



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Organisation of paediatric expert group meetings		
Applies to: Paediatric Medicines Section		
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1. Changes since last revision

New WIN

2. Records

When completed and approved the original, signed hard copy of the form is filed in the master file. Electronic copies are saved in DREAM cabinet: 02b. Administration of Scientific Meeting/PDCO - Administration/3. Other activities/02. Expert groups meetings

3. Definitions

D-CM:	Communications Sector
DREAM:	Document records electronic archive management system
ECD:	Eudra Common Directory
FDA:	United States Food and Drug Administration
H-HM-PDM:	Paediatric Medicines Section
HoS:	Head of Sector, Human Medicines Special Areas
MMS:	Meetings management system
Paed Co:	Paediatric coordinator
Paed Sec:	Paediatric secretary



PDCO:	Paediatric Committee
PIP:	Paediatric investigation plan
SA:	Scientific administrator
SH:	Section Head H-HM-PDM

4. Related documents

- SOP/EMA/0040: Evaluation of conflicts of interests of experts for involvement in EMA activities, located at:
http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500002703.pdf
- WIN/EMA/0094 Registration of meeting participants and coordination of visits to the EMA, located at:
http://emeaplus.corp.eudra.org/EMEAPlus_Documents/IQM/IQM_Manual/SOPsWINs/General/WIN_EMA_0094.pdf

5. Documents needed for these WIN

- Paediatric External Experts List (available in DREAM at: Cabinets/02b. Administration of Scientific Meeting/PDCO - Administration/2. Meeting Organisation/06 External experts – Observers)
- Template 1: Checklist for the Coordination of EMA Meetings (located at:
http://emeaplus/EMEAPlus_WebsiteNew/ISERV/html/Services/Security_forms.html)
- Template 2: Thank you letter to Expert (available at: X:\Templates\Others\H – Paediatric Templates)

6. Instructions

Note: PDCO identifies the need for ad hoc expert group meetings during its plenary discussions.

Step	Action	Responsibility
1.	Ensure that PDCO nominates a Chairperson for the meeting either at the plenary or via written procedure. <i>Note: This should normally be a PDCO member.</i>	Paed Co
2.	Nominate a SA in H-HM-PDM to support the Chairperson.	SH
3.	Agree a tentative date and title for the meeting, number of participants and duration of the meeting with the Chairperson. Liaise with Paed Sec to check availability of rooms for the meeting.	Paed Co
4.	Inform SH and HoS of tentative arrangements and obtain approval. Inform the H-HM-PDM.	Paed Co
5.	Set up a folder in DREAM to include necessary subfolders such as agenda, list of participants, list of questions and answers, minutes/report, correspondence etc.	Paed Sec

Step	Action	Responsibility
6.	Book the meeting room in MMS and request reimbursement of delegates. Include booking for function room if required for informal meeting during lunchtime break.	Paed Sec
7.	Liaise internally with other sections/sectors according to WIN/EMEA/0094.	Paed Sec
8.	<p>Upon receipt of experts' names nominated by the PDCO, academic societies, EMA and patients' organisations, approach the nominated experts and ask them to confirm their interest to participate in the meeting, outlining the meeting objectives.</p> <p><i>Note: You may use also experts' names from the Paediatric External Experts List. Involvement of 1-2 experts from the related EMA committees/WGs/WPs/SAGs is highly recommended to ensure appropriate interaction. Consider also involving the FDA, Health Canada, Pharmaceuticals and Medical Devices Agency (PMDA) Japan and other relevant bodies.</i></p>	Paed Co
9.	<p>Identify potential speakers in collaboration with Chairperson.</p> <p>Ask them to confirm their interest to participate with presentation.</p>	Paed Co
10.	<p>When the experts' acceptance has been received finalise the list of participants. Provide mailing list to Paed Sec.</p> <p>If not enough experts confirmed their participation, return to Step 8 (see note).</p>	Paed Co
11.	<p>Prepare agenda and a short list of questions on topics to be discussed at the meeting. Liaise with the Chairperson, other PDCO members where applicable and SA in H-HM-PDM to finalise the documents.</p> <p><i>Note: The topics should be practical and specific with the aim of providing expert views on drug development in the paediatric population. Avoid any confidential information in the questions.</i></p>	Paed Co
12.	<p>Check conflicts of interests of the experts as necessary (see SOP/EMA/0040).</p> <p><i>Note: Official invitation could be sent to an expert even if he/she has conflict of interests as long as no specific products are discussed at expert group meetings.</i></p>	Paed Co
13.	<p>Send an invitation to the experts, including the list of questions, deadline, practical information on issues such as lunch and reimbursement.</p> <p><i>Note: The deadline for submission of answers to the list of questions and presentations (where needed) should be at least 1 week before the meeting.</i></p>	Paed Sec

Step	Action	Responsibility
14.	Send Outlook invitation to internal participants.	Paed Sec
15.	On receipt save the answers from experts in DREAM. Create a spreadsheet (questions in row, experts in columns) and send it to the Paed Co and experts. Update the list of participants.	Paed Sec
16.	Update Paediatric External Experts List including experts participating, their risk level and possible future involvement.	Paed Sec
17.	Collect and save presentations in the meeting folder in DREAM. Liaise with Paed Co on re-formatting if needed.	Paed Sec
18.	Compose a text for publishing on the internal website announcing the meeting. Inform Paed Sec when complete.	Paed Co
19.	A week before the meeting: <ul style="list-style-type: none"> Complete checklist (Template 1) for the coordination of EMA meetings and forward it to: ISERV Helpdesk, MMC Meetings, Catering and Security e-mail groups to make arrangements for printing the meeting documents, creating nameplates, badges etc.; Send the text to the news editors for publishing on the internal website announcing the meeting; Make arrangements to meet and greet experts on arrival. 	Paed Sec
20.	Ensure normal flow of the meeting. Take detailed minutes focusing on key outcomes.	Paed Co
21.	Send a thank you letter to experts by e-mail or by post (Template 3).	Paed Co
22.	Prepare a report on the meeting, focusing on the outcomes of greatest interest to the Agency and to the other stakeholders.	Paed Co
23.	Send the report to participants for comments/editing (via track changes) with a 2 weeks deadline. Remind the experts that all presentations will be published unless an objection is received before the deadline.	Paed Co
24.	Implement the changes and finalise the report within 2 weeks after receiving comments. Review all PowerPoint presentations ensuring that they contain no confidential information.	Paed Co

Step	Action	Responsibility
25.	Prepare the agenda, report and presentations for publishing (formatting, creating pdf files). Send the documents to D-CM for publishing.	Paed Sec
26.	When all documents are published, make sure that the participants, paediatric team and other EMA teams involved are informed via e-mail.	Paed Co