17 December 2024
Executive Director
EMA/550476/2024

Representing the Agency at external events or in professional bodies

POLICY/0029

Status: Public
Effective date: 1 January 2025
Review date: 31 December 2027
Supersedes: EMA/451020/2008, Rev 2 and supersedes and replaces Policy on scientific publication and representation for European Medicines Agency scientific committees and their members (Policy 0025, EMA/231477/2005 rev. 1)

1. Introduction and purpose

The European Medicines Agency (EMA) receives a large number of invitations to contribute to different fora and to attend external events such as conferences or workshops. This policy harmonises the Agency's approach to these requests and aims to provide consistency of responses and facilitate a rapid reply. The policy should be considered in all cases, and provides for exceptions in certain circumstances. Where an exception is requested, it should be duly justified and documented.

When EMA accepts an invitation, the contribution may be provided either by EMA staff, members of Scientific Committees and other EMA bodies or experts from the European regulatory network.

EMA should consider in all cases the opportunities that such invitations bring to the Agency, taking into consideration the mid- to long-term strategic priorities of the Agency, the Agency's mandate, and availability of economic and human resources.

2. Scope

This Policy addresses the handling of requests for participation to external events by EMA staff, members of Scientific Committees working parties, scientific advisory groups and other bodies (i.e. ETF, MSSG and MDSSG), members of the EMA Management Board and experts from the European regulatory network.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

This policy also addresses the membership in professional bodies. Membership in professional organisations by EMA staff members (as part of their duties or as an outside activity[1]) are not in the scope of this policy.

Scientific publications and activities on editorial boards by EMA staff and EMA Scientific Committees members relating to the Agency's remit are handled in a separate policy (Policy 0015 on publications by EMA staff and EMA Scientific Committee members on EMA's work).

3. Definitions

EMA staff: for the sole purpose of this policy, means EMA staff members (Temporary Agent, Contract Agent) and Seconded National Expert;

EMA or Agency: European Medicines Agency;

ETF: Emergency Task Force;

Event request: includes requests for conferences, workshops, information days. A specific request to meet with an organisation in order to discuss one or more issues or to inform EMA on the main activities of such organisation is not within the scope of this Policy;

Experts: individuals nominated to participate to the work of supporting EMA's Scientific Committees, Working Parties, scientific advisory groups and other EMA bodies;

MedTech: Medical Technology Industry, including medical devices, diagnostics, and digital health.

MSSG: Executive Steering Group on Shortages and Safety of Medicinal Products;

MDSSG: Executive Steering Group on Shortages and Safety of Medical Devices;

Professional bodies: includes learned societies, professional membership organisations, editorial boards of peer reviewed journals. For the purpose of this policy, it also includes other organisations such as ethics committees, data safety monitoring boards, research networks;

Request to participate: an invitation for participation as an active contributor (e.g. speaker, chair, panellist) at an event;

Request to attend: an invitation to be present at an event, but without active contribution (e.g. as observer);

Scientific Committees and other EMA bodies: Scientific committees, working parties, scientific advisory groups and other bodies (i.e. ETF, MSSG, MDSSG), as well as the Management Board;

S Division: Stakeholders and Communication Division.

[1] Management Board decision - Outside activities and occupational activities after leaving the Service

4. Policy statement

The purpose of the Policy is to identify potential conflicts of interest, to allow prioritisation and to harmonise the response according to the nature of the request for contributions by EMA staff and other individuals representing the Agency, such as members[2] of Scientific Committees and other EMA bodies' and experts acting on behalf of the Agency.

The Agency's independence policies apply regarding conflicts of interest as set out in respect of the Management Board (policy 0058), scientific committee members and experts (policy 0044) and staff – the Decision of the EMA relating to Articles 11, 11a and 13 of the Staff Regulations.[3]

4.1. Representation of the Agency at external events

In general, a request to participate in an external event shall be limited to cases where there is no *prima facie* perception of a conflict of interest. This is to ensure a high level of public trust, which is especially important in relation to the role of third parties and how they seek to influence EU staff members.

In general terms, participation in events of so-called conferences for consensus, usually focused on the production of disease management guidelines (including treatment), should be refused. However, it is acceptable to provide information from the regulatory point of view if the event is not funded by pharmaceutical or MedTech companies.

In case of a request to attend, the status of "observer" should be carefully considered, in particular if event proceedings or similar documents (e.g. guidelines, recommendations) will follow. If the presence of a person on behalf of the Agency is going to be perceived as an endorsement of conclusions, the request should be refused.

Guidance for acceptability of invitations

Guidance regarding acceptability of invitations depending on the nature of the requester is provided in Annex 1. Exceptions are indicated.

The criteria are based on considering the interests of the Agency and identifying the risk of conflicts of interest, whether real, potential or perceived as regards the inviting body.

In reaching a decision on acceptability, consideration should be given not only to the nature of the organiser, but also to sponsorship of the event. For example, where an event or session is proposed by a not-for-profit organisation but sponsored by a single pharmaceutical or MedTech company, participation should be declined.

Alignment with the Agency's strategic priorities, prioritisation and resource implications, as well as the expected impact of the event, will also be considered.

The Agency as well as the individuals representing EMA at any event do not accept fees for their participation.

Travel and accommodation expenses can be met by the inviting body only where the funding of the event is not sponsored by an individual pharmaceutical, MedTech company or industry trade

[2] References to members also apply to alternates.
[3] Policy 0058: European Medicines Agency policy on the handling of competing interests of Management Board members; Policy 0044: European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts; Decision of the European Medicines Agency on rules relating to Articles 11,11a, and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment.

association. Travel and accommodation expenses should be reasonable in line with the mission rules for staff or reimbursement rules for delegates and only be related to the purpose of the invitation.

Digital recordings and remote meeting options are encouraged and should be indicated by the organiser, as appropriate, with the invitation for the event.

In exceptional cases, where normally under this Policy the Agency would decline participation in an event, for example from a for-profit organisation, the Agency may, nevertheless, decide to accept participation. Such a case could arise if a topic of strategic importance cannot be satisfactorily addressed in other venues and if the particular event would provide a unique platform and visibility to the Agency's stakeholders. In such a case, due justification must be provided for agreement by the relevant Head of Division/ Task Force or the Executive Director and properly documented.

The considerations for member of scientific committees and other EMA bodies and experts who participate in external events that may or may not be part of their scientific activities are set out in Annex 2. This annex contains the disclaimer to be used when attending an event on an individual basis or on behalf of EMA or the scientific committees and other EMA bodies.

Responsibility for implementing this policy for EMA staff lies with the relevant Head of Divisions/Task Force according to its organisation as per the "Internal guidance on Coordination of EMA participation to external organised events". For the Scientific Committees and other EMA bodies, the relevant secretariat will coordinate as appropriate and communicate it to its members. The procedure should follow the considerations set out in Annex 2.

S-Division will facilitate monitoring and a tracking system of requests for participation.

4.2. Membership of professional bodies

Members of scientific committees and other EMA bodies and experts, may become members of professional bodies. When accepting such memberships, the member or expert will clearly state that this membership is extended to him/her only as an individual, and in no way he/she can be considered a member on behalf of the EMA, scientific committees or other EMA body, as appropriate. This membership has to be declared to the Agency, so that any potential conflict of interest during an evaluation process or for other EMA activity can be anticipated and mitigated.

Members and experts may participate in initiatives undertaken within the official arrangements of the Agency i.e. following nomination in relation to EMA's representation in an external group which has been formally foreseen (e.g European Commission, European Directorate for the Quality of Medicines).

Other requests for an individual to represent EMA as a member of an ad-hoc or permanent body belonging to any kind of professional organisation is treated as an exception. Such requests must be justified and are considered on a case-by-case basis.

5. Related documents

Annex 1: Guidance on acceptability of invitations (depending on the nature of the requester).

Annex 2: Considerations for scientific committees and other EMA bodies members and experts.

6. Changes since last revision

The policy has been updated to take account of the Agency's experience in the area of representation and participation to external events as well as for procedural, organisational and reference document changes. The policy now encompasses representation of the Agency by both EMA staff, members of

Scientific Committees and other EMA bodies, members of the Management Board and experts from the European regulatory network. It also addresses their participation/membership of professional bodies. Consequently, relevant content from superseded Policy on scientific publication and representation for European Medicines Agency's scientific committees and their member (Policy 0025) has been included in this policy. The title of the policy has been updated to reflect the changes.

Annex 1 has been updated in the light of experience gained.

Annex 2 has been added to address the considerations for members of scientific committees and other EMA bodies and experts, with disclaimers depending on whether they attend on behalf of EMA or its scientific committees or other EMA bodies or on an individual basis.

Amsterdam,

[Signature on file]

Emer Cooke
Executive Director

Annex 1: Guidance on acceptability of invitations (depending on the nature of the requester)

Organiser (or sponsor, as appropriate)	Type (if applicable)	Acceptability*
European Parliament		Yes
European Commission		Yes
EU Agencies		Yes
National Agencies/ National Competent Authority		Yes
Governmental Research Institutions *(e.g. MRC, Karolinska, Platz, NICE)*		Yes
University		Case by case
Academic & Learned societies	National	Exceptional
	EU	Yes
	International	Case by case
Patients, Healthcare Professionals	National	No
	EU	Yes
	International	Exceptional
For-profit organisations *(e.g. commercial event organisers)*		Exceptional
International public organisations *(e.g. WHO, UN, OECD)*		Yes
Non-Governmental organisations *(e.g. MSF, Bill & Melinda Gates Foundation)*		Yes
Consortia (e.g. IHI)	Private	No
	Private-Public	Case by case
	Public	Yes
Non-for-profit organisations *(e.g. charities, nationally funded research bodies)*	National	Exceptional
	EU	Yes
	International	Exceptional
Other non-for-profit organisations ((e.g. EHFG) and professional membership organisations (e.g. BIO, DIA, TOPRA, RAPS))	National	Exceptional
	EU	Yes
	International	Case by case
Pharmaceutical, or MedTech Trade Associations *(e.g. EFPIA, AESGP, Medicines for Europe, EuropaBio, AnimalhealthEurope, EGGVP, PhARMA, JPMA)*	National	Exceptional
	EU	Yes
	International	Case by case
Pharmaceutical companies / MedTech companies / Consultancies		No

*Acceptability will also take into consideration alignment with the Agency's strategic priorities, prioritisation and resource implications.

Annex 2: Considerations for scientific committees and other EMA bodies' members and experts on participation to external events

Scientific committees and members of other EMA bodies and experts may participate in external events, as part of their EMA activities.

Two situations are envisaged:

1. The member or expert participates as an individual at an event related to his/her EMA activities, and does not formally represent the EMA, the scientific committee or other EMA body to which they belong. When deemed appropriate, he/she should declare so in the meeting, and the following disclaimer can be used in any material or presentation to be displayed:
   "I attend this event as an individual expert, and do not represent the EMA <scientific committee or other EMA body name, as appropriate>. The views expressed here are my personal views, and may not be understood or quoted as being made on behalf of the <scientific committee or other EMA body name, as appropriate> or reflecting the position of the <scientific committee or other EMA body name, as appropriate> or EMA"

2. More rarely, a member/expert may participate at an event and represent EMA, the scientific committee or the other EMA body to which they belong. The individual, in this case, will be mandated only to express the views of EMA or the scientific committee or other EMA body, as appropriate, and the following disclaimer should be used in any material or presentation to be displayed:
   "I attend this event to represent the <EMA scientific committee or other body name, as appropriate>. The views expressed here are the current views of the <EMA scientific committee or other EMA body name, as appropriate>, but in no way shall be binding for the <EMA scientific committee or other EMA body name, as appropriate> or EMA."

In this case, the following particulars will apply:

- Prior to any decision on participation, the Agency's secretariat will check the nature and the funding of the event and will decide whether or not it is appropriate to participate (in line with section 4.1 and Annex I). The decision will always be made on the basis of the Agency's Code of Conduct.
- Information on the event, as well as the request for participation of a representative will be circulated to the scientific committee, the other EMA body.
- The scientific committee, other EMA body will nominate a member or an expert who will attend and represent the group.
- In any case, and whatever the type of the participation, the member or expert will abide by the principles set out in the Agency's Code of Conduct. Special attention must be paid to avoid disclosure of any information of confidential nature.
- The representative will ensure that the views expressed at the event are those of the scientific committee, other EMA body.
- Copy of the presentation, as well as his/her report from the event should be made available to other members.