

## Procedure for authorisation request for congresses and meetings

Every Marketing Authorisation Holder (MAH) or the company responsible for the marketing of medicinal products, organising or contributing to organise in Italy or abroad, through direct or indirect funding, a congress, a convention or a meeting about the use of its pharmaceutical products, should submit to the competent Unit of the Italian Medicines Agency (AIFA) at least 60 days before the event, an application containing the following information:

- ✚ Name, postal address and corporate data of the pharmaceutical company.
- ✚ Venue and starting day of the event.
- ✚ Categories of participants addressed by the event.
- ✚ Topic of the event and its correlation with the pharmaceutical company's medicinal products.
- ✚ Professional qualifications and scientific title of the speakers.
- ✚ Provisional analytical budget of the expenses.

The application form mentioned above is to be forwarded through "Autorizzazione Convegni e Congressi (ACC)" on-line portal available at the following link: <http://www.agenziafarmaco.gov.it/ACC/>, by the responsible for congresses and meetings, designated by the company (Representative).

In order to use this application:

- the representative should apply for a user identification and password on AIFA website, as described at <http://www.agenziafarmaco.gov.it/en/content/aifa-new-information-systems>.
- "Company User Administrator" (for further details, please refer to [AIFA new information systems](#)) have to send representative approval request via email to AIFA Helpdesk ([helpdesk@aifa.gov.it](mailto:helpdesk@aifa.gov.it)).

The authorization request have to be submitted and validated (through the online portal [Autorizzazione Convegni e Congressi](#)) within 60 days preceding the date of the event.

### **Smart card**

The validation of the request must be done only through the electronic signature, for this reason the representative must necessarily be provided with a smart card certificated.

To obtain a smart card certificated for electronic signature working in Italy, it is necessary to refer to a Qualified Certification Service Providers, as specified in the *Agenzia per l'Italia Digitale* website at the following link:

<http://www.agid.gov.it/agenda-digitale/infrastrutture-architetture/firme-elettroniche/qcsp-english>

### **Single sponsor event**

When a pharmaceutical company sponsors a congress or a meeting, must update and validate the request within 60 days preceding the date of the event, accessing the following link: <https://www.agenziafarmaco.gov.it/ACC/>

Data to be inserted:

- ✚ Identification data of the event (Venue and date)
- ✚ Continuous Medical Education accreditation codes if applicable and an attachment with an Abstract of the Congress (programme, scientific background, professional and scientific qualifications of the speakers);
- ✚ Objectives and topics of the congress;
- ✚ Medicinal products relevant to the Congress in relation to the Marketing Authorisation Holder as well as any other authorised entity;
- ✚ Provisional budget of expenses;
- ✚ Comments to the request if required;

For further information please refer to the following link:

<http://www.agenziafarmaco.gov.it/en/content/authorization-congresses-and-meetings>

## **Events with more than one sponsor (Multisponsor event)**

When more than one pharmaceutical company sponsor the same congress or meeting, the information mentioned above are to be jointly submitted by an organising secretariat through the web address: <http://www.impresainungiorno.gov.it/>.

Through this functionality it is possible to compile the authorisation pre-request which allows to include contemporaneously the requests from more than one pharmaceutical company. This should happen indicatively at least 70 days before the date of the meeting. Within the following days and latest within 60 days before the date of the event, each pharmaceutical company will have to complete and validate the requests forwarded according to the procedure previously mentioned (single sponsor event).

The online form requires that the secretariat provide the following information about the event itself:

- ✚ Title of the event
- ✚ Starting date
- ✚ Ending date
- ✚ Country
- ✚ Region
- ✚ Town
- ✚ Venue of the event
- ✚ Sponsor companies (From selection list. To access the pop-up with the company list, click on the 'Aggiungi Azienda' (Add Company) button in the page where the pre-request has been registered).
- ✚ Data about the Organiser:
  - Name of the Organizer
  - VAT number
  - Legal address
  - Surname of the Legal Representative
  - Name of the Legal Representative
  - E-mail of the Legal Representative

## **Fees**

If the total amount of the provisional budget is over 25.822,84 € or in case of meetings held abroad (only for Italian companies) a fee of 2.045,16€ must be paid and the receipt attached to the request jointly the POL code (if available).

The payment has to be performed by :

<http://www.agenziafarmaco.gov.it/en/content/notice-pharmaceutical-companies-information-regarding-online-system-payment-fees>

Please include as reason for payment the event's title and the name of the pharmaceutical company, the date and the POL (if available).

For any information on the payment please don't hesitate to contact:

Supporto Amministrativo: [a.supporto@aifa.gov.it](mailto:a.supporto@aifa.gov.it)

Massimo Bifaretti: [M.Bifaretti@aifa.gov.it](mailto:M.Bifaretti@aifa.gov.it)

Federico Gallo: [F.Gallo@aifa.gov.it](mailto:F.Gallo@aifa.gov.it)

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Reference:

D.lgs. 219/06 art. 124

Decreto 24 maggio 2004

Decreto 21 dicembre 2012