



SPONSORSHIP OF INTERNATIONAL CONGRESSES IN ITALY

General Rule

Any pharmaceutical company that is going to organise or support a congress by any kind of sponsorship, is subject to an authorisation by the AIFA (Agenzia Italiana del Farmaco / Italian Drug Agency), according to an Italian Government Decree (Decreto Legislativo 219 / 06)

Pre-request of Authorisation (in case of multi-sponsored congresses)

Deadline: within 70 days prior to the starting of the Congress

- All the pharmaceutical companies shall send a written note to the Organising Secretariat of the congress (or to the Official Italian Agency appointed by the Organising Secretariat) declaring their intent to sponsor the event.
- The OS (or the Official Italian Agency) shall submit to AIFA a Pre-request of authorisation, including the list of all the sponsoring companies.
- It is not possible to update the pre-request with additional companies after its submission.
- The OS (or the Official Italian Agency) and all the sponsors will receive, by e-mail, the confirmation of the pre-request receipt.

In case of mono-sponsored meetings, the pharmaceutical company shall directly submit its Request of Authorisation to AIFA. (See details below)

Request of Authorisation

Deadline: within 60 days prior to the starting of the Congress

- All the companies must submit on-line the *Request of Authorisation* to AIFA within the deadline. (<http://nsis.sanita.it>).
- The company shall provide some information concerning its participation to the congress: **in particular a detailed budget of the estimated expenses and the data concerning the drug(s) connected to the event.**
- *A tax (Euro 1.859,24) is due if the budget exceed Euro 25.822,84*
- After the validation of the Request no changes are accepted by the system.
- The Request will be analyzed by the authorities and the authorisation will be transmitted by e-mail to the company.

Procedures of Request submission

In order to submit the on-line Request, a Company must be registered within the AIFA Website.

1. Foreign sponsors already registered can easily submit their request directly through the website (<http://nsis.sanita.it>)
2. Foreign sponsors which have a branch or a representation in Italy can have the Request submitted through their Italian subsidiary (if registered within AIFA website)
3. Foreign sponsors (without any representation in Italy and not selling their drug in Italy): AIFA is preparing specific guidelines for these subjects (please verify the status of this process with the Organising Secretariat or the Official Italian Agency appointed by the Organising Secretariat)



PROMOTIONAL MATERIAL DISSEMINATED DURING CONGRESS

General Rule

It is forbidden to use the name of the drug in any material distributed to the medical doctors (or in the booth of the pharma companies, gadgets, pens, congress bags, etc.) unless accompanied by the full Summary of Products Characteristics (SPC).

However it is possible to show the pharma company name or the drug molecule / ingredients / active principle.

Any advertising messages which the companies wish to provide to medical practitioners, other than the mere reproduction of the Summary of Products Characteristics (SPC), must be previously submitted to:

AIFA

Ufficio Informazione e Comunicazione

Ms. Mannino

Via della Sierra Nevada 60

00144 Roma , Italy

The "tacit approval" rule is valid, namely if the pharma company does not receive any reply from AIFA within 10 days from the arrival of the material at the Office in Rome, then it results accepted and confirmed.

Advertising of medicinal products may relate only to products for which the marketing authorisation has been issued. (See details below)

The distribution of scientific papers (sponsored by a pharmaceutical Company) to doctors is permitted subject to prior submission to AIFA pursuant to the 10-day negative clearance system.

(We suggest verifying the eligibility requirements of the documents with the Italian subsidiary before submitting them to AIFA)

At scientific meetings it is possible for independent speakers, belonging to the scientific community, to provide information regarding new active principles or new off-label indications, discuss recent developments of clinical trials regarding unlicensed products, or indications.

In such a case, however, the reference to the product is generally made to the active ingredient only.

Publishing information on unauthorised medicines

At International congresses, the distribution, in the original language, of information material complying with the marketing authorisation issued in the foreign country is permitted, provided that physicians of such foreign country are attending the meeting.

New guidelines are to be prepared by AIFA on this subject.

Information material already disseminated during previous international congresses

It can be disseminated, and the name of the drug can be used, together with the active principle.

The logo of the drug cannot be showed, but the name of the producer (or co-promoter, or local distributor) can be mentioned.

If the drug hasn't marketed in Italy yet, the promotion must be done according to the authorisations released in other countries.

Disclaimer

The Organiser and the Italian Agency declines any responsibility in case these rules will be amended by AIFA without due notice given.