



Agenzia Italiana del Farmaco

AIFA

**GUIDELINE
PARTICIPATION OF AIFA PERSONNEL IN EXTERNAL ACTIVITIES
(congresses, conferences, master, university formative courses)**

INTRODUCTION

The Italian Medicines Agency (AIFA) is a public body operating autonomously, transparently and according to cost-effectiveness criteria under the direction and the vigilance of the Ministry of Health and the Ministry of Economy, and cooperating with the Regional Authorities, the National Institute of Health, Research Institutes, Patients' Associations, Health Professionals, Scientific Associations, Distributors and the Pharmaceutical Industry.

AIFA contributes to and defends the right to health (guaranteed by the National Constitution - art. 32) through the use of medicines in order to:

- ensure unity of the national pharmaceutical system in accordance with the Regions;
- facilitate the access to innovative and orphan drugs as well as to those used for rare diseases;
- promote the safe and appropriate use of medicines;
- encourage investments in pharmaceutical research and development in Italy;
- enforce the relationship with the Agencies of other member states, the European Medicines Agency (EMA) and other international bodies.

AIFA specifically acts and works according to the main strategy based on Membership, Transparency and Responsibility.

The present guideline defines the administrative instructions for the participation in external activities (congresses, conferences, master, university formative courses, etc.) to which the AIFA personnel is invited as *spokesman/lecturer/moderator* by corporate body organizers.

Since in AIFA an internal standard operating procedure describing these activities is currently in place (authorization for the participation in the event, use of didactic materials, etc.), this guideline is essentially directed to the activities that the corporate body organizer has to set up and the corresponding rules to follow.

The formalities for the participation are defined according to the nature of the corporate body organizer and the typology of the proposed events, indicating specific criteria for the selection of the AIFA personnel invited.

DEFINITIONS

Corporate body organizer: subject organising the event and inviting the AIFA personnel to participate as *spokesman/lecturer/moderator*. Events organised by the following corporate bodies are acceptable:

- public structures (Central Administrations, Regions, SSN Structures, Universities, other public corporate bodies)
- Scientific societies
- Patients' associations
- Category associations
- Non-profit Organizations
- Societies organising courses, conferences and interinstitutional manifestations whose activities are specifically included among the strategic priorities identified by the Office of the Director General. In these cases the presence at the courses will have to be regulated by a specific Convention among AIFA and the corporate body organizer.

Invitations from Pharmaceutical Companies and/or sponsored/partially sponsored by Pharmaceutical Companies as well as all those cases where the participation may give rise to conflict of interests for AIFA – in accordance with the *Conflict of Interest Regulations* (“*Regolamento per la disciplina dei conflitti d’interesse all’interno dell’Agenzia Italiana del Farmaco*”) approved by the AIFA Board of Directors (26.01.2012) and published on the Official Journal (“*Gazzetta Ufficiale*”) of 20.03.2012 - cannot be taken into consideration.

The participation in predominantly recreational or non appropriate events - whatever the corporate body organizer is - is not acceptable, except for those cases where the participation is of great interest and importance for AIFA.

Institutional activities: activities conferred by reason of the Office/Unit of the AIFA personnel invited and carried out within the institutional functions of the participants.

INSTRUCTIONS

Presentation of the application for participation in events by the corporate body organizer

The corporate body organizer inviting AIFA personnel to take part in external events (congresses, conferences, master, university formative courses, etc.) as *spokesman/lecturer/moderator*, has to present the application for the participation to the Agency using the proper form downloadable from the AIFA institutional portal (Template 352/01 "Application to AIFA for participation in an event" - "Richiesta ad AIFA di partecipazione ad un evento").

This form, properly filled in, has to be addressed to the Executive of the AIFA Office/Unit (together with the interested person, in case this is different from the Executive of the Office/Unit) and Cc to the Director General Technical Secretary Office (STDG) with enclosed a copy of the program (provisional but consolidate) of the event.

Both form and enclosed documentation have to be sent to AIFA via e-mail (exceptionally via regular postal mail) at least 30 days before the event date. The participation in specialization and improvement courses, master etc. as lecturer is subordinated to the previous signing of a proper Convention among AIFA and the corporate body organizer (ref.: Standard Convention among AIFA and the corporate body organizer).

Remuneration

The AIFA personnel taking part in the event as *spokesman/lecturer/moderator* has to receive a remuneration by the corporate body organizer based on the AIFA Table of Charges (Document 352/01 "Table of charges" - "Tariffario compensi").

The payment has to be done in favour of the Agency (Fund for financing the remuneration of position and result) and, regarding the payment conditions, in accordance with the formalities indicated in the Template 352/01 "Application to AIFA for the participation in an event".

The participation in institutional events organised by Public Administrations or *non-profit* bodies is generally carried out free of charge, if the learners participate free of charge too.

In any case the corporate body organizer is always responsible for the reimbursement of the travelling and staying expenses of the participant.

At his own discretion, the Director General can rarely make exceptions to the above mentioned conditions.

Requirements for the evaluation of the application for participation

In order to be authorized, the events to which AIFA personnel is invited have to correspond to the following qualitative characteristics:

- importance for AIFA of the theme object of discussion;
- results for AIFA arisen from the participation (in terms of realization of institutional objectives, of acquisition and transmission of experiences and competences or of external visibility and in economic terms);
- importance e/o prestige of the program of the event and, if any chance, of the session to which the participant takes part, included the professional profile of the other spokesmen.

Moreover the following situations are considered incompatible:

- those causing conflicts of interest;
- those that - for requested commitment and formality/place of carrying out the event - do not allow the parallel timely and punctual accomplishment of the working duties to satisfy the participant's own Office/Unit demands.

Furthermore, the corporate body organizer has to guarantee that both travel and accommodation reimbursement as well as any possible remuneration do not derive from funding received by pharmaceutical companies. Participations in events – economically or in any other possible way sponsored by the pharmaceutical industry - are not accepted.

For hardly attainable places, it can be useful to propose a participation in videoconference.

Fulfillments of the corporate body organizer regarding the event program

The corporate body organizer cannot make name and qualification of the AIFA participant known without having previously obtained the authorization. In any case, before the final authorization, the program has to be printed as provisional (but consolidate) and beside the participant's name the wording "awaiting confirmation" ("in attesa di conferma") has to be specified. The corporate body organizer will be informed about the participation by the AIFA participant invited or his/her own Executive of the Office/Unit.

Publication of the presentation on the institutional portal of the corporate body organizer

The corporate body organizer willing to publish the didactic materials presented by AIFA personnel on its own institutional portal, can carry on with the publication only if previously authorised by AIFA and provided that the didactic materials are in PDF non-editable file format.

Rome, 27th April 2012

The Director General

(Luca Pani)

