“Congresses and meetings in Italy”


Agenzia Italiana del Farmaco
AIFA

# Congresses and meetings in Italy

| | | | |
|---|---|---|---|
| **The Decree** | **Procedure for the authorization** | **Advertising** | **Hospitality** |

The Decree

## Legislative Decree 24th April 2006, N° 219 (The Decree)

Nowadays congresses and meetings on topics related to the use of pharmaceutical products is governed by Article 124 of the Legislative Decree 24th April 2006, N° 219 (The Decree) which has replaced the old D.L.vo 541/1992

## "Titolo VIII" section

## Advertising to health care professionals

## Congresses and Meetings

In Italy each pharmaceutical company which sponsors a meeting or a congress on topics in anyway related to the use of their own pharmaceutical products, must be submit to the competent Unit of the Italian Medicines Agency (AIFA) an application to obtain a specific authorization.

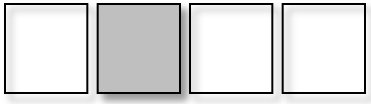
The Decree

**The Aifa authorization is not necessary**

- when a company promotes by advertising only medical devices or food supplements during a congress (products without Marketing Authorisation)
- when a company sponsors a meeting about arguments not related to the use of any of their own medicinal products;in this case the company is not allowed to expose or distribute any kind of advertising material during the meeting (Section 9 art. 124 D.L. n.219/06)

**The Aifa authorization is necessary**

- for every pharmaceutical company ( Marketing Authorisation Holder or the companies responsible for the actual marketing of pharmaceutical products) which sponsors a meeting or a congress on topics in anyway related to the use of their own pharmaceutical products.



Procedure

# Procedure for the Aifa authorization

Section 1 art. 124 D.L. 219/06

In order to obtain the authorization, an application containing the details of the expenses is to be submitted **60 days before the day of the meeting** by the pharmaceutical company ( Marketing Authorisation Holder or the companies responsible for the actual marketing of pharmaceutical products) to the competent Unit of Aifa, which will issue its approval after 45 days from the moment the application form has been received

the authorization procedure is carried out through the Aifa website area **ACC** (authorization for congresses and meetings) and on this porpouse, pharmaceutical companies must be registrated

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

https://www.agenziafarmaco.gov.it/ACC/

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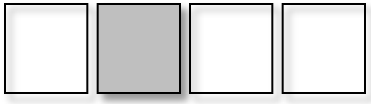


# The event planner or secretariat or organizer

Section 2 art.124 of D.L.219/06

In cases where several pharmaceutical companies contribute to the organization of a congress, convention or meeting, the communications referred to in paragraph 1 must be delivered jointly, through the event planner, with a list of the companies taking part. Communications not conforming to this role shall be considered invalid.

The part of the event planner can be played by the secretariat of the congress it self or delegate it to another organization of events and conferences.

# Role of event planner

Fills an e-form of the pharmaceutical sponsors, including only the ones registrated in the Aifa website at least 70 days before the meeting. https://www.agenziafarmaco.gov.it/prerichiesta/ServletCaricaDati?azione=cercaDati

Collect and send jointly to Aifa by ordinary mail all the copies of the application forms of the companies which are unable to fullfill the online registration.

It must be sent at least 60 days before the meeting to Aifa, excluding the starting date of the meeting

Collect in a document for the pharmaceutical companies the following information:

- the program of the meeting
- the professional and scientific qualifications of the speakers
- Scientific Rationale

Procedure

# Step by step to the online procedure

SIS code assigned by Aifa

+

Digital signature (smart card)

+

Registration in ACC website area

=

online procedure for the submission of the application

**http://www.agenziafarmaco.gov.it/it/content/codice-sis-procedura-di-attribuzione**

**http://www.infocert.it**

**https://www.agenziafarmaco.gov.it/ACC/**



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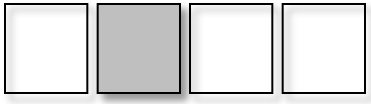

Procedure

# SIS code

The SIS code is an identification code assigned by AIFA to identify each company with any commercial activities in the pharmaceutical field. This code facilitates and accelerates the identification of the various practices that come to AIFA by any pharmaceutical company and ensures the necessary level of confidentiality of information.

http://www.agenziafarmaco.gov.it/sites/default/files/aifa__sis_en_apr2011_0.pdf

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AIFA > Interrogazione

**Richiesta**

**Identificativo:**

Rif. Azienda
Denominazione:
Indirizzo:
Partita IVA :
Referente:
Telefono:
Fax:
Cellulare:
Indirizzo e-mail:

Name, postal address and corporate data of the paharmaceutical company

1. Comma , Art. 124 D.to L.vo 219/06 - Finanziamento oltre 25.822,84 Euro o all'estero

2. L'azienda richiedente non è sponsor unico

3. Altri sponsor:

ASTELLAS PHARMA S.P.A.
ASTRAZENECA S.P.A.
BAXTER S.P.A.
DOMPE' FARMACEUTICI SPA
ELI LILLY ITALIA S.P.A.
FERRING S.P.A.
GLAXOSMITHKLINE S.P.A.
IPSEN S.P.A
JANSSEN CILAG S.P.A.
MERCK SHARP E DOHME (ITALIA) S.P.A.
NEOPHARMED SPA
NOVARTIS FARMA S.P.A.
PFIZER ITALIA S.R.L.
PIERRE FABRE ITALIA S.P.A.
RECORDATI INDUSTRIA CHIMICA FARMACEUTICA S.P.A.
ROCHE S.P.A.
SANOFI-AVENTIS S.P.A.
SANOFI-SYNTHELABO S.P.A.
SCHERING PLOUGH SPA
SCHERING SPA
TAKEDA ITALIA FARMACEUTICI S.P.A.

List of the other pharmaceutical companies partecipating as sponsors at the meeting.

this form has to be filled by the “event planner”

4. Titolo evento:
5. Date evento: Dal al Durata ore:
Data Validazione:
6. Identificativo ECM: Evento : Dettagli Altre richieste per lo stesso evento ECM

6.1 Id Richiesta Master:

7. Sede in cui si svolge l'evento:

Nazione:
Regione:
Provincia:
Comune:
Sede:

Venue and starting day of the event, topic of the event and its correlation with the medicinal products of the pharmaceutical company

8. Oggetto della tematica trattata e correlazione con i farmaci di cui l'azienda richiedente è titolare:

9. Farmaci di cui lo scrivente è titolare di A.I.C. attinenti alle tematiche congressuali:

10. Modalità di erogazione del finanziamento:

11. Dettaglio analitico delle spese (EURO):

| | Preventivo | Consuntivo |
|---|---|---|
| a) Spese complessive di viaggio ed ospitalità partecipanti: | 0,00 | 0,00 |
| b) Spese di viaggio ed ospitalità relatori: | 0,00 | 0,00 |
| c) Compenso per relatori: | 0,00 | 0,00 |
| d) Affitto sala: | 0,00 | 0,00 |
| e) Spazi espositivi: | 0,00 | 0,00 |
| f) Coffee break e colazioni di lavoro: | 0,00 | 0,00 |
| g) Altre spese: | 0,00 | 0,00 |
| h) Quota stand: | 0,00 | 0,00 |
| i) Scheda tecnica in cartella: | 0,00 | 0,00 |
| j) Quote di iscrizione: | 0,00 | 0,00 |
| TOTALE | 0,00 | 0,00 |
| Numero partecipanti con rimborso spese: | 8 | |
| Numero relatori con rimborso spese: | 0 | |
| Numero relatori con compenso: | 0 | |

provisional analytical budget of the expenses

12. Note spesa:

13. Segreteria organizzativa:

Nominativo:
Partita IVA:
Sede:
Rappresentante:
E-Mail:

14. Estremi di Versamento:

Id indicato su causale versamento:
Importo (EURO):
Riferimenti operazione (C.R.O.) :
Data valuta:
ABI:
CAB:
IBAN:

If the total amount of the provisional budget is over € 25.822,84 a fee of € 2.045,16 must be paid to Aifa

Verifica del Versamento:

Verifica positiva del contributo:
Data verifica:
Note di verifica:

La richiesta E' STATA APPROVATA DALL' AIFA.

Motivazioni ufficio AIFA:

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

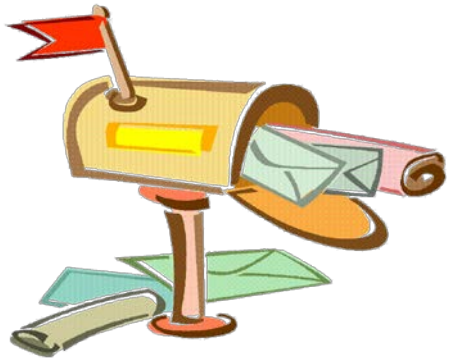
Torna Indietro

Procedure

# Procedure for companies which can't fulfill the online registration

The Event Planner must collect and send jointly to AIFA by ordinary mail each copy of all the **application forms** of the participating companies, along with the program, the scientific background, the Continuous Medical Education accreditation codes (if present) and the professional and scientific qualifications of the speakers.

AGENZIA ITALIANA DEL FARMACO
Sezione convegni e congressi
VIA DEL TRITONE N 181
00187 ROMA, ITALIA



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Procedure

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

products promoted during the congress (relating to the event subjects)

provisional budget of expenses

copy of Identity Document of the Company's Meeting and Congress Manager

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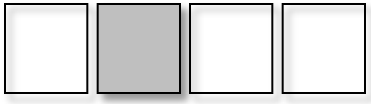
Procedure

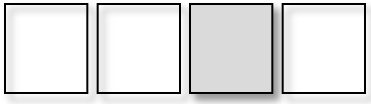
# Example of application form for companies without a SIS code

| | |
|---|---|
| IDENTIFICATION OF THE EVENT – TITLE | |
| IDENTIFICATION OF THE EVENT – VENUE | |
| IDENTIFICATION OF THE EVENT – COURSE DATE | |
| OBJECTIVE / TOPIC OF THE EVENT | |
| CATEGORIES OF PARTICIPANTS ADDRESSED BY THE EVENT | |
| NAME OF THE PHARMACEUTICAL COMPANY | |
| POSTAL ADDRESS OF THE PHARMACEUTICAL COMPANY | |
| CITY | |
| STATE | |
| ZIP CODE | |
| PHONE | |
| E-MAIL | |
| CONGRESS SUBJECT AND THE RELATED CORRELATION WITH THE COMPANY ‘s MEDICAL PRODUCTS | |
| LIST OF THEIR OWN MEDICINAL PRODUCTS | |



Procedure

| DETAILED BUDGET IN EURO | | |
|---|---|---|
| PARTICIPANTS' TRAVEL AND HOLPITALITY EXPENSES | | PARTICIPANTS NUMBER (…) |
| SPEAKERS TRAVEL AND HOSPITALITYEXPENSES | | |
| SPEAKERS FEE | | |
| EXHIBITION AREA | | |
| COFFEE BREAK AND WORK LUNCH | | |
| DIFFERENT EXPENSES | | |
| STANDS RATE | | |
| REGISTRATION RATES | | |
| TOTAL AMOUNT | | |



Advertising

# Advertising to health-care professionals

Advertising to health-care professionals is regulated by art. 119 to 123 of the Legislative Decree no. 219/06

Advertising to health professionals is subjected to a 10 days negative clearance system. Any advertising messages or documents that companies wish to provide to medical practitioners, other than the mere reproduction of the SmPC must be previously submitted to Aifa and cannot be used until 10 days have expired since the day of submission.

The date of the last submission must be reported on this material

Anytime this material is updated it must be submitted again to Aifa

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# Printed materials which can be distributed or exhibited

During a convention, conference or a meeting relating to the use of medicinal products, the pharmaceutical companies participating as sponsors, in the field of scientific information activity, can distribute or show the following:

- display Panels
- visuals
- summary of Product Characteristics (SmPC)
- exhibition Banners
- gadgets

Advertising

Panels, banners and visuals exposed or distributed to deliver information by the pharmaceutical companies must follow these criteria:

- promotion must be accurate, balanced, fair, objective to enable the recipient to make up his or her own opinion about the therapeutic value of the medicinal product concerned

- all the information related to the medicine must derive from the Summary of Product Characteristics and be therefore correct, updated, verifiable and sufficiently completed to deliver adequate information on the characteristics of the medicinal product in terms of effectiveness and safety

- the trade name of the medicine, specifying the common denomination of its active substance or substances can be indicated, together with the name of the Marketing Authorisation Holder or of the company responsible for the actual marketing. The Summary of Product Characteristics must be available and accessible inside the stand

Advertising

- any form of illustrative materials related to the medicinal product like images of the packaging is not allowed, even the distribution of samples.

- the quotation of sentences, tables and diagrams drawn from scientific articles can be included, as long as the corresponding references are integrally provided. These published scientific papers must be accessible in the stand. Therefore all reported information cannot be drawn from abstracts, articles in press and posters

- all artwork, including graphs, illustration and tables taken from published studies included in promotional materials should clearly indicate the precise source and be faithfully reproduced

Advertising

Promotional information which appears on exhibition stands or is distributed to partecipants at **international events** must be:

- in accordance with the Marketing Authorisation of the medicinal product as authorised in other countries. on condition that doctors coming from those countries are present at the congress

- when this material is refered to medicinal products (or uses) which are not registered in our country it must be accompained by a suitable statement indicating that the product or the use ***is not registered locally.***

- Any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the medicinal product is registered should be accompanied by an explanatory statement indicating that registration conditions differ internationally

- For the congresses and meetings above mentioned, the information material of medicinalproducts without or awaiting a Marketing Authorization in Italy has to clearly and visibly contain a warning that the product (or the new therapeutic indication) ***is not authorised in Italy.***

Advertising

- during the meeting is possible for all the pharmaceutical companies to exhibit inside their stands printed materials about molecules under investigation. This kind of information must be related only to their mechanism of action without mentioning any therapeutic indications which has not been authorised yet

# Gadgets

Pharmaceutical companies are allowed to give gadgets to the participants.
They must be of negligible value relating to the professional activity of participants (doctors, nurses, biologists and so on).

All gadgets can reproduce:

- the name of medicinal product
- and/or the denomination of the active principle
- and/or the corporate name of the pharmaceutical company about a medicinal product with a valid Marketing Authorisation.


# About hospitality

- is regulated by paragraph 4, art.124 of the Decree 219/06
- may only be extended to persons who are qualified as participants
- is related to travel, accomodation and registration fees. In addition, hospitality will not be offered for more than 12 hours prior to the congress and 12 hours following its conclusion, nor it will be such as to overshadow the technical and scientific purposes of the event

Farmindustria Code provides more strict limitation regarding the offer of hospitality

http://www.farmindustria.it/Farmindustria/html/codice_deontologico.asp

# Final Q&A

- the italian CME accreditation:

  The Continuing Medical Educations is a subject which is not regulated by the Aifa Agency. The Istitutional Body that in Italy has the faculty to “give” accreditation to the meetings is Age.Na.S. http://ape.agenas.it/homeEsterno.aspx

- games and competitions:

  this aspect of the meeting is not subjected to any regulamentation.

  There isn’t any specific guideline about it.

- advertising to the general public:

  advertising to the general public (in places like: railway station, airports or on public means of transport like buses, or so on) is regulated by the Italian Ministry of Health and is admitted only for “over the counter” medicinal products (OTC)

  Advertising to the general public is regulated in sections 115 to 118 of Decree 219 http://www.salute.gov.it/

# Final Q&A

- printed advertising materials for health care professionals:

  A copy of all the informative materials must be submitted to the Medical and scientific informational Unit of the Aifa, while only the bibliography can be trasmitted on CD's

  http://www.agenziafarmaco.gov.it/en/content/medical-and-scientific-information

- Farmindustria Code:

  this code of professional conduct issued by Farmindustria (the italian association of pharmaceutical industries) contains several provisions dealing with advertising, meetings, hospitality and so on;

  it binds only the members of the association

- about panels:

  there aren't any limits in size for display panels.

  It is possible to reuse the panels already presented in other European events if in agreement with the Italian legislation

# Thank you for your attention!

Please let us know what you think, sending suggestions and advice to help us to make **ACC** website area more useful to you. We realize that your time is extremely valuable and we appreciate your feedback.

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