AIFA (Italian Medicine Agency)

Guidelines for Meetings & Congresses in Italy

AIFA Regulation

In Italy, any pharmaceutical company supporting a congress is subject to an authorization by AIFA (Italian Medicine Agency), according to an Italian Government Decree (DL 219/06 – art. 124).

Official AIFA website https://www.aifa.gov.it/en/acc

When more than one pharmaceutical company are involved in a conference or meeting, joint communications should be sent, via the appointed agency (MCI Italy), at least 70 days prior to the event start date.

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.

OPTIONS

There are two different scenarios:

1st Italian and Foreign Companies registered in AIFA database (with a SIS code*)

2nd Foreign Companies not-registered in AIFA database (without a SIS Code*)

** SIS code — It 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.*

More info here

Italian and Foreign Companies registered in AIFA database (with a SIS code)

The request of authorization must be submitted latest within 60 days before the beginning of the event for Italian and Foreign registered companies (with a SIS Code).

Deadline for pharma companies with AIFA SIS code to apply for AIFA submission is 60 days prior to the event.

Foreign Companies not-registered in AIFA

CASE 1:

Companies not registered in Italy (without a SIS Code), which have a branch or a representation in Italy could directly contact the Italian affiliate to submit the application through the Italian subsidiary.
This is possible for pharmaceutical companies with an affiliated branch in Italy registered in AIFA website.

Deadline for pharma companies with AIFA SIS code to apply for AIFA submission is 60 days prior to the event.

Foreign Companies not-registered in AIFA

CASE 2:

It is mandatory for foreign Pharmaceutical Companies to register in AIFA website and submit an application to obtain AIFA authorization. If the company does not have an affiliated Italian Company registered in AIFA, it has to start directly with AIFA process by and no later than 60 days prior to the event.

Important steps to follow:

- Appoint a "Company User Administrator": the person in each pharmaceutical company responsible for accessing AIFA's online services

- Obtain a "SIS code": an identification code of each pharmaceutical companies

Steps of the Authorization Process

The authorization process for a multi-sponsor event follows the steps below:

1. Submission of the pre-request by MCI Italy.

2. AIFA website automatically notifies to the Pharma Companies about pre-request submission.

3. Application completion and validation by each Pharma Company accessing to the Aifa website.

4. E-mail notice about AIFA authorization/rejection release to Pharma Company contact person.

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For further information do not hesitate to contact our office or refer to the website:

https://www.aifa.gov.it/en/web/guest/acc

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