



Standard operating procedure

Title: Organisation of Innovation Task Force briefing meetings (medicines for human/veterinary use)		
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1. Purpose

To describe the procedure for managing EMA Innovation Task Force briefing meetings with applicants on medicinal products for human or veterinary use.

2. Scope

This SOP applies to the Scientific Support and Projects Section, and to EMA coordinators in the Paediatric Medicines Section, Orphan Medicines Section, Scientific Advice Section, Quality of Medicines Sector, Safety and Efficacy of Medicines Sector and Development and Evaluation of Veterinary Medicines Section.

3. Responsibilities

It is the responsibility of each Head of Sector/Section Head to ensure that this procedure is adhered to within own sector/section. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

- To reflect the involvement of veterinary and herbal medicines experts
- Improving organisational steps (e.g. ORGAM)
- Better reflect the involvement of scientific committees, working parties and drafting groups experts
- Adding the involvement of international regulatory authorities



5. Documents needed for this SOP

- Form 1: Briefing meeting request form (located at (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000334.jsp&mid=WC0b01ac05800ba1d9))
- Form 2: Eudralink Account Request Form (located at <http://www.eudra.org/eudraportal2/showgenericfiles.do?ctrl=files&action=Expand¶m=eudradocuments%2FEudralink>)
- Form 3: Visitor request form (located at <http://visitors.emea.eu.int/acdc/visitorRequest.do>)
- Template 1: Email to applicant informing of the (non) validation of the request (located in X:/Templates/Others/ITF)
- Template 2: Details of upcoming Innovation Task Force meeting (located in X:/Templates/Others/ITF)
- Template 3: Email to applicant inviting them to the meeting (located in X:/Templates/Others/ITF)
- Template 4: Email to Unified Collaboration Section (I-IF-UC) to book teleconference facilities – Adobe connect (located in X:/Templates/Others/ITF)
- Template 5: Teleconference instructions (located in X:/Templates/Others/ITF)
- Template 6: Email to identified EMA staff proposing to act as ITF coordinator (located in X:/Templates/Others/ITF)
- Template 7: Company summary report of briefing meeting (located in X:/Templates/Others/ITF)
Following internal consultation it has been decided on 01/11/2012 to remove logos and official EMA references from the templates in order to be consistent with the approach taken in other early meetings with applicants, e.g. pre-submission paediatrics and SME.
- Template 8: Email to applicant with list of participants and summary report template (located in X:/Templates/Others/ITF)

6. Related documents

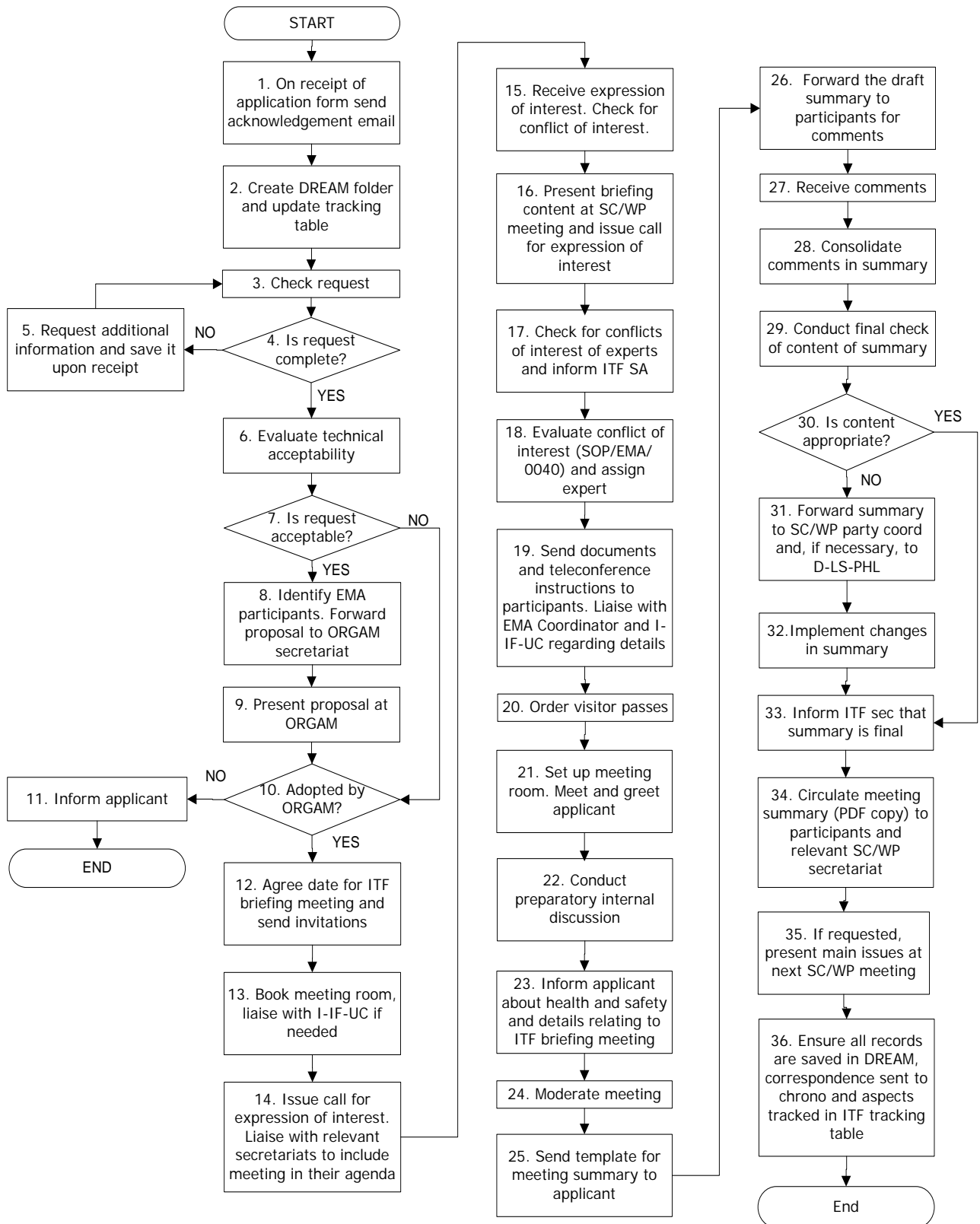
- SOP/EMA/0040: Evaluation of conflicts of interests of experts for involvement in EMA activities
- SOP/EMA/0101: Conducting checks for conflicts of interest of Agency employees assigned duties relating to medicinal products for human or veterinary use

7. Definitions

D-LS-PHL:	Pharmaceutical Law Section
DREAM:	Document Records Electronic Archive Management system
EMA coordinator:	Staff member selected from ITF contacts or a paediatric/orphan coordinator, a scientific advice administrator, a product team leader or a veterinary project manager acting as coordinator for the briefing meeting
I-IF-UC:	Unified Collaboration Section
ITF:	Innovation Task Force
ITF SA:	ITF scientific administrator

ITF sec: ITF secretary
ORGAM: Organisational matters coordination group of the CHMP
SC: Scientific committee
WP: Working party

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



9. Procedure

Step	Action	Responsibility
Receipt of request and validation		
1	<p>Upon receipt of application form (Form 1) and briefing document (maximum 30 pages) sent to ITF secretariat mailbox by the applicant, check whether request falls within the scope of ITF briefing meeting and acknowledge receipt with a standard (non)validation e-mail reply accordingly (Template 1).</p> <p><i>Note: Only requests including draft briefing document can be validated by EMA.</i></p> <p><i>Applicants should be advised to apply for a Eudralink account to secure their documents transmission using link provided in application form (Form 2).</i></p>	ITF SA/ITF sec
2	<p>Create a new folder in DREAM.</p> <p>Include information in ITF tracking table to ensure organisational tracking.</p>	ITF sec
3	Check request within 5 working days.	ITF sec
4	<p>If request is not complete, ask for additional information from applicant and go to step 5.</p> <p>If request is complete, inform ITF SA and go to step 6.</p>	ITF sec
5	On receipt of additional information, go back to step 3.	ITF sec
6	Evaluate technical acceptability of request within 10 working days.	ITF SA
7	<p>If request is acceptable, inform ITF sec and go to step 8.</p> <p>If request is not acceptable, go to step 11.</p>	ITF SA
8	<p>Identify potential EMA participants.</p> <p>Forward proposal to ORGAM secretariat for inclusion in ORGAM agenda (Template 2).</p>	ITF sec
9	Present proposal at ORGAM for confirmation of expertise, expression of interest and adoption.	ITF SA
10	<p>If ORGAM does not adopt proposal, go to step 11.</p> <p>If ORGAM adopts proposal, go to step 12.</p>	ITF sec
11	Inform applicant (Template 1, part 2). End of procedure.	ITF SA
Briefing meeting organisation		
12	<p>Agree date for ITF briefing meeting and send an electronic invitation to applicant (Template 3).</p> <p><i>Note: the revised briefing document needs to be sent to ITF sec latest 2 weeks prior to meeting. Presentation and list of</i></p>	ITF sec

Step	Action	Responsibility
	<i>participants should be sent latest 3 days prior to meeting.</i>	
13	Book meeting room and, if needed, liaise with I-IF-UC regarding virtual meeting arrangements (Template 4).	ITF sec
14	<p>Send list of topics to be discussed to ITF contacts and other relevant EMA staff members and issue call for expression of interest to participate in briefing meeting and act as EMA coordinator.</p> <p>Liaise with SC or WP secretary to include the briefing meeting request in agenda of upcoming plenary meeting or teleconference.</p> <p>Invite international regulatory authorities as appropriate.</p> <p><i>Note: At the request of the applicant experts from international regulatory authorities (e.g. US Food and Drug Administration, Health Canada, Ministry of Health, Labour and Welfare (Japan) and Pharmaceuticals and Medical Devices Agency (Japan) may be involved, if agreed by the agencies concerned.</i></p>	ITF sec
15	<p>Receive expression of interest from ITF contacts and EMA staff.</p> <p>Check that the EMA staff members have no potential conflict of interest in relation to the meeting (see SOP/EMA/0101).</p>	ITF SA
16	Present briefing meeting content to SC/WP at their meeting or teleconference and issue call for expression of interest to act as coordinator and to participate as expert in briefing meeting.	ITF SA/identified EMA coordinator
17	<p>When appropriate, check for potential conflicts of interest of experts who expressed their interest to attend briefing meeting and inform ITF SA.</p> <p><i>Note: Not applicable for international regulatory authorities.</i></p>	ITF sec
18	Evaluate conflicts of interest of experts (see SOP/EMA/0040) and assign expert.	ITF SA
19	<p>Send meeting documents to participants.</p> <p>Forward teleconference instructions to participants when appropriate (Template 5).</p> <p>Liaise with nominated EMA coordinator on meeting arrangements and his/her tasks (use Template 6 if needed).</p> <p>Liaise via email with I-IF-UC (or send meeting request from Outlook) regarding list of teleconference participants and other details relevant to the particular virtual meeting type.</p>	ITF sec
20	Upon receipt of presentation and final list of participants from applicant (at least 3 working days prior to the meeting), order visitor passes for external participants using visitor request forms (Form 3).	ITF sec

Step	Action	Responsibility
Conduct of briefing meeting		
21	<p>Set up meeting room with the fire safety instructions running on screens.</p> <p>Prepare for display of presentation(s) and ensure that teleconference starts as arranged.</p> <p>Meet and greet applicant upon arrival in lobby area.</p>	ITF sec
22	Conduct preparatory internal discussion with SC/WP experts and EMA participants, prior to the meeting with applicant (max. 30 minutes).	EMA coordinator
23	<p>Upon conclusion of preparatory discussion invite applicant in to the meeting room. Provide:</p> <ul style="list-style-type: none"> • health and safety instructions • disclaimer information specific to ITF briefing meeting • instructions on short draft summary applicant has to prepare after the meeting 	EMA coordinator
24	<p>Moderate meeting with following structure:</p> <ul style="list-style-type: none"> • presentation by applicant • discussion of topics identified • brief conclusions summarised after each discussion point • closing remarks. 	EMA coordinator
Meeting summary		
25	Send template for briefing meeting summary (Template 7) and complete list of participants to applicant electronically within 1 working day after the meeting (using Template 8).	ITF sec
26	Upon receipt of draft briefing meeting summary from applicant via email or Eudralink (within 5 working days) (Word format only), forward draft meeting summary to participants for their comments (in track changes).	ITF sec
27	Receive comments from participants within 10 working days.	ITF sec
28	Consolidate comments in the meeting summary.	EMA coordinator
29	Conduct final check that content of meeting summary is appropriate.	ITF SA
30	<p>If content is not appropriate, go to step 31.</p> <p>If content is appropriate, go to step 32.</p>	ITF SA
31	Forward the meeting summary to SC/WP coordinator and, if necessary, to D-LS-PHL advisors.	ITF SA

Step	Action	Responsibility
32	On receipt of the feedback implement the changes in the meeting summary.	EMA coordinator
33	Inform ITF sec that meeting summary is final.	EMA coordinator
34	Circulate the final meeting summary: <ul style="list-style-type: none"> to applicant via email or Eudralink (PDF version without track changes). to participants for information (see list of participants). to relevant SC/WP secretariat. 	ITF sec
35	If requested by SC/WP secretariat, present the main issues discussed at the briefing meeting at the next SC/WP meeting. <i>Note: This may be done by the WP coordinator in agreement with the EMA coordinator.</i>	EMA coordinator
36	Ensure that organisational aspects are tracked in the ITF briefing meetings and the participants table in DREAM	ITF sec

10. Records

All records are saved electronically in DREAM and sorted by year and applicant's name in: 01. Evaluation of Medicine/Innovation Task Force/2. Meeting Organisation/02 ITF Briefing Meetings.

All email correspondence apart from the first contact is sent to chrono in: Outlook/Public Folders/All public folder/Human Products/7 – Innovation Task Force/<year> Briefing meetings.