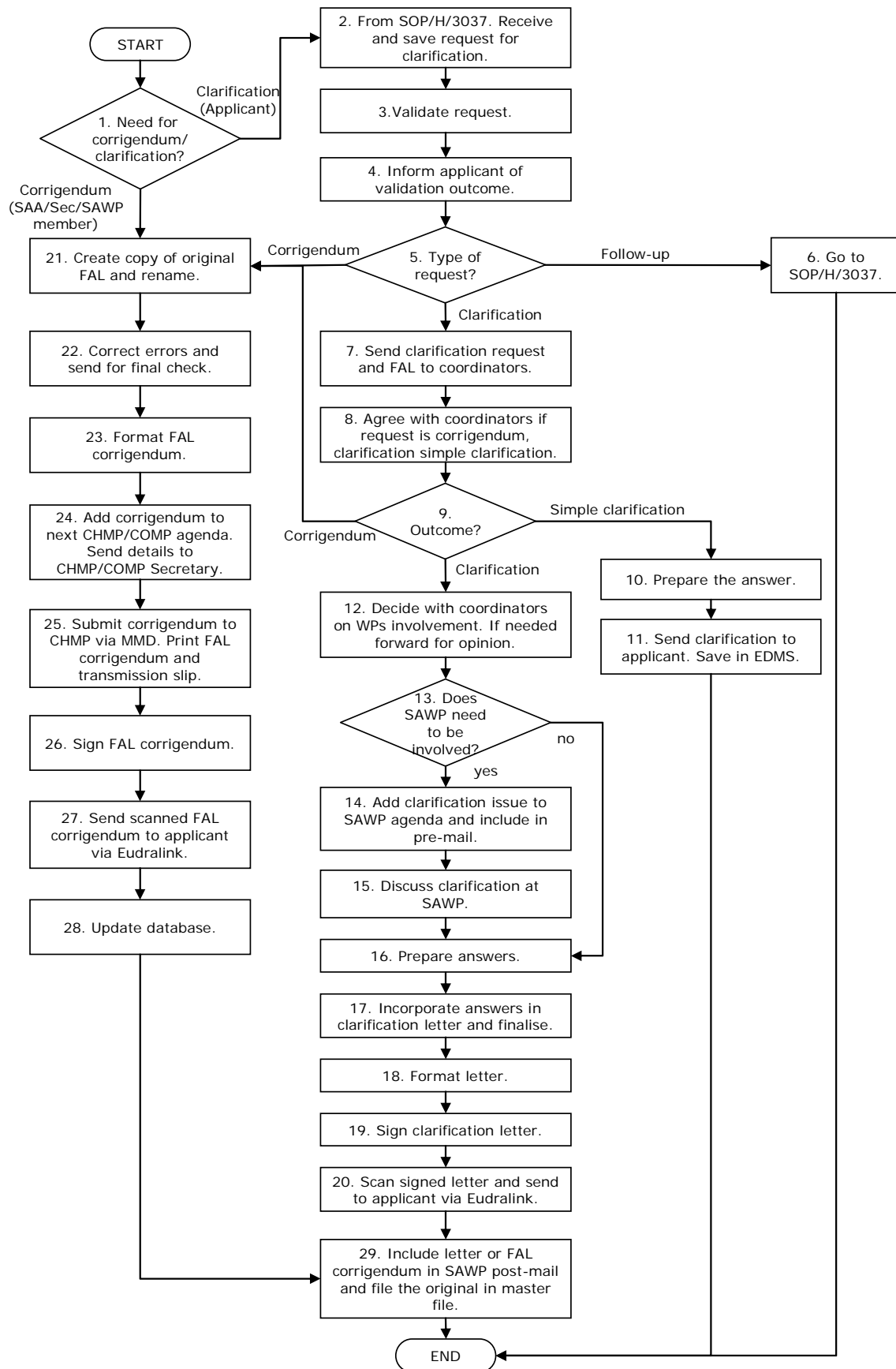
4. Documents needed for these WIN

Template 1: Clarification letter (located at X:\Templates\Others\H – Scientific advice)

5. Related documents

SOP/H/3037: Scientific Advice and Protocol Assistance procedure

6. Process map(s)/Flow chart(s)



7. Instructions

Step	Action	Responsibility
1	If an applicant sends in a clarification request, go to step 2. If SAA/Sec/SAWP member identifies the need for a corrigendum to FAL go to step 22.	SAA/Sec
2	From SOP/H/3037. Receive a request for clarification from the applicant and save it in EDMS.	Sec
3	Validate the request to determine whether it is a follow-up, clarification or corrigendum.	SAA with Section Head
4	Inform the applicant and the secretary about the validation outcome.	SAA
5	Outcomes of the validation: <ul style="list-style-type: none"> If the request is a follow-up procedure (includes new information and a new assessment is necessary to be able to respond to the request for clarification) go to step 6. If the request is valid as clarification go to step 7. If the request is referring to a typing / wording error and a corrigendum of FAL is required, go to step 21. 	SAA with Section Head
6	Follow SOP/H/3037. End of procedure.	
7	Send the clarification request together with the respective FAL to the coordinators of the original procedure.	Sec or SAA
8	Decide together with the coordinators if the request can be responded to directly, by a clarification letter, or if a corrigendum of the FAL needs to be created.	SAA & coordinators
9	Agreement outcome: <ul style="list-style-type: none"> If it is a simple clarification, that can be responded to directly, go to step 10. If a formal clarification letter will be created, go to step 12. If the request is a typing/wording error, go to step 21. 	SAA & coordinators
10	Prepare response to clarification request.	SAA & coordinators
11	Send clarification response to applicant and save it in EDMS. End of procedure.	SAA/Sec
12	Decide together with the coordinators on WPs involvement. If WPs need to be involved forward to other WPs for their opinion.	SAA & coordinators
13	Decide if the clarification needs to be discussed in the SAWP plenary	SAA &

Step	Action	Responsibility
	<ul style="list-style-type: none"> If SAWP needs to be involved, go to step 14. If clarification letter can be created directly, go to step 16. 	coordinators
14	Add the clarification issue to next SAWP meeting agenda and include in pre-mail together with the respective FAL.	Sec
15	Discuss the clarification issue at SAWP.	SAWP members
16	Prepare answers.	SAWP members
17	Incorporate the agreed answers (including WPs comments if applicable) in the clarification letter (Template 1) and finalise it.	SAA
18	Format the clarification letter and print for sign-off.	Sec
19	Sign the clarification letter.	Section Head
20	Scan the signed clarification letter and send it via Eudralink to the applicant. Go to step 29.	Sec
21	Create a copy of the original FAL and rename it (add "Corrigendum" to the title of the document). Add "Corrigendum" to the document number in the top right corner of the FAL corrigendum and in footer.	Sec
22	Correct the typing/wording errors in the FAL corrigendum and send it for final check to coordinators.	SAA
23	Format the finalised FAL corrigendum.	Sec
24	Inform the CHMP/COMP secretariat that the FAL corrigendum will be added to the next CHMP/COMP agenda. Send the procedure details (paragraph concerning the procedure from the SAWP agenda) to CHMP/COMP secretary.	Sec
25	Submit the FAL corrigendum to the CHMP via MMD. Print FAL corrigendum and transmission and forward for sign-off.	Sec
26	Sign the FAL corrigendum.	CHMP chair / COMP chair
27	Scan the signed FAL corrigendum and send it via Eudralink to the applicant.	Sec
28	Replace the FAL in the database with the FAL corrigendum.	Sec
29	Include the clarification letter/FAL corrigendum in the SAWP post-mail and file the original in the product master file.	Sec