Human Medicines Division
EMA/156497/2024

Business process description

Title: Scientific meeting management		
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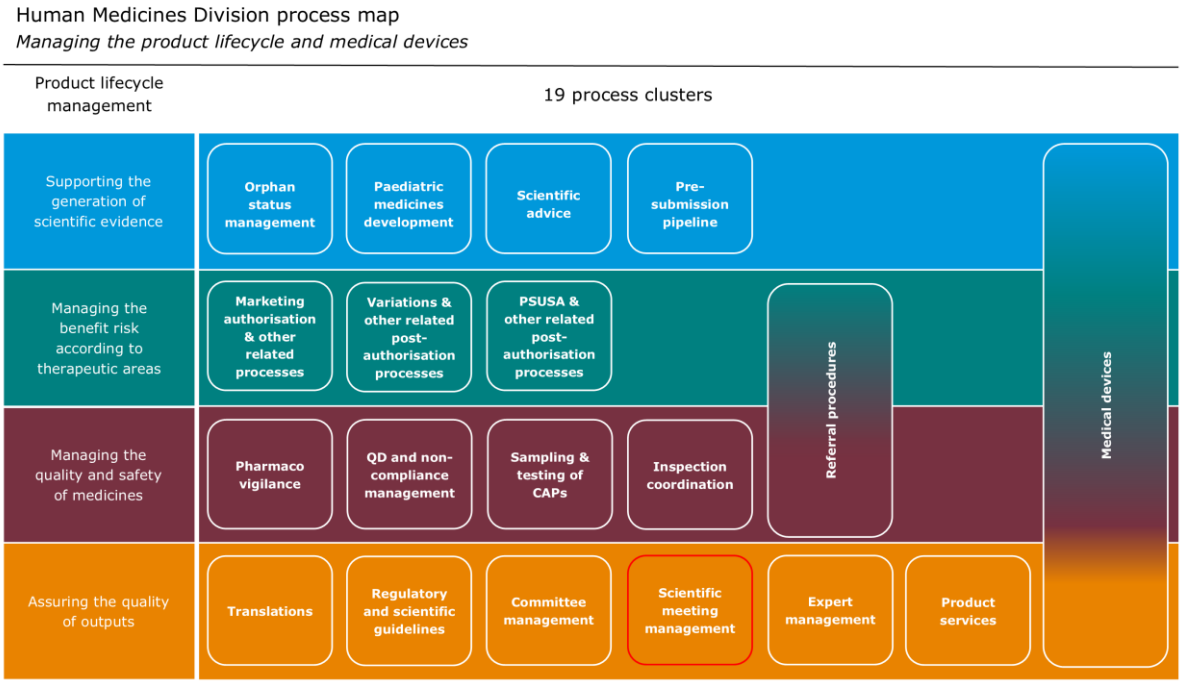
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the scientific meeting management, so that a consistent approach is taken, allowing smooth preparation, and running of each scientific meeting organised by the Human Medicines Division at European Medicines Agency.

This process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.



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Scientific meeting management process:

It describes the process for preparing and delivering scientific meetings (EMA's scientific committees, working parties and other groups) organised by the Human Medicines Division.

2. Changes since last revision

New business process description

3. Related documents

Policies:

- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts – Policy 0044

Guidance documents:

- Guidance document on voting in the framework of discussion and adoption of committee opinions
- 0126 SOP - Arrangements for handling of conflicts of interests for EMA scientific meetings (europa.eu)
- 0040 SOP - Evaluation of conflicts of interests of experts for involvement in Agency activities (europa.eu)

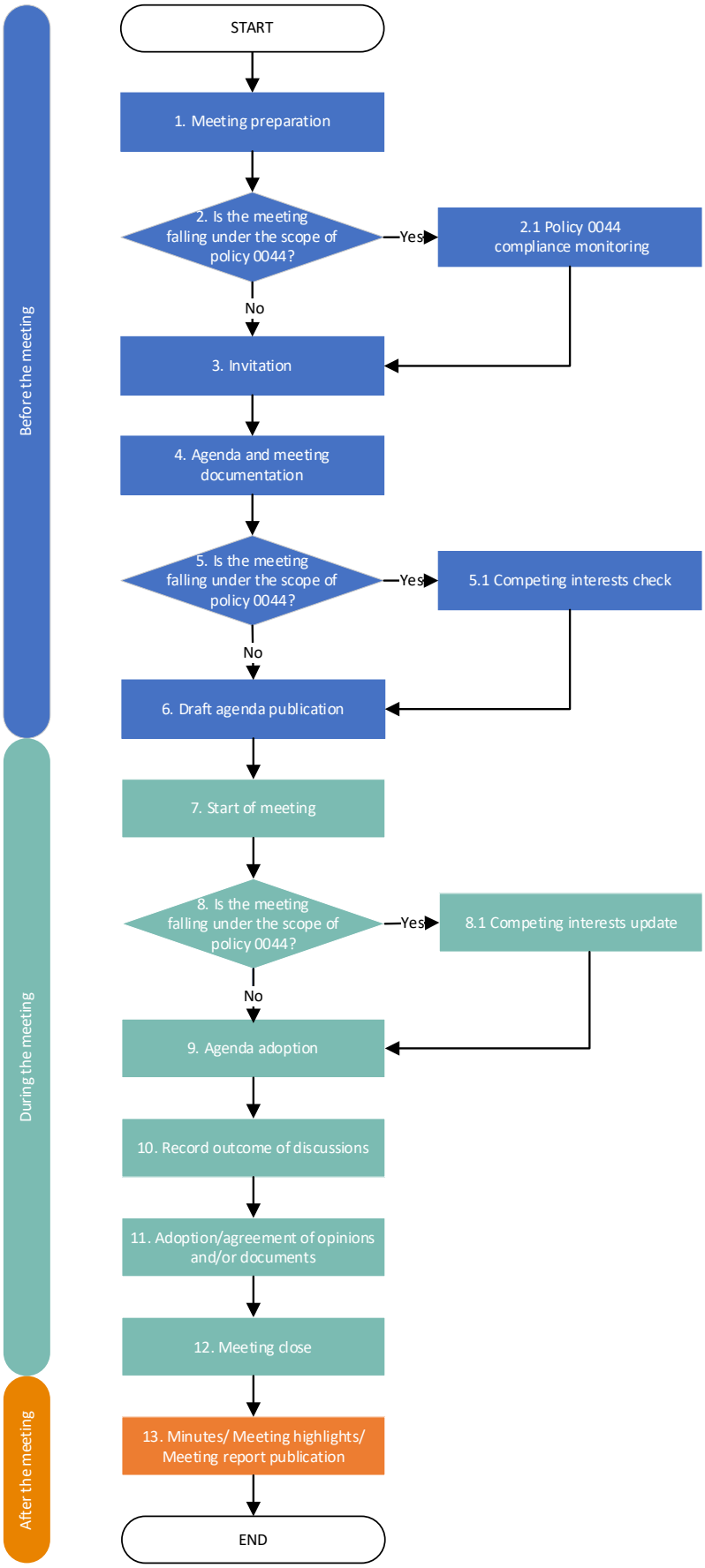
Relevant information:

- How the committees work
- Working parties and other groups | European Medicines Agency (europa.eu)

4. Abbreviations/Definitions

CAPs	Centrally authorised products
CV	Curriculum vitae
DoI	Declaration of interests
EMA	European Medicines Agency
PSUSA	Periodic safety update report single assessment
QD	Quality defect

5. Process map(s)



6. Procedure

Step	Description
Before the meeting	
1.	**Meeting preparation** • Ensure meeting room booking, availability of the necessary equipment (e.g. web and video conferencing tools) and reimbursement & meeting approval, where applicable
2.	**Is the meeting falling under the scope of policy 0044?** • If yes, go to step 2.1 • If no, go to step 3
2.1	**Policy 0044 compliance monitoring** • Verify participants' membership validity and/or participants' inclusion in EMA's Experts Management Tool, as applicable • Evaluate DoI/CV and identify restrictions, if any Go to step 3
3.	**Invitation** • Send meeting invitation to participants, according to status (member/alternate, expert, observer, etc.) and meeting type (in-person, remote)
4.	**Agenda and meeting documentation** • Coordinate the preparation of the agenda and organise their review by chair, participants and relevant EMA staff • Inform participants that the meeting documentation is available (in one or more iterations)
5.	**Is the meeting falling under the scope of policy 0044?** • If yes, go to step 5.1 • If no, go to step 6
5.1	**Competing interests check** • Cross-check recorded restrictions against topics on the agenda to determine the level of participation (full or restricted involvement) • Inform chair and participants about identified restricted involvements due to competing interests, to allow EMA secretariat & chair to apply the restrictions Go to step 6
6.	**Draft agenda publication** • Publish the draft agenda on relevant website, where applicable

Step	Description
	• Circulate the agenda to any other relevant EMA scientific groups, as per rules in place
During the meeting	
7.	**Start of meeting** • Display Health & Safety related information • Formally open the meeting
8	**Is the meeting falling under the scope of policy 0044?** • If yes, go to step 8.1 • If no, go to step 9
8.1	**Competing interests update** • Ask participants to declare any changes, omissions or errors in relation to their declarations of interests or in relation to competing interests concerning the matters for discussion • Record any revised/additional competing interest declared by participants and associated restrictions, as applicable Go to step 9
9.	**Agenda adoption** • Adopt the agenda at the start of the meeting
10.	**Record outcome of discussions** • Take notes of the meeting discussions and their respective outcomes • Amend opinions and/or documents according to the discussions
11.	**Adoption/agreement of opinions and/or documents** • Formally adopt/agree on opinions and/or documents *Note: 'Opinions' cover the range of deliverables adopted by the scientific committees and other bodies as described in their respective rules of procedure, including scientific opinions, recommendations, decisions, advice, agreements and positions*; *adoption of an opinion takes place according to a formally adopted timetable for regulatory procedures on human and veterinary medicines.*
12.	**Meeting close** • Ensure all agenda topics have been covered during the meeting • Formally close the meeting
After the meeting	

Step	Description
13.	**Minutes/Meeting highlights/Meeting report publication** • After being reviewed and adopted, publish the minutes (where applicable). Circulate the minutes to any other relevant EMA scientific group, as per rules in place. • Publish meeting highlights and/or meeting reports on relevant website (where applicable)