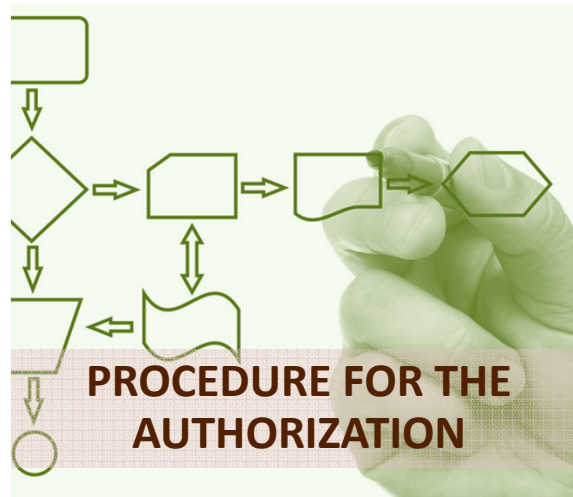

AIFA procedure

for international congresses in Italy

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The decree



AIFA (Italian Drug Agency)

is the national authority responsible for drugs regulation in Italy

Any **pharmaceutical Company** that is going to organise or support a congress by any kind of sponsorship, is subject to an authorization by AIFA (Italian Drug Agency), according to an Italian Government Decree (Decreto Legislativo 219 / 06 – art. 124).

Procedure for the authorization



THE AIFA AUTHORIZATION IS NOT NECESSARY

- ❑ When a Company promotes only medical devices or food supplements during a congress (products without Marketing Authorization);
- ❑ When a Company sponsors a meeting about arguments not related to the use of any of its pharmaceutical 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)0

Procedure for the authorization



According to Italian laws, the authorization for all the Companies must be made by an Italian Agency, appointed by the Congress Organizer. The request has to be validated within 60 days prior to the event.

STEP 1

- Request to AIFA for a **SIS code** (for Companies without a SIS code). The SIS code is an identification code assigned by AIFA to identify each Company. The SIS code is mandatory for authorization requests and does not imply any cost.
- Appoint a "Company Users Administrator", referred as "**CUA**". The appointed person, an internal employee of the Company, will have access to all applications
- Register in AIFA website accessing with the SIS Code

Procedure for the authorization



➤ Payment of Event Tax to AIFA:

Total amount of the sponsorship up to Euro 5.000 – a fee of Euro 208,81 must be paid to AIFA

Total amount of the sponsorship up to Euro 10.000 – a fee of Euro 417,62 must be paid to AIFA

Total amount of the sponsorship between Euro 10.000,01 and Euro 25.822,85 - a fee of Euro 835,64 must be paid to AIFA

Total amount of the sponsorship over Euro 25.822,86 - a fee of Euro 2.156,82 must be paid to AIFA

Detailed information about payment procedure will be given in our Guidelines.

STEP 2

- Buy a **smart card** certified for electronic signature in Italy mandatory for carrying out the AIFA request. 2 Italian providers for SMART Card (Aruba or Banca Intesa).

The procedure takes around 1 month.

Procedure for the authorization



STEP 3

- The Italian Official Agency makes the **pre-request for AIFA authorization**
 - The sponsor Company completes and validates the request in AIFA website: the validation is possible **ONLY** by electronic signature with smart card
 - The Request will be analyzed by the authorities and the authorization will be transmitted by e-mail to the company
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Promotional materials



PROMOTIONAL MATERIAL

- Any promotional material the Companies wish to provide at the congress must be sent by carrier directly by the Company to AIFA.
Advertising is subjected to a 10 days negative clearance system. Any Advertising messages or documents cannot be used until 10 days have expired since the day of submission

RULES FOR PROMOTIONAL MATERIAL

Detailed rules and restrictions will be provided. Just some issues:

- All information related to the medicine must come from the Summary of Product Characteristics
 - The Summary of Product Characteristics must be available and accessible at the booth
 - Any form of illustrative materials related to the medicinal product like images of the packaging is not allowed, even the distribution of samples
 - Pharmaceutical companies are allowed to give gadgets to the participants. They must be of negligible value relating to the professional activity of participants.
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