EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2010
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Replies to external requests for contributions by European Medicines Agency staff

POLICY/0029 Rev 2
Effective date: 22-JUL-10
Review date: 22-JUL-13
Supersedes: POLICY/0029 Rev 1 (21-AUG-09)

1. Introduction and purpose

The EMA receives a large number of invitations to contribute to different kind of forums, to meet with organisations and to attend conferences. This Policy harmonises the Agency's approach to these requests, provides consistency to responses and facilitates a rapid reply in some cases. However, it is not intended to cover all cases; some invitations should be decided on a case by case basis and exceptions can me made.

When EMA accepts an invitation, the contribution could be provided either through EMA staff members or via experts from the European network in accordance with the "Policy on Representation of EMEA Scientific Committees by its Members". EMA should consider in all cases the opportunities that such invitations bring to the Agency, the mid to long-term perspective of the request, its own level of competence, and economic and human resources availability.

Training activities are excluded from this Policy.

2. Scope

This Policy applies to all Agency staff.

3. Definitions

- **Request to a meeting:** a specific request to meet with an organisation in order to discuss one or more issues or to be informed on the main activities of such organisation. This is not within the scope of this Policy.
- **Request to participate**: an invitation for participation as active contributor (i.e. speaker, chair, etc.) at an event.

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- **Request to attend**: an invitation to be present at an event, but without active contribution.

CXMP: Any EMA Committee

NA: Not applicable

NCA: National Competent Authorities

4. Policy statement

The purpose of the Policy is to identify conflicts of interest, to allow prioritization and harmonise the response according to the kind of request for contributions by European Medicines Agency staff.

A **Request to be member of ad-hoc or permanent bodies** belonging to any kind of organisation should be refused, with the exception of initiatives undertaken within official arrangements of the EMA (e.g. PSTC as part of the C-Path initiative).

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 individual pharmaceutical companies.

In case of a **Request to attend**, the condition of "observer" should be carefully considered in particular if event proceedings or similar documents (guidelines, recommendations, etc.) will follow. If the presence of someone on behalf of the EMA is going to be considered as endorsement of conclusions, the request should be refused.

Annex 1 provides guidance regarding acceptance of invitations and reimbursement and its main criteria is based on identifying potential conflict of interest, although prioritisation is also considered. EMA members of staff must not accept any fee for their participation at any event.

Each of the above requests is made to the EMA and therefore involvement of staff is considered always on behalf of the EMA and mission rules apply.

The use of video recordings and videoconferencing facilities should also be encouraged.

The procedure for the implementation of this policy should be set up by each Unit according to its organisation. Each Unit should develop a monitoring and follow-up tracking system.

5. Related documents

- Annex 1: Criteria for acceptance/reimbursement
- POLICY/0025: Policy on Representation of EMEA Scientific Committees by Its Members (EMEA/231477/2005)
- EMEA mission rules (*http://emeaplus/EMEAPlus_Documents/Staff_matters/Missions/New%20Mission%20rules%20as%20of%201%20July%202009.pdf*).

6. Changes since last revision

The changes concern a clarification of the scope of the Policy (4. Policy statement) and including Non-for-profit Organisations in Annex 1

London, 20 July 2010

On file

Thomas Lönngren

Executive Director

Annex 1: Criteria for acceptance/reimbursement

		Acceptance to participate	Acceptance for reimbursement if offered*	Comments
European Parliament		YES	YES	
European Commission		YES	NA	
EU Agencies		YES	YES	
National Agencies		YES	YES	
Governmental Research Institutions		YES	YES	i.e. MRC, Karolinska, Platz, NICE, etc.
University		Case by case	YES	
Academic & Learned societies	National	Exceptional	YES	Refer to NCA In all cases, information/liaison with Medical Information Sector
	EU	YES	YES	
	International	Case by case	YES	
Patients, Healthcare Professionals	National	NO	NA	
	EU	YES	YES	
	International	Exceptional	YES	
Training Organizations non-profit		YES	YES	i.e. DIA, TOPRA, RAPS, etc.
Organizations for profit		NO	NA	
International public organisations		YES	YES	i.e. WHO, UN, OECD, etc.
Non Governmental Organizations		YES	YES	i.e. MSF, Bill & Melinda Gates Foundation, etc.
Consortiums	Private	NO	NA	
	Private-Public	Case by case	Case by case	i.e. IMI (see policy: http://www.emea.europa.eu/pdfs/24929308en.doc)
	Public	YES	YES	
Non-for-profit organisations.	National	Exceptional	YES	i.e. charities, nationally-funded research bodies. In case of National: refer to NCA. If meeting is sponsored by a single company, all expenses should be bore by EMA.
	EU	YES	YES	
	International	Exceptional	YES	
Pharmaceutical Trade Associations	National	Exceptional	YES	Refer to NCA
	EU	YES	YES	i.e. EFPIA, AESGP, EGA, EuropaBio, IFAH-Europe, EGGVP
	International	Case by case	YES	i.e. PhARMA, JPMA,

Pharmaceutical companies		NO	NA	
Non regulated companies		YES	YES	i.e. IT providers

* Reimbursement: travel, accommodation.
NA: Not applicable; NCA: National Competent Authorities