EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Use of scientific advice and protocol assistance database		
Applies to: SA Administrative Assistant, SAWP Scientific Secretary and SA secretarial team in Scientific Advice Section		
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1. Changes since last revision

Extensive revision of WIN.

2. Records

All records created are saved in the scientific advice database (http://scad.emea.europa.eu/scientificadvice/) and are reflected in SAWP agendas and validation cover sheets.

3. Related documents

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

WIN/H/3039: Validation of Scientific Advice and Protocol Assistance Requests

SCAD User Manual

(located at: Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CHMP - SAWP/1. Governance/05. Planning and Reporting/Statistics and databases/SCAD)

4. Definitions

ATC:	Anatomical-therapeutic-chemical classification
CHMP:	Committee for Medicinal Products for Human Use

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CAN:	Customer Account Number in SCAD
DREAM:	Document records electronic archive management
FAL:	Final scientific advice letter
FU:	Follow-up
INN:	International non-proprietary name
LoI:	Letter of intent
PA:	Protocol assistance
SA:	Scientific advice
SAWP:	Scientific Advice Working Party
SCAD:	Scientific advice database
SME:	Small and medium-sized enterprises
VCS:	Validation cover sheet

5. Instructions

The SCAD workflow consists of 6 main phases according to the cycle of a SA/PA procedure request:

1. Pre-submission phase (from receipt of LoI to start of validation)
2. Validation phase (from start of validation to start of procedure)
3. Ongoing (from SAWP1 to SAWP2 meeting)
4. Ongoing with discussion (from SAWP2 to SAWP 3 meeting, if applicable) and clock stop/restart
5. Final advice
6. Closure of a procedure

The numbering allocation of a SA/PA procedure is automatically created by the SCAD upon validation. The agenda is generated from a Word document template with macros that place automatically all the procedures of SA/PA in the various cycles.

The SCAD has been also designed to collect data such as receipt of the first reports, joint reports, written responses to list of issues (when requested by the SAWP), nominated coordinators, peer reviewers, assessment teams and experts to keep a record of the documents flow as well as the SAWP members and their teams involved in individual procedures at given time.

For more details on how to access the database and data entry, refer to the SCAD User Manual.

5.1. Pre-submission phase

A record for a request of SA/PA is created for the first time upon receipt of the LoI from the applicant (see SOP/H/3037); (2 months or 1 month prior to SAWP1).

Before starting data entry, a preliminary check of the LoI has to be performed (see WIN/H/3039).

5.1.1. Extracting data from LoI to create new procedures:

Open the LoI interactive pdf form.

Ensure that all mandatory fields (marked with an asterisk) have been filled in by the applicant. In case information is missing contact the applicant and request the submission of a completed LoI.

When mandatory fields are not filled in, under the heading there will appear text in red “This form is not complete, please fill in all the mandatory fields”. At the end of the form a list of all incomplete fields will appear in red while every single incomplete field will be highlighted in yellow.

By completing all mandatory fields the text in red will read “This form is validated”.

Once the form is validated go to **document > forms > export data** to create the .xml file that will be used to upload the data on the database.

The .xml files do not have to be archived in any folder. They can be saved on the desktop or any other folder at the discretion of the user.

5.1.2. Create a procedure record in SCAD as a new procedure (not FU or subsequent)

Open the database and login.

Click on **procedure management.**

Click on **intent letter.**

Click on **click here to go to step 1 – upload the data.**

Click on **browse.**

Locate the desired .xml file, select it and click on **open.**

Click on **upload**.

You are now in **step 2 – edit the uploaded file**.

Under the tab **product information**:

- Ensure that in the boxes **INN**, **applicant code** and/or **tradename** there is one entry per line. If entry is n/a or similar delete the entry.
- Copy and paste the text for the agenda in the **description** box**.**
- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **scientific information**:

- If indication text is too long simplify the text.
- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **procedure information and other information**:

- Ensure that all fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Click on **import**.

You are now in **step 3 – map data to create procedure**.

Fields that require your attention are highlighted in yellow.

Under the tab **product information**:

In the **substances** boxes make sure that there is only one entry per line. If an entry already exists in SCAD there will be a number of matches indicated. If matches are 0 a new entry will be created automatically.

Under the tab **scientific information**:

- Ensure that all fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **procedure information**:

- If applicant information has no matches this is highlighted in yellow. This can happen either because applicant is new or because of difference in the way the name of the applicant is written. Click on 'edit applicant' to map the applicant. If there is already another entry with minor differences such as e.g. new entry ABC Ltd with the CAN 00006xxxxx and an old entry ABC Limited with the CAN 00006xxxxx select the old entry to avoid multiple entries of the same applicant. If applicant does not exist, return to previous window to proceed.
- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Click on **create procedure**. SCAD will create automatically the **procedure summary page.**

Move to any tab and enter further information not contained in the LoI (e.g. scientific administrator's name).

5.1.3. Create a procedure record in SCAD as FU or subsequent

If a procedure is identified as being a follow-up of a previous procedure or a subsequent procedure (for more details refer to WIN/H/3039),

Click on **intent letter**.

Click on **click here to go to step 1 – upload the data**.

Click on **browse**.

Locate the desired .xml file, select it and click on **open**.

Click on **upload**.

You are now in **step 2 – edit the uploaded file**.

Under the tab **product information**:

- Ensure that in the boxes **INN**, **applicant code** and/or **tradename** there is one entry per line. If entry is n/a or similar delete the entry.
- Copy and paste the text for the agenda in the **description** box.
- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **scientific information**:

- If indication text is too long simplify the text.

- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **procedure information**:

- Ensure that all fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **other information:**

- Go to box **additional procedure information.** Check that **follow-up** box is ticked for FU procedures and/or **other CHMP scientific advice** is ticked for subsequent procedures.
- Ensure that **procedure number** fields that follow the tick box are populated. If not, insert procedure numbers manually omitting the first part of the full procedure number (EMEA/H/SA/).
- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Click on **import**.

You are now in **Step 3 – map data to create procedure**.

Fields that require your attention are highlighted in yellow.

Under the tab **product information**:

In the **substances** boxes make sure that there is only one entry per line. If an entry already exists in SCAD there will be a number of matches indicated. If matches are 0 a new entry will be created automatically.

Under the tab **scientific information**:

- Ensure that all fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Under the tab **procedure information**:

- If applicant information has no matches, the field is highlighted in yellow. This can happen either because applicant is new or because of difference in the way the name of the applicant is written. Click on 'edit applicant' to map the applicant. If there is already another entry with minor differences such as e.g. new entry ABC Ltd with CAN 00006xxxxx and old entry ABC Limited with CAN 00006xxxxx select the old entry to avoid multiple entries of the same applicant. If applicant does not exist, return to previous window to proceed.
- Ensure that all other fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant.

Click on **create procedure**. SCAD will create automatically the **procedure summary** page**.**

Move to any tab and enter further information not contained in the LoI (e.g. scientific administrator's name).

The concept of number assignment is as follows. If more than one fee reduction is applicable for a single procedure (paediatric, advanced therapy, protocol assistance, SME) multiple relevant codes will appear in the procedure number for statistical purposes (PED, SME, ADT, PA). In this case the fee reduction/waiver that will be applied will be the most convenient for the applicant.

For scientific advice initial requests

EMEA / H / SA / xxxx / xxxx / YYYY / (SME) / (ADT) / (PED) / x

EMEA for requests submitted to the EMA

H for requests submitted for medicines for human use

SA for scientific advice

Identification number of the product

Request number

Year of submission of the request (four figure number)

SME for small and medium-sized enterprise
(note: verify with SME Office if SME status has been assigned)

ADT for advanced therapy product

PED for paediatric request (full waiver only)

Assign level of area of advice:

I - quality development or safety development, or bioequivalence studies for generic medicinal products

II - clinical development, or quality and safety development, or quality and bioequivalence studies for generic medicinal products

III - quality and safety and clinical development, or quality and clinical development, or safety and clinical development

For protocol assistance initial requests

EMEA / H / SA / xxxx / xxxx / YYYY / PA / (SME) / (ADT) / (PED) / x

EMEA for requests submitted to the EMA

H for requests submitted for medicines for human use

SA for scientific advice

Identification number of the product

Request number

Year of submission of the request (four figure number)

PA for protocol assistance

SME for small and medium-sized enterprise
(note: verify with SME Office if SME status has been assigned)

ADT for advanced therapy product

PED for paediatric request (full waiver only)

Assign level of area of advice:

I - quality development or safety development, or bioequivalence studies for generic medicinal products

II - clinical development, or quality and safety development, or quality and bioequivalence studies for generic medicinal products

III - quality and safety and clinical development, or quality and clinical development, or safety and clinical development

0 for request concerning only demonstration of significant benefit

For scientific advice follow-up requests

EMEA / H / SA / xxxx / xxxx / FU / xxxx / YYYY /(SME)/(ADT)/(PED)/ x

EMEA for requests submitted to the EMA

H for requests submitted for medicines for human use

SA for scientific advice

Identification number of the product

Request number for a product

FU for follow-up

Request FU number

Year of submission of the FU request (four figures number)

SME for small and medium-sized enterprise
(note: verify with SME Office if SME status has been assigned)

ADT for advanced therapy product

PED for paediatric request (full waiver only)

Assign level of area of advice:

I - quality development or safety development, or bioequivalence studies for generic medicinal products

II - clinical development, or quality and safety development, or quality and bioequivalence studies for generic medicinal products

III - quality and safety and clinical development, or quality and clinical development, or safety and clinical development

For protocol assistance follow-up requests

EMEA / H / SA / xxxx / xxxx / FU / xxxx / YYYY / PA/(SME)/(ADT)/(PED)/ x

EMEA for requests submitted to the EMA

H for requests submitted for medicines for human use

SA for scientific advice

Identification number of the product

Request number for a product

FU for follow-up

Request FU number

Year of submission of the FU request (four figures number)

PA for protocol assistance

SME for small and medium-sized enterprise
(note: verify with SME Office if SME status has been assigned)

ADT for advanced therapy product

PED for paediatric request (full waiver only)

Assign level of area of advice:

I - quality development or safety development, or bioequivalence studies for generic medicinal products

II - clinical development, or quality and safety development, or quality and bioequivalence studies for generic medicinal products

III - quality and safety and clinical development, or quality and clinical development, or safety and clinical development

0 for request concerning only demonstration of significant benefit

5.2. Validation phase

5.2.1. Change of procedure record in SCAD from (pre-)submission to new request:

Before SAWP1 the procedure will be validated by scientific administrators and a VCS record for each procedure will be saved in DREAM (see WIN/H/3039). When the VCS is completed and after the validation meeting, the remaining missing data of the VCS need to be entered in SCAD.

Open the VCS interactive pdf form.

Ensure that all mandatory fields (marked with an asterisk) have been filled in by the scientific administrator. In case information is missing contact the scientific administrator and request a completed VCS.

When mandatory fields are not filled in, under the heading there will appear text in red ‘This form is not complete, please fill in all the mandatory fields’. At the end of the form a list of all incomplete fields will appear in red while every single incomplete field will be highlighted in yellow.

By completing all mandatory fields the text in red will read ‘This form is validated’.

Once the form is validated go to **document > forms > export data** to create the .xml file that will be used to upload and update the data on the database.

The .xml files do not have to be archived in any folder. They can be saved on the desktop or any other folder at the discretion of the user.

Open the database and login.

Click on **procedure management**.

Click on **intent Letter**.

Click on **click here to go to step 1 – upload the data**.

Click on **browse**.

Locate the desired .xml file, select it and click on **open**.

Click on **upload**.

You are now directly in **step 3 – map data to create procedure**.

Fields that require your attention are highlighted in yellow.

Ensure that all fields have been populated correctly. If not, make necessary corrections according to LoI as submitted by applicant**.**

Click on **update procedure**. SCAD will create automatically the **procedure summary** page.

Move to **procedure information'** page, (at this stage the names of coordinators appointed in previous SAWP meeting should have already been entered) and if the procedure had a pre-submission meeting, enter relevant data (list of comments); refer to the User Manual for SCAD for more details.

Move to **procedure workflow** page. Insert actual date of final submission of dossier and date of validation. At this point the procedure has been validated and the procedure number will be created automatically. Status of the procedure will be **new request**.

At this point chapter IV of the agenda (New Requests) can be created. The procedures will be systematically sorted within each section of the chapter according to the selected ATC code and in alphabetical order, according to their forecasted start date.

5.3. Ongoing phase

5.3.1. Change the procedure status from 'new request' to 'ongoing':

After the SAWP1, the procedure is in the ongoing phase and the status needs to be changed.

Select each procedure that has a **new request** status from the **meetings list**; scroll the list until the **new requests** appear.

Select each procedure and go to the section **workflow**.

Insert the date of SAWP1 (first day of the meeting).

By saving your data, the status will be changed automatically.

Repeat this step for each **new request** in the **meetings list**.

Before the SAWP2, the dates of first reports received need to be inserted, as well as the names of the experts involved in the coordinators' assessment teams. Refer to the 'User manual for SCAD' for more details.

5.4. Ongoing with discussions phase (or clock stop)

5.4.1. Change the procedure status from 'ongoing' to 'ongoing with discussions' (or clock stop):

After the SAWP2, the procedure could be agreed on final advice or will go on SAWP3 with a discussion meeting, or a clock stop at the request of the applicant.

Select those procedures that will have to be changed into this status from the **meetings list**; scroll the list until the **ongoing** are found.

Select each procedure and go to the **workflow** section.

Insert the date of SAWP2 (first day of the meeting).

Change the timeline from 40 days (or 40 days with pre-submission) to 70 days (or 70 days with pre-submission) from the drop-down menu.

If there is a clock stop, insert date of last day of SAWP 2 into the clock stop tab. Make the tab visible.

If written answers are requested, insert the date on the written answers tab. Make the tab visible.

By saving your data, the status will be changed automatically.

Repeat this step for the relevant procedures in the **meetings list**.

5.4.2. Change the procedure status from 'clock stop' to 'ongoing with discussions':

Select those procedures that will have to be changed into this status from the **meetings list**.

Select the relevant procedure and go in the section **workflow**.

To restart the clock, insert the date on the clock restart tab (first day of the meeting SAWP3). Make the tab visible.

If written answers are requested, insert the date on the written answers tab. Make the tab visible.

By saving your data, the status will be changed automatically.

Repeat this step for the relevant procedures in the **meetings list**.

5.5. Final advice

5.5.1. Change the procedure status from 'ongoing' to 'final':

After the SAWP2, the procedures that have been agreed on final advice and a joint report are expected from coordinators.

Select those procedures that will have to be changed into this status from the **meetings list**; scroll the list until the **ongoing** are found.

Select each procedure and go in the section **workflow.**

Insert the date of SAWP2 (first day of the meeting).

Insert the date of joint report if already discussed during the meeting.

By saving your data, the status will be changed automatically.

Repeat this step for the relevant procedures in the **meetings list.**

5.5.2. Change the procedure status from 'ongoing with discussions' to 'final advice':

After the SAWP3, the procedures that have had a discussion meeting and whose status is ongoing with discussions will have to be changed into final advice and a joint report is expected from coordinators.

Select those procedures that will have to be changed into this status from the **meetings list**; scroll the list until the **ongoing with discussions** are found.

Select each procedure and go in the section **workflow**.

Insert the date of SAWP3 (first day of the meeting).

Insert the date of joint report if already discussed during the meeting.

By saving your data, the status will be changed automatically.

Repeat this step for the relevant procedures in the **meetings list**.

5.6. Closure of a procedure

After the CHMP has adopted the FAL, the procedure can be closed.

Select those procedures that will have to be changed into this status from the **meetings list**; scroll the list until the **final advice** set is found.

Select each procedure and go in the section **workflow.**

Insert the date of joint report if it has not been done before.

Insert the date of written procedure (first day of CHMP meeting).

Insert the date of CHMP meeting (last day of CHMP, when FAL is signed).

By saving your data, the status will be changed automatically into **closed**.

When adopted, link the FAL electronic document from DREAM in the procedure record workflow.

The agenda then will place automatically the procedures that have an ongoing status in chapter II, procedures that are ongoing with discussion or clock stop in chapter III or final advice in chapter I. Procedures which status has been changed to 'closed' should not appear on the agenda.