



Work instructions

Title: Finalisation of Scientific Advice and Protocol Assistance letters		
Applies to: Scientific Advice Section in Human Medicines Special Areas Sector		
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1. Changes since last revision

Extensive revision to rewrite WIN.

2. Records

- All documents are saved electronically in product folder: Cabinets/01. Evaluation of Medicine/SA/H/2- New & Ongoing Requests/<actual year>
- FAL without track changes is copied into the folder: Cabinets/01. Evaluation of Medicine/SA/H/3- Final SA and PA Letters
- At the end of the procedure, product folder is moved in DREAM to: Cabinets/01. Evaluation of Medicine/SA/H/4- Closed PA Procedures or 5- Closed SA Procedures
- At the end of the procedure, the original, signed hard copy of the FAL is placed in the master file along with the signed transmission slip.
- FAL adopted at CHMP are archived according to EMA guidance.

3. Definitions

CHMP: Committee for Medicinal Products for Human Use

COMP: Committee for Orphan Medicinal Products

FAL: Final advice letter



FDA:	United States Food and Drug Administration
H-HM:	Human Medicines Special Areas Sector
H-HM-SA:	Scientific Advice Section
H-SE:	Safety and Efficacy of Medicines Sector
MMD:	Managing Meeting Documents software
PA:	Protocol assistance
SCAD:	Scientific advice database
SA:	Scientific advice
SAA:	Scientific advice administrator
SAWP SAA:	SAA responsible for SAWP meeting
SAWP:	Scientific Advice Working Party
Sec:	Secretary
SH:	Section Head
ToD:	Table of decisions
TS:	Transmission slip
WHO:	World Health Organisation
WP:	Working party

4. Related documents

- SOP/H/3037 on scientific advice and protocol assistance procedure
- WIN/H/3139 on scientific advice/protocol assistance peer review

5. Documents needed for this WIN

All templates are located at X:\Templates\Others\H – Scientific advice.

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|-------------|------------------------------------------------|
| Template 1: | Checklist for formatting advice letter |
| Template 2: | SAWP Report to the CHMP |
| Template 3: | Transmission slip for signature |
| Template 4: | Final advice letter to Applicant via Eudralink |
| Template 5: | Final advice letters for discussion at CHMP |

6. Instructions

Note: These work instructions supplement the scientific advice and protocol assistance procedure described in SOP/H/3037.

Step	Action	Responsibility
1	According to SAWP decisions, change status of all relevant procedures in SCAD to "Final advice" stage.	Sec
2	In SCAD, generate pre-draft FALs for all procedures in "Final advice" stage and rename them accordingly: <Name of product (according to ToD)> <FAL> _ <procedure number>.	Sec
3	Save all generated FALs in DREAM folder of the last SAWP meeting in the subfolder "FALs" and link them to respective product folders/ subfolder "01 SA letter". Make sure, that DREAM document numbers have been created in all FALs. <i>Note: Example of path to SAWP meeting subfolder "FALs":</i> <i>Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CHMP – SAWP/2011/08: 30 August – 01 September 2011/CHMP – FALs/FALs</i> <i>Path to SA product folders:</i> <i>Cabinets/01. Evaluation of Medicine/SA/H/2- New & Ongoing Requests/<actual year></i>	Sec
4	Create signature transmission slips (Template 1).	Sec
5	On page 1 of the FALs fill in, correct, delete or modify the following details, as applicable. <ul style="list-style-type: none"> • "DRAFT" is included in document title on the first page; • discussion meeting date, date of receipt of written responses and/or amended development plan; • date of FDA parallel advice received; • WHO experts involvement; • all dates relevant to the FAL. 	Sec
6	Table final SAWP ToDs in MMD for intended CHMP meeting (to be included in CHMP pre-mail) in line with CHMP secretariat deadlines (usually Tuesday prior to CHMP meeting),	Sec responsible for SAWP meeting
7	Check CHMP agenda before CHMP begins (week before CHMP meeting) to ensure all procedures are included or deleted in case finalisation is postponed.	Sec/ SAWP SAA
8	After receipt of final joint report and, if applicable, forward it to the designated peer review group for comments and follow WIN/H/3139.	SAA
9	Prepare draft FAL based on joint report, WP reports and experts' comments received i.e. save copy of joint report into FAL and make relevant editorial changes. Inform SA sec when completed.	SAA

Step	Action	Responsibility
10	Format draft FALs using checklist (Template 2).	Sec
11	In SAWP meeting subfolder "FALs" (see step 3 for path) create a document with all procedures identified for detailed discussion at CHMP meeting (Template 3). Provide link to SAAs for finalisation.	Sec
12	Together with SAWP chair identify procedures for detailed discussion by CHMP and complete listing (Template 3): <ul style="list-style-type: none"> • specific issues and; • name of CHMP peer reviewer of each procedure. Inform SA sec when finalised. Link the document to post-mail 1.	SAWP SAA
13	Perform internal quality control check of FALs and when complete inform SA sec.	SAA
14	Provide draft FALs in electronic format for inclusion in SAWP post-mail for adoption by SAWP members via written procedure.	Sec
15	Review draft FALs and incorporate comments received by deadline from SAWP coordinators and SAWP members.	SAA
16	Incorporate peer review comments if agreed by SAWP coordinators (see WIN/H/3139).	SAA
17	Perform second check and formatting on draft FAL using checklist (Template 2) when the SAAs ask for a further check.	Sec
18	By Wednesday prior to next CHMP meeting week (or deadline specified by CHMP secretariat): <ul style="list-style-type: none"> • Table all joint reports (and FALs that are ready for the products that are going to be adopted in CHMP) in MMD for CHMP meeting. • Provide CHMP secretariat with the list of procedures identified for detailed discussion for the CHMP . • Send the same list of procedures together with the FALs (or joint reports) to CHMP members via Eudralink. 	Sec
19	Table any remaining FALs (or joint reports if there is no FAL ready) in MMD for CHMP meeting no later than Wednesday of CHMP meeting.	Sec
20	Prepare short PowerPoint presentation on those procedures selected by the chairperson for detailed presentation to CHMP members (Template 4) and save in DREAM. Inform sec when presentation is final.	SAA

Step	Action	Responsibility
21	Table presentation in MMD for CHMP meeting on Friday before the CHMP week and retable during the CHMP week before the SA takes place.	Sec
22	Attend CHMP discussion on draft FALs, as and when scheduled, and present PowerPoint slides together with SAWP chairperson. Make note of changes to letters, adoptions or postponements decided by CHMP.	SAA/ SH
23	If changes are requested by the CHMP implement them in FALs.	SAA
24	Inform SA sec of CHMP outcome: <ul style="list-style-type: none"> FALs adopted; procedures postponed to following month pending further discussion. 	SAA
25	Change status of procedures in SCAD according to CHMP outcome.	Sec
26	Perform final check of FALs and remove "DRAFT" from document title on the first page of FAL.	Sec
27	Prepare FALs for signature of following persons, as applicable: <ul style="list-style-type: none"> SAA; SH; CHMP chairperson; COMP chairperson following adoption at next COMP meeting if PA FAL includes questions on significant benefit issues. <p><i>Note: CHMP and COMP chairpersons do not sign transmission slip.</i></p>	Sec
28	Ensure that FALs have been signed. Scan FALs. <ul style="list-style-type: none"> In case FAL contains significant benefit issues to be adopted by COMP go to step 29. If COMP adoption not needed go to step 32. 	Sec
29	Forward letters in Word format to COMP sec and provide paper copies of FAL signed by CHMP chair.	Sec
30	Ensure that discussion and adoption of significant benefit issues takes place at COMP meeting. <p>Save copies of adopted COMP answer in FAL or apply changes as requested by COMP (if any).</p>	SAA
31	Ensure that FALs have been signed. <p>Scan FALs with CHMP and COMP chairs signatures. Send FALs to applicant via Eudralink. Go to step 33.</p>	Sec

Step	Action	Responsibility
32	Send FALs to applicant via Eudralink on Friday of CHMP meeting week (Template 5) or next working day after last day of CHMP meeting.	Sec
33	Send FALs (Word format) electronically together with ToD, for information, to following recipients: <ul style="list-style-type: none"> • SAWP members (via Eudralink) • Relevant H-SE representatives (see annex) 	Sec
34	Table final version of FAL for CHMP (to be included in CHMP postmail).	Sec
35	File original signed FALs in product master files.	Sec
36	Link Word format of FAL to SCAD.	Sec
37	Copy (do not link) all FALs to designated DREAM folder according to actual year: Cabinets/01. Evaluation of Medicine/SA/H/3- Final SA and PA Letters	Sec