

## SPONSORSHIP OF INTERNATIONAL CONGRESSES TO BE HELD IN ITALY

### *General guidelines*

*To whom it may concern:*

*The following document includes only some of the current regulations and represents just a general guideline that AIM Group provides to its clients.*

*AIFA (Agenzia Italiana del Farmaco) does not provide, at present, for a specific procedure applicable to foreign sponsors, and consequently AIM Group companies accept no responsibilities in case some changes, specific rules or new procedures are introduced, with possible direct or indirect repercussions to the present or future relationship with the foreign sponsors.*

*Therefore, to avoid any misunderstanding, the sponsor will be totally responsible to know and to observe the applicable rules and to follow up on any possible changes or updates.*

## Sponsorship of international congresses to be held in Italy.

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| <b>General rule</b>  | <p>Any pharmaceutical company that is going to organise or support a congress by any kind of sponsorship, is subject to an authorization by the AIFA (Italian Medicines Agency), according to an Italian Government Decree (Decreto Legislativo 219 / 06 – art. 124)</p>  |
| <b>Pre-request of Authorization</b><br>(in case of multi-sponsored congresses)<br><br><p style="text-align: center;">Deadline :<br/> <b>Within 70 days prior to the starting of the Congress</b></p>                       | <ul style="list-style-type: none"> <li>• All the pharmaceutical companies shall send a written note to the Organizing Secretariat of the congress (or to the Official Italian Agency appointed by the Organizing Secretariat) declaring their intent to sponsor the event .</li> <li>• The OS (or the Official Italian Agency) shall submit to AIFA a Pre-request of authorization, including the list of <u>all the sponsoring companies</u>.</li> <li>• It is not possible to update the pre-request with additional companies after its submission.</li> <li>• The OS (or the Official Italian Agency) and all the sponsors will receive, by e-mail, the confirmation of the pre-request receipt. <i>(the code to finalize the procedure)</i></li> </ul> <p><i>In case of mono-sponsored meetings, the pharmaceutical company shall directly submit its Request of Authorization to AIFA.</i><br/>         (See details below)</p>   |
| <b>Request of Authorization for the pharmaceutical companies registered in ITALY with a SIS code</b><br><br><p style="text-align: center;">Deadline :<br/> <b>Within 60 days prior to the starting of the Congress</b></p> | <ul style="list-style-type: none"> <li>• All the companies sponsoring a congress and registered in ITALY with a SIS code must <u>submit on-line</u> the Request of Authorization to AIFA within the deadline. (<a href="http://nsis.sanita.it">http://nsis.sanita.it</a>)</li> <li>• <u>Foreign sponsors which have a branch or a representation in Italy, not involved in the same congress</u>, can have the Request submitted through their Italian subsidiary if registered within AIFA website (please note that the Italian branch is not obliged to accept your request – in case of negative response please follow instructions for not registered companies)</li> <li>• The company shall provide some information concerning its participation to the congress: <b>in particular a detailed budget of the estimated expenses and the data concerning the drug(s) connected to the event.</b></li> <li>• A tax (Euro 1.859,24) is due, if the total amount of the provisional budget (<i>sponsoring investment</i>) is over Euro 25.822,84. The payment has to be performed by bank transfer on the following AIA account:<br/>             Name: Agenzia Italiana del Farmaco (AIFA)<br/>             Bank: Banca Nazionale del Lavoro<br/>             IBAN: IT33 V010 0503 3820 0000 0211 252<br/>             SWIFT BIC: BNLIITRR<br/>             (Please include as reason for payment the event's title and date).</li> <li>• After the validation of the Request no changes are accepted by the system.</li> <li>• The Request will be analyzed by the authorities and the authorization will be transmitted by e-mail to the company.</li> </ul> |

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| <p><b>Request of Authorization for the pharmaceutical companies <u>not registered in ITALY</u> without a SIS code</b></p> | <p>For the pharmaceutical companies sponsoring a congress and <u>not registered in Italy</u> 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.</p> <p>The address is: Agenzia Italiana del Farmaco<br/>Via della Sierra Nevada 60<br/>00144 Roma (Italy)</p> <p><u>Information to be sent to the secretariat by each company:</u></p> <ul style="list-style-type: none"> <li>- Name, postal address and corporate data of the pharmaceutical company</li> <li>- Identification of the event (Venue and starting day of the event)</li> <li>- Categories of participants addressed by the event</li> <li>- Topic of the event</li> <li>- List of medicinal products promoted during the congress (relating to the event subjects)</li> <li>- Provisional budget of expenses</li> <li>- Copy of the identity document of the person responsible for Meeting and Congress</li> <li>- A € 14,62 administrative stamp</li> </ul> <ul style="list-style-type: none"> <li>• A tax (Euro 1.859,24) is due, if the total amount of the provisional budget (<i>sponsoring investment</i>) is over Euro 25.822,84. The payment has to be performed by bank transfer on the following AIA account:<br/>Name: Agenzia Italiana del Farmaco (AIFA)<br/>Bank: Banca Nazionale del Lavoro<br/>IBAN: IT33 V010 0503 3820 0000 0211 252<br/>SWIFT BIC: BNLITRR<br/>(Please include as reason for payment the event's title and date).</li> </ul> |
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## Promotional material disseminated during an international congress to be held in Italy

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| <b>General rules</b> | <p><b>Information regarding conventions, conferences and meetings according to art.124 of D.L 219/06.</b></p> <p>In the context of a convention, conference or a meeting relating to the use of medicinal products, the Pharmaceutical companies participating as sponsors can distribute or expose the following:</p> <ul style="list-style-type: none"><li>• gadgets of negligible value relating to the professional activity of doctors and pharmacists. On gadgets of medicines with a valid Marketing Authorisation in Italy, the name of the medicinal product and/or the denomination of the active principle and/or the corporate name of the Pharmaceutical Company can be indicated. On gadgets of medicines with valid Authorisations in other Countries of the European Union, but not in Italy, only the denomination of the Pharmaceutical Company can be indicated.</li><li>• During congresses and meetings the Pharmaceutical Companies can use the panels inside their own stands to deliver information provided they abide to the following criteria:</li></ul> <p>All the information relating to the medicine must derive from the Summary of Product Characteristics and be therefore correct, updated, verifiable and sufficiently complete to deliver adequate information on the characteristics of the medicinal product in terms of effectiveness and safety.</p> <p>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 person responsible for the actual marketing. The Summary of Product Characteristics must be available and accessible in the stand. The display of any form of promotional materials relating to the medicinal product (visuals, images of the packaging, etc.) is not allowed.</p> <p>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 submitted to AIFA and available in the venue where the meeting is held. Therefore all reported information cannot be drawn from abstracts, articles in press and posters.</p> <ul style="list-style-type: none"><li>• With respect to international conferences only, Pharmaceutical Companies can disseminate information material in accordance with the Marketing Authorisation of the medicinal product as authorised in other countries of the European Union. By information material the following is meant:<ol style="list-style-type: none"><li>1. Summary of Product Characteristics authorised in other countries of the EU;</li><li>2. Congressional records;</li><li>3. Scientific papers, provided they are complete and have been submitted to AIFA.</li></ol></li></ul> <p>For the congresses and meetings above mentioned, the information material of medicinal products without or awaiting a Marketing Authorisation in Italy has to clearly and visibly contain a wording that the product (or the new therapeutic indication) is not authorised in Italy.</p> <ul style="list-style-type: none"><li>• Regarding molecules under investigation information referring exclusively to their mechanism of action without mentioning any therapeutic indications not yet authorised can be provided.</li></ul> |
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## FAQ (FREQUENT ASKED QUESTIONS)

To view the most frequently asked questions, please consult  
the AIFA website:

[http://www.aifa.gov.it/AFF\\_AMM/sectionc70b.html?target=&area\\_tematica=AFF\\_A  
MM&ion\\_code=AIFA\\_AA\\_CONV\\_FAQ&cache\\_session=false](http://www.aifa.gov.it/AFF_AMM/sectionc70b.html?target=&area_tematica=AFF_A<br/>MM&ion_code=AIFA_AA_CONV_FAQ&cache_session=false)