

# **Guideline for the management of external activities (university formative courses, congresses, conferences, etc.) from AIFA personnel**

## **1. INTRODUCTION**

The participation of the personnel of the Italian Medicines Agency (AIFA) as spokesman (spokeswoman) in university formative courses, congresses, conferences, seminars, etc. is to be considered a qualifying activity from a scientific point of view and it contributes to spread and to valorize the job carried out by the Agency.

Nevertheless it is also a "time consuming" activity requiring a lot of time for both the preparation of the material to be presented and the travelling from/to the place of the venue. For these reasons it must be limited to those events and demonstrations of strategic importance for AIFA as inherent to its mission.

To this purpose and in accordance with the document of previsionsal budget, the General Direction annually predisposes a document highlighting the strategic priorities and planning the events to which AIFA intends to participate with a high profile. In particular, the General Direction identifies and annually programs the institutional participation to:

- Working groups and European meetings
- Conferences and other institutional international meetings of strategic importance
- Institutional events with the stakeholders
- Academic formative events

## **2. OBJECTIVES, FIELD OF APPLICATION AND DEFINITIONS**

Objective of the present Guideline is to define on the base of the nature of the corporate body organizer and of the typology of the proposed events (point 3) the criteria of selection of the Executives invited (point 6), before forwarding an application of authorization to the DG.

The administrative formalities of participation are also defined (point 7).

Beside, the present Guideline has the purpose of making the participation to external activities coherent with the institutional communication of AIFA.

The formative activities to which AIFA personnel participates as learner and the compulsory training courses for the technical personnel (physicians/chemists) - otherwise disciplined - are excluded from the present Guideline.

### **Definitions:**

**Committee:** the Committee in charge of the evaluation of the external activities concerning the participation to university formative courses, congresses, conferences, seminars, etc. from the AIFA personnel, with the objective to evaluate the typology of events according to the criteria of selection

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and the administrative formalities of involvement, in order to make the participation to the aforesaid external activities consistent with the institutional communication of AIFA and the present Guideline.

**STDG Office:** DG Technical Secretary Office.

### **3. ORGANIZERS**

The no profit nature of the organizer is decisive for the acceptability of the invitation. The following ones are acceptable:

- Events organized by public structures (Central Administrations, Regions, SSN Structures, Universities, other public corporate bodies).
- Scientific societies
- Patients' associations
- Category associations
- Other organized no profit groups

Not acceptable are the invitations coming from:

- Single pharmaceutical company
- Profit-making societies organizing courses, conferences and interinstitutional manifestations unless activities are specifically included among the strategic priorities identified by the General Direction

The participation to predominantly recreational or non appropriate events - whatever the origin is - is not acceptable.

## **4. ACTIVITY**

### **4.1 Institutional activities**

For the conferred activities "by reason of one's own office" and carried out within one's own institutional functions, a preventive authorization is necessary for the participation and for the content of the report or the didactic material within one's own hierarchical line. Being understood the preventive evaluation of the committee (point 7), the participation will have to be submitted to the approval of the Executive of the Office/Unit and only subsequently will be able to be presented to the attention of the General Director for the definitive decision of approval or denial.

### **4.2 Extraintitutional activities**

For the extraintitutional activities, conferred taking into account particular professional competences or working experiences, "not by reason of one's own office" and anyway not in

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contrast with the interests of AIFA, a written authorization is however necessary from the Executive of the Office/Unit and the General Director and will be granted only if the activity is carried out of the working hours and in accordance with the commitments of the office.

## **5. FORMALITY OF PAYMENT FOR THE PARTICIPATION TO THE EVENT**

### **5.1 Institutional activities**

The participation to events organized by central Public Administrations is generally carried out free of charge.

In case of participation to events for which a remuneration is expected for AIFA personnel, the payment has to be done in favour of the Agency (Fund for financing the remuneration of position and result) through the formalities indicated in the enclosure 1 (Template for application to AIFA for the participation to an event).

The participation to formative events, particularly those for which a registration fee is expected for the participants (specialization courses, improvement, master, etc.), is also subordinated to the previous signing of proper Convention among AIFA and the subject organizer with the purpose to regulate the economic aspects (enclosure 2 - Standard Convention among Italian Medicines Agency and Corporate body Organizer).

### **5.2 Extraintituzional activities**

In case of participation to extraintituzional activities, the respective remunerations are integrally corresponded to the Executive.

## **6. CRITERIA OF SELECTION**

In order to be authorized, the events to which the 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 to the event (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 (spokeswomen).

Moreover the following situations are considered incompatible:

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

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

## **7. ADMINISTRATIVE FORMALITIES OF PARTICIPATION**

The applications for participation to events non included in the annual planning drawn up by the General Direction, will be managed individually according to the following formalities:

### **7.1 Application from the corporate body organizer and assessment phase**

Every application for participation to either institutional or extrainstitutional events has to be made by the corporate body organizer through a special form (enclosure 1 - Template for application to AIFA for participation to an event), downloadable from the AIFA website.

The form has to be addressed to both the AIFA General Director and the STDG Office, with enclosed copy of the program of the event e/o of the publication and with the administrative details (expenses of trip, stay, possible offer of remuneration for the participation to event) and Cc to the Executive of the Office (if any, also to the interested person, in case this is different from the Executive of the Office).

The STDG Office will insert in a report the principal information of the application (e.g. reception date, corporate body organizer, AIFA resource involved) in order to subsequently monitor the applications received and those that will be indeed considered. The interested Executive of the Office/Unit will evaluate in advance the proposal of participation according to the criteria defined to the point 6 of the present Guideline. The same Executive of the Office/Unit will have to compile the space reserved to AIFA of the enclosure 1 "Template for application to AIFA for participation to an event", expressing favorable or negative opinion on the application for participation either this directly concerns him/her or it is addressed to hierarchically dependent resource.

In case the Executive of the Office/Unit believes that the invitation is consistent with the criteria of selection, he/she will express favorable opinion while - in case of absence of the criteria or in case of work overload – he/she will express a negative one providing a comment of the expressed opinion that justifies the choice.

The form, duly compiled and signed, together with the received documentation will have to be presented to the attention of the Head of the reference Area to allow a further evaluation of the strategic opportunity of participation. The Head Area will have to compile the space reserved to AIFA of the enclosure 1 "Template for application to AIFA for participation to an event", providing the approval or the denial to the application for participation.

Every Head Area, directly or through delegated person, will collect all the received applications and, accessing to the specific shared folder, will compile one of the following reports according to the type of application:

- Report participation to external activities (university courses) from AIFA personnel: this concerns in particular the participation to university formative courses (schools improvement, specialization schools, master of I° and II° I level, etc.);

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- Report participation to external activities (congresses, conferences) from AIFA personnel: this concerns in particular the participation to events of different nature compared to the university courses such as Congresses, Conferences, seminars, etc..

The information of the received applications (in detail: title event, dates, place, corporate body organizer, participant AIFA, title of the speech) has to be summarized in both reports. Additionally it has to be included:

- opinion of the Executive of the Office/Unit (either in case the participation is required directly to him/her or in case it is required to a hierarchically dependent resource);
- evaluation of approval or denial of the Head Area.

In the shared folder it has to be inserted the documentation regarding the event, associated to the event itself.

The report will have to be discussed within the AIFA Internal Committee designed to evaluate the applications. This will judge the applications and insert the definitive evaluation of approval or denial to the event in the report.

Considering that the Committee meets on April 15 and October 15 of every year or the first following working day in case the suitable dates are a festive day, the applications from the corporate body organizers will have to be sent at least 15 working days before the suitable dates to allow the preparatory activities to the evaluation.

In case the applications of participation to external activities are received after the date of the Committee meeting for the approval, for events that will take place before the date of the next meeting for approval, exceptionally the Committee will reserve the right to evaluate or not the applications.

## **7.2 Authorization of the AIFA DG**

At the end of the Committee meeting, the STDG Office will print both the reports complete with the decisions of approval or denial and will submit them to the signature of the General Director (in case he/she holds the role of President of the Committee). The STDG Office will have care to send the reports, signed and scanned, to the Administrative Business, Accounting and Budget Office and to the Human Resources Office for the fulfillments of competence.

It has to be avoided to submit applications for approval to the signature of the General Director without the Committee evaluation has occurred.

## **7.3 Management of the expenses of trip and stay**

The discipline dealing with missions applies for the management of the expenses for trip and stay, except for extrainstitutional tasks for which there is no reimbursement.

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## **NORMATIVE REFERENCES**

Artt. 24 e 53 del D. lgs. 30 marzo 2001, n. 165, concernente “*Norme generali sull’ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche*”;

Art. 60, CCNL – Area I – Dirigenza – sottoscritto in data 21 aprile 2006.

## **OTHER REFERENCES**

*EMEA Guidance for Staff on Invitations and Gifts.*

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