



## Work instructions

|  |                       |                                       |
|--|-----------------------|---------------------------------------|
| Title: Organisation of discussion meetings for scientific advice and protocol assistance |                       |                                       |
| Applies to: Scientific Advice Section in Human Medicines Special Areas Sector            |                       |                                       |
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### 1. Changes since last revision

- Minor editorial changes
- Replaced "List of experts table" with "List of discussion meetings with experts and status table".
- Step 2: "Save this table in DREAM and link to the SAWP post mail folder" added, eliminating previous step 4.
- Step 10: "Insert the date of receipt of written responses in the SA database" added.
- Step 11: "(major amendments from the initial request) or additional points" and "SAWP (if the applicant wants to submit an amended development plan or additional points)" added.
- New steps 13 and 20 introduced.
- Step 15: "Liaise with SAA regarding any exceptional documents (e.g. Experts' comments etc)" added.
- Step 19: "and to the peer reviewers separately" added.

### 2. Records

All records are saved in the electronic and paper master files.

### 3. Documents needed for these WIN

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

Template 1: E-mail list of issues to applicants



Template 2: List of discussion meetings with experts and status table

Template 3: E-mail invitation to applicants to discussion meetings

Template 4: E-mail to applicant with list of attendees

## 4. Related documents

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

WIN/H/3195: Organisation of Scientific Advice Working Party meetings

Teleconference or videoconference instructions and 'best practice guides' (available at: [fmp7://fmapps.emea.eu.int/Conference+Meetings](http://fmapps.emea.eu.int/Conference+Meetings))

## 5. Definitions

DM: Discussion meeting

DREAM: Document records electronic archive management system

e-DoI: Electronic declaration of interests

Eudralink: System for secure transmission of e-mails and file attachments

H-HM: Human Medicines Special Areas Sector

LoIs: List of issues

MMD: Managing meeting documents system

MMS: Meetings management system

PA: Protocol assistance

SA: Scientific advice

SAA: Scientific administrator coordinating SA/PA request

SAWP: Scientific Advice Working Party

SAWP Co: SAWP coordinator

SAWP SAA: Scientific secretary of the SAWP

Sec: SA secretary

## 6. Instructions

| Step  | Action   | Responsibility |
|---|--|----------------|
| <b>At the 2<sup>nd</sup> SAWP meeting and immediately after (Days +28 to +30)</b> |  |                |
| 1   | On the day following the SAWP meeting e-mail the adopted LoIs (Template 1), as a PDF, to applicants (via Eudralink) and SAWP Cos.  | Sec            |
| 2   | Create list of discussion meetings with experts and status table, as MS Word document (Template 2), with details of up-coming DMs. | Sec            |

| <b>Step</b>  | <b>Action</b>   | <b>Responsibility</b> |
|--|---|-----------------------|
|  | Save this table in DREAM and link to the SAWP post mail folder.   |                       |
| 3  | Allocate draft date and time for each DM (at the same time as the rolling plan).<br><br><i>Note: The DMs take place at the Agency usually at Day +60 of the procedure.</i>  | SAWP SAA              |
| 4  | Receive information regarding experts that should attend the DMs from SAWP Co on e-mail address SAWPsecretariat@ema.europa.eu.<br><br>Check that experts are in the European expert database.<br><br>Remind SAWP Co to provide updated or missing e-DoI, confidentiality undertaking and nomination form for those experts whose details are unclear. | SAWP Secretariat      |
| 5  | Enter details of experts in list of discussion meetings with experts and status table.  | Sec                   |
| 6  | Check new experts for potential conflicts of interests (see SOP/EMA/0040) and enter details and progress in list of discussion meetings with experts and status table.  | Sec / SAWP SAA        |
| <b>Leading to 3<sup>rd</sup> SAWP meeting (between Day +30 and +60 of the procedure)</b> |   |                       |
| 7  | Send invitation (Template 3) via Eudralink to each applicant not later than 15 working days before 3 <sup>rd</sup> SAWP meeting (Day +60) including PDF copy of the adopted LoIs.<br><br><i>Note: This is the deadline in the procedure for informing applicants of the date.</i>   | Sec                   |
| 8  | Process invitations to experts through the MMS system (see WIN/H/3195).<br><br><i>Note: Some experts only attend DMs but may also attend the debriefing in the SAWP plenary. Invitations are only sent once conflicts of interest have been clarified.</i>  | Sec                   |
| 9  | Receive written responses to LoIs from applicant approximately 2 weeks before next SAWP (only in case that the written responses have been specifically requested from the applicant through the LoIs).   | Sec                   |
| 10   | Save responses in product folder in DREAM and link to SAWP pre-mail folder.<br><br>Insert the date of receipt of written responses in the SA database.  | Sec                   |
| 11   | Receive summaries of amended development plan (major amendments from the initial request) or additional points from applicant approximately 1 week before next SAWP (if the applicant wants to submit an amended development plan or additional   | Sec                   |

| <b>Step</b>   | <b>Action</b>   | <b>Responsibility</b> |
|---|---|-----------------------|
|   | points).  |                       |
| 12  | Save summaries or additional points in product folder in DREAM and link to SAWP pre-mail folder.  | Sec                   |
| 13  | On receipt of a report or individual experts' comments from working party, save them in DREAM and link to SAWP pre-mail folder.   | Sec                   |
| 14  | Send DM documentation via Eudralink to external experts about one week before the DM takes place (if any experts are involved).   | Sec                   |
| 15  | <p>Print out background documentation to be tabled at the DM (circulate hard copies to all participants at start of DM):</p> <ul style="list-style-type: none"> <li>• SAWP Cos' first reports</li> <li>• LoIs to be addressed</li> <li>• Other relevant documentation; amended development plan, written responses or working party contributions, guidelines, articles, etc.</li> </ul> <p>Liaise with SAA regarding any exceptional documents (e.g. Experts' comments etc).</p> | Sec                   |
| 16  | If DM is a teleconference or videoconference follow instructions (see 'best practice guides').  | Sec                   |
| 17  | Receive list of participants from applicant by e-mail. Save e-mail in DREAM and prepare nameplates for both applicant's participants and experts.   | Sec                   |
| 18  | Receive draft MS PowerPoint presentation from applicant and save it in DREAM.   | Sec                   |
| 19  | Send presentation via Eudralink to experts who participate by telephone/videoconference (if applicable).  | Sec                   |
| 20  | Create a zip folder with all the documents (including presentation) relevant to the DM and save it in SAWP pre-mail folder.   | Sec                   |
| 21  | At the latest on the day before DM, enter visitors' details in visitor request forms to inform reception and security.  | Sec                   |
| <b>3<sup>rd</sup> SAWP meeting (Day +60: DM and steps thereafter)</b> |   |                       |
| 22  | <p>Prepare meeting room at least 30 minutes before first DM is due to start.</p> <p>Check equipment and set up papers, nameplates, laptop, teleconference, video conference, projection (as applicable).</p> <p>Check that a wireless mouse or keyboard is available and working. In case of any technical problems request help from the audio visual team; dial 0 for reception and ask them to page AV support</p>   | Sec                   |

| <b>Step</b> | <b>Action</b>  | <b>Responsibility</b>                 |
|-------------|--|---------------------------------------|
|             | or call their direct number 6969.  |                                       |
| 23          | Meet and greet applicant's participants upon arrival.<br>Explain what is going to happen at meeting, remind them that they should prepare minutes and inform them that you will e-mail them a list of attendees after the meeting. | Sec or SAA<br>(agreed before meeting) |
| 24          | Get the applicant's MS PowerPoint presentation on CD-Rom (or USB memory stick) and hand-outs (15 copies).<br>Download presentation onto PC and start projection.   | Sec or SAA<br>(agreed before meeting) |
| 25          | Write down names of Agency and SAWP participants and experts present at the start of the meeting.  | Sec and SAA                           |
| 26          | After the DM, e-mail the list of participants to the applicant (Template 4).   | Sec                                   |
| 27          | Receive minutes from applicant within 3 days of the meeting.   | Sec                                   |
| 28          | On receipt of applicant's minutes forward the e-mail to SAWP Cos for information, save in product folder and link to SAWP mailing.   | Sec                                   |