

Procedure for authorisation request for congresses and meetings

Every Marketing Authorisation Holder (MAH) the person responsible for the actual marketing, 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 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 mentioned above is to be forwarded through the AIFA website <http://www.agenziafarmaco.it/section8983.html>, by the responsible person designated by the company for conventions and congresses. In order to use this link, this should apply for a user identification and password from the NSIS website <https://nsis.sanita.it/NACC/accountprovisioningnsis/>. After authorisation by AIFA the responsible person in the company will have access to the *Autorizzazione Convegni e Congressi (ACC) function*.

The designated company responsible person must necessarily be provided with a smart card certificated for electronic signature, mandatory for the Authorisation requests to be validated. The organiser, or the organising secretariat on the other hand, does not need to be registered on the NSIS website.

Single sponsor event

When a pharmaceutical company sponsors a congress or a meeting, it must register, update and validate the request within 60 days preceeding the date of the event, accessing the following link:

[http://www.agenziafarmaco.it/AFF_AMM/section1e4b.html?target=&area_tematica=\\$ion_c ode=AIFA_AA_DOC](http://www.agenziafarmaco.it/AFF_AMM/section1e4b.html?target=&area_tematica=$ion_c ode=AIFA_AA_DOC)

Data to be inserted:

- ✚ Identification data of the event (Venue and date)
- ✚ Continuous Medical Education accreditation codes or, if not applicable, 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;

The electronic application procedures are explained in the “*Manuale Utente per le Aziende Farmaceutiche*”, which is available on the website:

http://www.agenziafarmaco.it/allegati/manuale_aziende_farmaceutiche.pdf

Events with more than one sponsor (Multisponsor event)

When more than one pharmaceutical company sponsors the same congress or meeting, the information mentioned above are to be jointly submitted by an organising secretariat through the web address:

<http://www.ministerosalute.it/AIFA/ServletCaricaDati?azione=cercaDati>.

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 the secretariat to provide the following information about the event itself:

- ✚ Title of the event

- ✚ Starting date
- ✚ Ending date
- ✚ Country
- ✚ Region
- ✚ County
- ✚ 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

For the pharmaceutical companies sponsoring a congress and not registered in Italy i.e. without a SIS code, the secretariat must collect and send jointly to AIFA (via mail or carrier) all the applications of the participating companies, together with the program, the scientific background, the Continuous Medical Education accreditation codes (if applicable) and the professional and scientific qualifications of the speakers.

The address is: AGENZIA ITALIANA DEL FARMACO
 VIA DELLA SIERRA NEVADA, 60
 00144 ROMA, ITALY

information to be sent to the secretariat by each company:

- Name, postal address and corporate data of the pharmaceutical company
 - Identification of the event (Venue and starting day of the event)
 - Categories of participants addressed by the event
 - Topic of the event
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- List of medicinal products promoted during the congress (relating to the event subjects)
- Provisional budget of expenses (*)
- Copy of the Identity Document of the person responsible for Meeting and Congress.
- A € 14.62 administrative stamp

(*) If the total amount of the provisional budget is over 25.822,84 € a fee of 1.859,24 € must be paid and the receipt attached to the request. The payment has to be performed by bank transfer on the following AIFA account

NAME: AGENZIA ITALIANA DEL FARMACO (AIFA)

BANK: BANCA NAZIONALE DEL LAVORO

IBAN: IT33 V010 0503 3820 0000 0211 252

SWIFT BIC: BNLITRR

Please include as reason for payment the event's title and date.

Reference:

D.Leg.vo 219/06 art. 124

D.M 24 Maggio 2004