EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Scientific Advice and Protocol Assistance procedure		
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1. Purpose

This SOP describes the procedure from submission of a request for scientific advice or protocol assistance to a final answer to the applicant (as per Regulations (EC) 726/2004 and (EC) 141/2000).

2. Scope

This SOP applies to the Scientific Advice office in the Product Development Scientific Support Department.

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3. Responsibilities

It is the responsibility of each Head of Department to ensure that this procedure is adhered to within their own department. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of the table in section 9. Procedure.

4. Changes since last revision

Updated website links.

EDMS has been replaced by DREAM.

Under the new policy of conflict of interest there is no longer a requirement for checking assessment teams.

The telephone conference with the SAWP Chairperson has been replaced by creation of slides for each product.

5. Documents needed for this SOP

Template 1: Template letter of intent for request of Scientific Advice (SA) / Protocol Assistance (PA) (located at: http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2009/11/WC500011910.pdf)

Template 2: Acknowledgement of receipt of Letter of Intent (no presubmission meeting) (located at tbc)

Template 3: Acknowledgement of receipt of Letter of Intent (with presubmission meeting) (located at tbc)

6. Related documents

SOP/EMA/0101 Standard operating procedure for conducting checks for conflicts of interest when assigning medicinal products for human or veterinary use to a product / project team leader / member or project manager

SOP/EMA/0040 Evaluation of conflicts of interests of experts for involvement in Agency activities - Evaluation of conflicts of interests of experts for involvement in Agency activities

WIN/H/3045: Scientific advice and protocol assistance user manual

7. Definitions

AA Administrative Assistant

COMP Committee for Orphan Medicinal Products

DM Discussion Meeting

FAL Final Advice Letter

LoI Letter of intent

PDCO Paediatric Committee

PRAC Pharmacovigilance Risk Assessment Committee

SO Scientific Officer

SAG Scientific Advisory Group

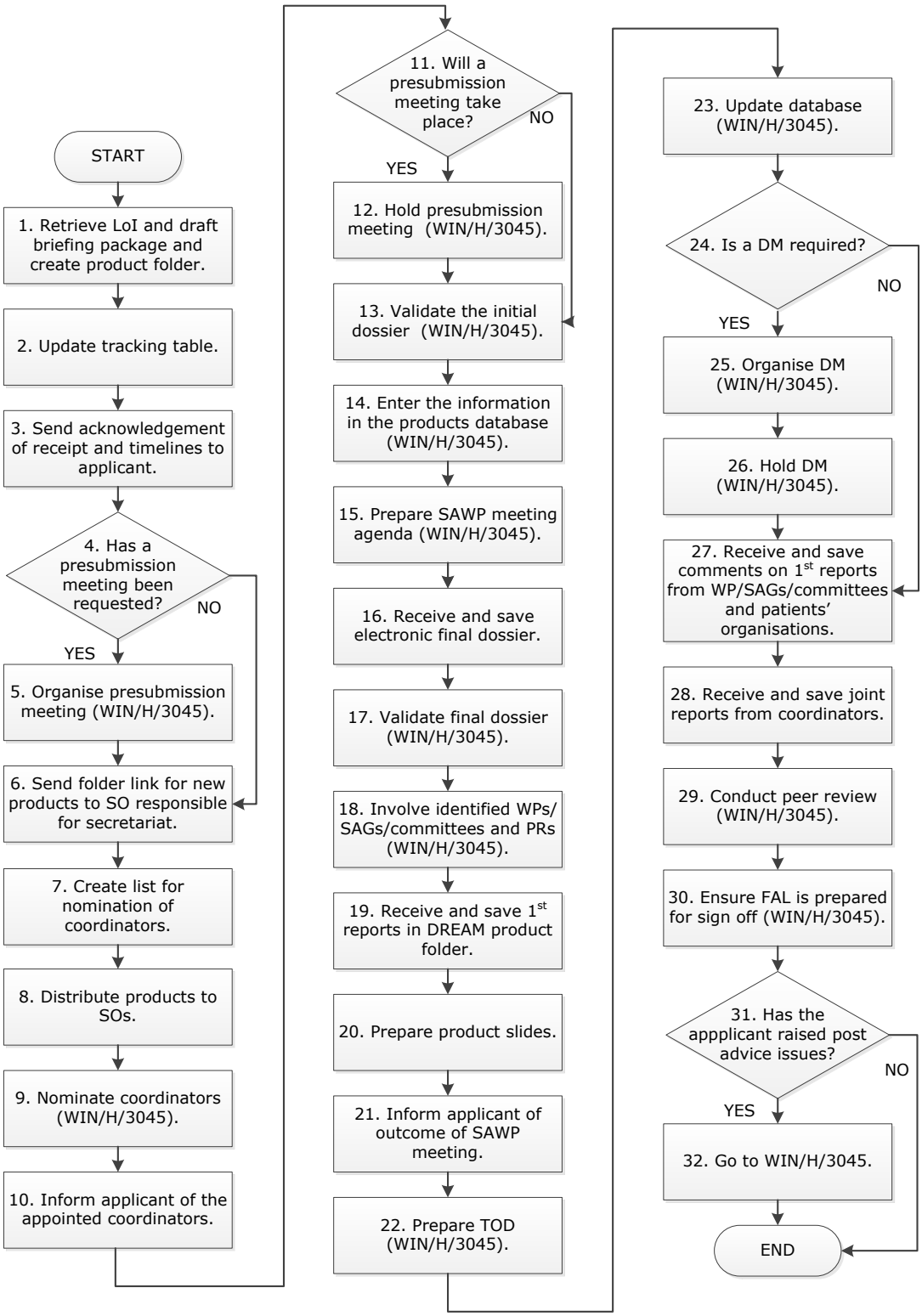
SAWP Scientific Advice Working Party

Sec Secretary

TOD Table of Decisions

WP Working Party of the Committee for Medicinal Products for Human Use

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



9. Procedure

The organisation of the SAWP meeting runs in parallel with this procedure. Refer to WIN/H/3045 for details.

Step	Action	Responsibility
1	Retrieve LoI and draft briefing package from scientific advice inbox. Create a new folder in DREAM for the product and save the LoI and draft briefing package.	Sec
2	Include relevant information in Excel tracking table and update table as and when necessary.	Sec
3	Send acknowledgment of receipt and timelines by e-mail to applicant within 2 working days after the deadline for receiving LoIs (template 2 or 3).	Sec
4	Has a presubmission meeting been requested? If yes, go to step 5. If not, go to step 6.	Sec
5	Organise presubmission meeting (see WIN/H/3045).	Sec
6	Send the link to the folder for the new products to the SO responsible for the secretariat.	Sec
7	Create the list of nominations of coordinators (see WIN/H/3045).	SO
8	Distribute the new products between the SOs.	SO
9	Nominate the coordinators before the SAWP meeting.	SO
10	Inform the applicant of the appointed coordinators (see WIN/H/3045).	Sec
11	Will a presubmission meeting take place? If yes, go to step 12. If not, go to step 13.	
12	Hold presubmission meeting (see WIN/H/3045).	SO
13	Validate the initial dossier (see WIN/H/3045).	SO
14	Enter the information on the products in the database (see WIN/H/3045).	AA
15	Prepare the SAWP meeting agenda (see WIN/H/3045).	AA
16	Receive and save electronic final dossier.	Sec
17	Validate final dossier (see WIN/H/3045).	SO
18	Involve identified WPs/SAGs/committees and patients' organisations (see WIN/H/3045).	Sec
19	Receive and save 1st reports in DREAM in the product folder.	Sec
20	Prepare product slides to be sent to the chairperson and vice-chairperson of SAWP. Discuss the important issues and discrepancies in the reports, relevant previous advices (if any) and bring up special points on the agenda if applicable.	SO
21	Inform the applicant (by phone or email) of the outcome of the SAWP meeting and if the applicant will be invited to a DM or not.	SO
22	Prepare the TOD (see WIN/H/3045).	AA
23	Update the database (see WIN/H/3045).	Sec

Step	Action	Responsibility
24	Is DM required? If yes, go to step 25. If no, go to step 27.	
25	Organise DM (see WIN/H/3045).	Sec
26	Hold DM (see WIN/H/3045).	SO
27	Receive comments on 1st reports from WP/SAG/PDCO/PRAC via SAWP secretariat inbox (see WIN/H/3045).	Sec
28	Receive and save joint reports from coordinators by deadline specified in TOD.	Sec
29	Conduct peer review (see WIN/H/3045).	SO
30	Ensure FAL is prepared for sign off (see WIN/H/3045).	SO
31	Has the applicant raised post-advice issues? If yes, go to step 32. If no, END of procedure.	
32	Go to WIN/H/3045.	SO

10. Records

All electronic records generated during the procedure are saved as described in WIN/H/3045.