EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Arrangements for handling of competing interests for EMA scientific meetings		
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1. Purpose

To describe the procedure for handling of competing interests at the level of the European Medicines Agency's scientific meetings falling within the scope of policy 0044, i.e. the risk minimisation measures and documented evidence in relation to competing interests for meeting participants (chairs, members, alternates and other experts) before, during and after the meeting.

2. Scope

This SOP applies to administrators and assistants in the meeting secretariats of:

- the Scientific Committees, Operational Expert Groups, Working Parties, Drafting Groups, Inspectors Working Groups, Scientific Advisory Groups, Ad Hoc Expert Groups, Emergency Task Force (ETF), Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), Executive Steering Group on Shortages of Medical Devices (MDSSG) and
- other scientific groups or bodies composed of European Experts involved in activities at the level of the Agency falling within the scope of policy 0044.

This SOP is applicable to participants involved in the Agency's meetings falling within the scope of the 'European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts' (policy 0044). This includes meeting attendance (in in-person meetings or virtual meetings), as well as participating in a written (consultation) procedure linked with a meeting.

The SOP does not apply to:

- observers participating in a meeting not requiring a declaration of interests;

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- NCA staff and experts participating in the work at national level for services provided to the Agency as covered by the Memorandum of Understanding between the Agency and the NCAs (e.g. meetings in the context of assessment falling under the role of the Rapporteur (pre-submission meeting, (co-)rapporteurs meetings with companies, peer review meetings, FDA teleconference, etc.). However, if NCA staff or experts attend a meeting at the Agency falling under the scope of policy 0044, the SOP becomes applicable;
- meetings with representatives of other EU and/or non-EU regulatory authorities (e.g. cluster meetings) which represent fora for exchange of information on requirements for marketing authorisation application dossiers;
- members, alternates and experts attending a training, conference or workshop (e.g. public discussion during guidance development) held at the Agency including participants not pertaining to NCAs (e.g. industry).

3. Responsibilities

It is the responsibility of each Head of Division, Head of Task Force, Head of Department and Head of Office to ensure that this procedure is adhered to within his/her own organisational entity. 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

Scope of revision:

- alignment vis-à-vis the latest revision of policy 0044 (resulting from the additional responsibilities for the Agency following its involvement in certain medical device and *in vitro* diagnostic procedures as set out in Regulations (EU) 2017/745 and 2017/746, as well as from its extended mandate in accordance with Regulation (EU) 2022/123);
- the reference to the EMA Experts Management Tool that replaced the Experts Database;
- alignment vis-à-vis EMA's organisational structure.

5. Documents needed for this SOP

- Declaration of interests and Confidentiality Undertaking form (within the Experts Management Tool)
- Evaluation of competing interests feature within the Experts Management Tool
- Meeting Agenda or specific meeting document
- SOP/EMA/0040 – Evaluation of competing interests of experts for involvement in EMA activities

6. Related documents

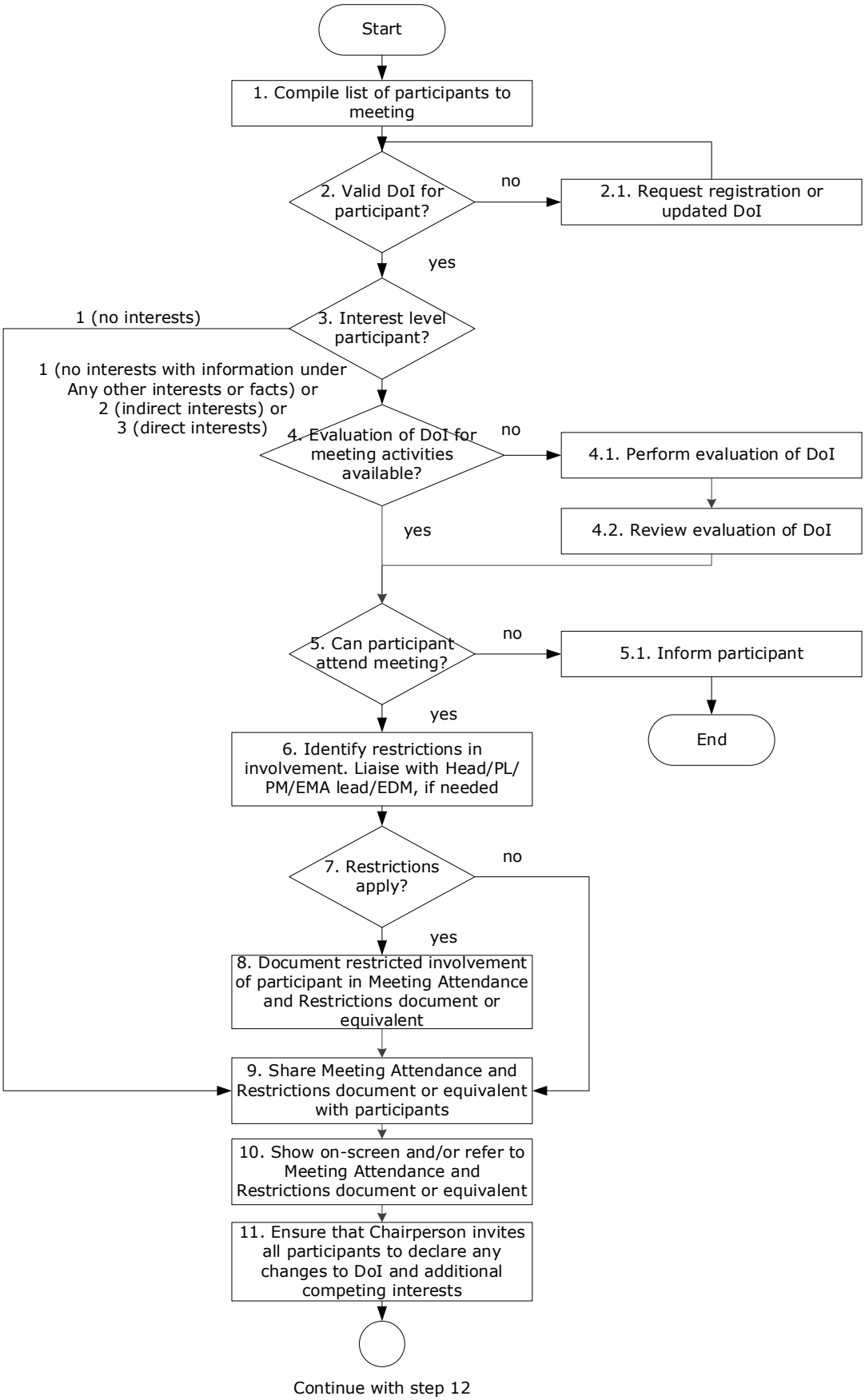
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, in particular Art. 63.2 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0726-20190128)

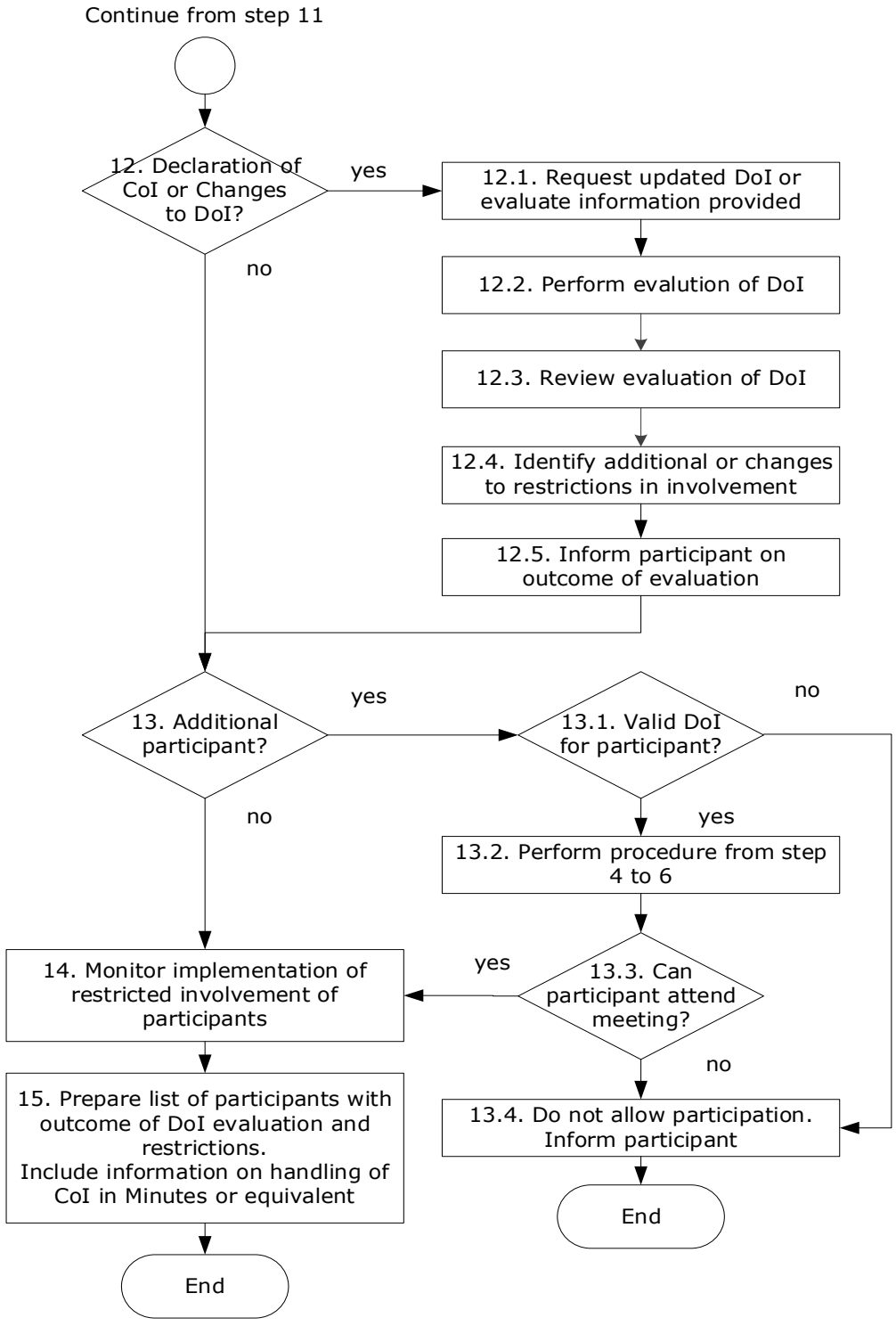
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745)
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746)
- Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0123)
- EMEA Code of Conduct (EMA/385894/2012 rev.1) (Intranet: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580028c78# - Home\About Us\How we work\Handling competing interests)
- European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (policy 0044)
  (Intranet: Integrated management system\Quality Manual\Policies; Internet: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en-0.pdf - Home\About Us\How we work\Handling competing interests)

7. Abbreviations

CoI:	Competing interests
DoI:	Declaration of interests and confidentiality undertaking form
EDM:	Experts and Declarations of Interests Management team within H-QA-SEC
EMA:	European Medicines Agency
PL:	Product Lead
PM:	Procedure Manager

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




Continue from step 11
12. Declaration of CoI or Changes to DoI?
yes
no
12.1. Request updated DoI or evaluate information provided
12.2. Perform evalution of DoI
12.3. Review evaluation of DoI
12.4. Identify additional or changes to restrictions in involvement
12.5. Inform participant on outcome of evaluation
13. Additional participant?
yes
no
13.1. Valid DoI for participant?
no
yes
13.2. Perform procedure from step 4 to 6
13.3. Can participant attend meeting?
yes
no
14. Monitor implementation of restricted involvement of participants
15. Prepare list of participants with outcome of DoI evaluation and restrictions.
Include information on handling of CoI in Minutes or equivalent
13.4. Do not allow participation. Inform participant
End
End

9. Procedure

Step	Action	Responsibility
Pre-meeting		
1	Compile a list of participants to the meeting.	Assistant
2	Verify for each meeting participant requiring a DoI if he/she is included in the Experts Management Tool with a valid DoI (green status and interest level). If yes, go to step 3. If no, go to step 2.1.	Assistant
2.1	Request the meeting participant to register in the Experts Management Tool or submit an updated DoI. Return to step 2.	Assistant
3	For meeting participants with interest level 1 (no interests declared), continue with step 9. For meeting participants with interest level 1 (no interests declared with information under Any other interests or facts), interest level 2 (indirect interests declared) or interest level 3 (direct interests declared), go to step 4.	Assistant
4	Verify for each participant with interest level 1 (no interests declared with information under Any other interests or facts), interest level 2 or (indirect interests declared) or interest level 3 (direct interests declared), if an evaluation of the competing interests on the current DoI for the meeting activities exists and if the outcome of this evaluation is still applicable (in particular with regard to the time frames for restrictions for declared interests, e.g. interest > 0 and ≤ 3 years versus > 3 years). If yes, go to step 5. If no, go to step 4.1. *Note: A (rolling) overview of the status of the DoI and evaluation of competing interests form for participants attending a meeting regularly can be maintained by the meeting secretariat.*	Assistant
4.1	Perform, in the Experts Management Tool, the evaluation of the DoI of the meeting participant for competing interests for involvement in the meeting activities. Submit the evaluation for approval by the Administrator.	Assistant
4.2	Review and approve, in the Experts Management Tool, the evaluation of the DoI of the meeting participant for competing interests for involvement in the meeting activities. In case the DoI evaluation is not correct, reject the DoI evaluation	Administrator

Step	Action	Responsibility
	in the tool and inform the Assistant for appropriate action. Continue with step 5.	
5	Determine if the participant can attend the meeting. If yes (with or without restrictions), go to step 6. If no (no involvement), go to step 5.1.	Administrator
5.1	Inform the participant by email that he/she is not allowed to attend the meeting. End of procedure.	Administrator / Assistant
6	Identify restricted involvement of the meeting participant for items (medicinal products, guidelines, etc.) on the draft agenda of the meeting based on the outcome of the evaluation of his/her DoI. If needed, liaise with Heads of Office, PLs/PMs/EMA leads responsible for a particular product/procedure/guideline/topic or the EDM team with regard to potential competing interests for items on the meeting agenda.	Administrator
7	If no restrictions apply to the meeting participant, continue with step 9. If restrictions apply to the meeting participant, go to step 8.	Administrator
8	Document the restricted involvement of the participant for the meeting in the 'Meeting Attendance and Restrictions document' or an equivalent document which includes details on the restrictions applicable.	Administrator
9	Save the document in the meeting folder in the EMA documents repository system. Share the 'Meeting Attendance and Restrictions document' or an equivalent document with all meeting participants, inviting them to review the document, to adhere to the identified restrictions during the meeting and to inform the secretariat of any changes, omissions or errors to declared interests and identified restrictions.	Assistant
During the meeting		
10	At the start of the meeting, show on-screen and/or refer to the Meeting Attendance and Restrictions document or an equivalent document for the meeting and refer to restricted involvement of participants.	Assistant
11	Immediately following the announcement from step 10, ensure that the Chairperson invites all participants present to declare any changes to their current DoI, any additional competing interests on	Administrator

Step	Action	Responsibility
	items on the agenda or any changes, omissions or errors to already declared interests and/or identified restrictions.	
12	Does a meeting participant declare changes to his/her current DoI or competing interests on items on the meeting agenda at the start or during the meeting? If no, go to step 13. If yes, go to step 12.1.	Administrator
12.1	Prior to any further participation of the expert in the meeting, request the meeting participant to submit an updated DoI as soon as possible or evaluate the information provided by the meeting participant against the items on the meeting agenda to identify potential additional changes to restrictions in involvement of the participant for items on the agenda. *Notes:* - *The expert may remain in the meeting, but cannot participate in the meeting until the declared interest has been evaluated. If the declared interest regards an interest which may result in the exclusion of the expert from involvement in the activity, the expert is requested to leave the meeting until the declared interest has been evaluated.* - *In order not to interrupt his/her support to the meeting, the Administrator can delegate under his/her responsibility the actions described in steps 12.1 to 12.5 to a colleague.*	Administrator
12.2	Perform the evaluation of the updated DoI in the Experts Management Tool.	Assistant
12.3	Review and approve the evaluation of the updated DoI in the Experts Management Tool. In case the DoI evaluation is not correct, reject the DoI evalution in the tool and inform the Assistant for appropriate action.	Administrator
12.4	Identify additional or changes to restrictions in involvement of the meeting participant for items on the meeting agenda based on the outcome of the evaluation of the updated DoI or the evaluation of the information provided against the items on the meeting agenda.	Administrator
12.5	Prior to the involvement in the meeting, inform the meeting participant by email on the outcome of the evaluation on the impact of his/her participation or (restricted) involvement in the meeting, as well as the Chairperson. Save the communicaton to the participant in the EMA documents repository system.	Administrator
13	Is an additional participant requiring a DoI attending the meeting	Administrator

Step	Action	Responsibility
	who was not foreseen prior to the start of the meeting? If no, go to step 14. If yes, go to step 13.1	
13.1	Prior to involvement of the additional participant in the meeting, verify for him/her if a valid DoI exists in the Experts Management Tool (green status and interest level). If yes, go to step 13.2. If no, go to step 13.4. *Note: In order not to interrupt his/her support to the meeting, the Administrator can delegate under his/her responsibility the actions described in steps 13.1 to 13.4 to a colleague.*	Administrator
13.2	Perform the procedure described in step 4 to 6 of this SOP.	Administrator
13.3	Can the additional participant attend the meeting? If no, go to step 13.4. If yes, add the additional participant and his/her restricted involvement for the meeting, if applicable, in the 'Meeting Attendance and Restrictions document' or an equivalent document which includes details on the restrictions applicable. Go to step 14.	Administrator
13.4	Do not allow the participant to attend the meeting, unless a valid DoI becomes available in the Experts Management Tool (green status and interested level). Inform the participant accordingly. End of procedure.	Administrator
14	Monitor the implementation of restricted involvement of participants, e.g., in terms of not participating in the discussions, not participating in the deliberations and voting. In case of non-compliance with the restrictions, immediately inform the Chairperson and the participant concerned. *Note: Participants with restricted involvement are not required to leave the meeting. Any participant, who would like to leave the meeting, is allowed to do so.* Remind the Chairperson in case restrictions apply to voting.	Administrator
Post-meeting		
15	Prepare a list of participants with the outcome of the evaluation of the DOI and, if any, the restriction(s) applicable for each participant. The information is included in the meeting Minutes or an equivalent document, or as an annex.	Assistant / Administrator

Step	Action	Responsibility
	Include in the meeting Minutes or an equivalent document, or in an annex the following information: • Statement that information on the restricted involvement of participants has been announced by the meeting secretariat at the start of the meeting, including clarifications or additional information. • Statement that the meeting participants were invited to declare any changes to their current DoI and any additional interests or restrictions concerning the items on the agenda. • Statement that discussions, deliberations and voting have taken place in full respect of the restricted involvement of participants. • Outcome of the evaluation of competing interests and any changes to restrictions in involvement in the meeting for participants, who declared changes to their current DoI and/or competing interests on items on the meeting agenda at the start or during the meeting. Save the meeting Minutes or an equivalent document, as well as the list of participants in the meeting folder in the EMA documents repository system.	

10. Records

The meeting Minutes or an equivalent document including the list of participants with information on restricted involvement for the meeting are saved electronically in the EMA documents repository system (retention time: as specified in the business classification scheme).

Correspondence on competing interests for meetings is saved in the meeting folder or the relevant folder on experts-related information in the EMA documents repository system.