



Work instructions

Title: Nomination of coordinators 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.

2. Records

All records are saved electronically in DREAM in relevant product and SAWP meeting folders.

The forms (list of nomination for coordinators) are saved in DREAM in the folder "Data" under the respective SAWP meeting.

3. Definitions

DREAM: Document records electronic archive management system

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

LoI: Letter of intent

SAA: Scientific advice administrator in Scientific Advice Section

SAWP: Scientific Advice Working Party

Sec: Secretary in Scientific Advice Section

SME: Micro, small and medium-sized enterprise

ToD: Table of decisions



4. Documents needed for these WIN

Template 1: Request for coordinatorship (located at X:\Templates\Others\H – Scientific advice)

5. Related documents

SOP/H/3037 on scientific advice and protocol assistance procedure

6. Instructions

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

Step	Action	Responsibility
Before SAWP meeting		
1	<p>Prepare the database text (same as used for the agenda) from the LoIs.</p> <p>The text is a summary of the information given in the LoI.</p> <ul style="list-style-type: none">• Name of product• Applicant• Description of product• Intended indication• Area of advice sought <p>Any additional information, e.g. SME, paediatric advice etc.</p>	SAA
2	<p>Prepare the form "Request for coordinatorship" (Template 1) to include requests with presubmission meetings and requests without.</p> <p>Use the template and insert the new products accordingly.</p> <p><i>Note: The information used is the same as for the agenda (see step 1).</i></p>	Sec
3	<p>Send the form to the SAWP members via Eudralink.</p>	Sec
4	<p>Receive the choices on the 1st day of the SAWP meeting.</p> <p>Combine all preferences into one document (List of Nomination for Coordinators – the same document as the request for coordinators but with a revised name).</p>	Sec
During SAWP meeting		
5	<p>Decide which product will go to which coordinator and highlight this in the List of Nomination for Coordinators.</p> <p>Liase with other SAAs if required.</p> <p><i>Note: The decision is made based on the coordinators' preferences</i></p>	SAA in charge of SAWP secretariat

Step	Action	Responsibility
	<i>and should be distributed evenly if possible.</i>	
6	Circulate the updated List of Nomination for Coordinators at day 2 of the SAWP meeting.	Sec
7	Once SAWP has adopted the final List of Nomination for Coordinators on the last day of the SAWP meeting save it in the relevant meeting folder in DREAM.	Sec
After SAWP meeting		
8	<p>Start with products with pre-submission meetings.</p> <p>a) Create contact sheets for all new requests (using the information from LoI, ToD and List of Nomination for Coordinators) and save the contact sheet under folder 9 in the respective product folder.</p> <p>b) Create "Attachment" for every single product (using the information sheets, SAWP group contact list and ToD) (use Template 1).</p> <p>c) Send out the contact sheets to applicants via Eudralink (copy coordinators and project managers). Save all Eudralinks containing the contact sheet in Request/Correspondence folder.</p> <p>Follow with same steps for those products that do not have pre-submission meeting.</p>	Sec