Conventions or conferences concerned with medicinal products.

Art.124 D.L. 219/06

1. Any pharmaceutical company holding a license to sell medicinal products (referred to titolo III or titolo IV) which organizes or helps to organize, whether by direct or indirect funding, in Italy or abroad, a congress, convention or meeting on topics in any way related to the use of medicines, shall notify the competent Unit of the Italian Medicines Agency (AIFA) at least 60 days prior to the beginning of the congress or meeting.
The communication, which must bear an authenticated signature, containing the following information:

a. Name, postal address and corporate data of the pharmaceutical company
b. venue and starting day of the event
c. categories of participants addressed by the event
d. topic and scientific rational of the event and its correlation with the pharmaceutical company's medicinal products
e. professional qualifications and scientific title of the speakers
f. provisional analytical budget of the expenses

2. When more then one pharmaceutical company sponsor the same congress or meeting, the information mentioned above are to be jointly submitted by an organising secretariat. Communications not conforming to this rule shall be considered invalid.

3. Events referred to paragraphs 1 and 2 shall keep strictly to criteria of a technical nature and shall aim to further knowledge in the fields of chemistry, pharmaceutical technology, biochemistry, physiology, pathology and clinical medicine. Pharmaceutical companies may not take part in trade-union conventions or meetings.

4. In the context of events of the kind referred in paragraphs 1 and 2, free travel or hospitality shall be restricted to participants with specific qualifications and may not be extended to persons accompanying them. In addition, hospitality shall not be offered for more than 12 hours prior to the congress and 12 hours following its conclusion, nor shall it be such as to overshadow the technical and scientific purposes of the event.

5. Pharmaceutical Company may organize or help to organize a congress, convention or meeting if, within 45 days of the application referred in paragraph 1, the competent Unit of AIFA has not given back any notification of refusal accompanied by reasons. Pharmaceutical company shall notify the real expenditure at the end of the congress

6. In case of meetings held abroad or if the total amount of the provisional Budget is over € 25.822,85, a fee of 1.859,24 € must be paid to Aifa as stipulated in art.158, paragraph 8 - the competent Unit of AIFA express its own opinion within 45 days of receiving the communication referred to paragraph 1.

7. Samples of medicinal products or illustrative material may not be distributed or exhibited in any form at congresses or conventions. Pharmaceutical Companies can disseminate information materials. By information material the following is meant:

- summary of Product Characteristics authorised.
- congressional records;
- scientific papers, provided they are complete and have been submitted to AIFA as stipulated in art.120, paragraph 1.

As international congresses are concerned, it is possible to deliver, in the original languages, informative material in accordance with the Marketing Authorisations, issued in other countries, on condition that doctors coming from those countries are present at the congress.

8. The provisions of the present article shall also apply to congresses, conventions and meetings of pharmacists on topics in any way concerned with medicinal products.

9. Pharmaceutical companies of the kind referred in paragraph 1 which organizes or helps to organize, whether by direct or indirect funding, in Italy or abroad, a congress, convention or meeting on topics not related to the use of medicines that are produced or sold by them, don't undergo the disposition of this article, it being understood that, is not allowed to promote in any form their medicinal products to the doctors at the congress.

10. Competent Unit of AIFA department won't give any authorization for congresses or meetings organized in a different way from what described above.

Information regarding conventions, conferences and meetings according to art.124 of D.L 219/06.

In the context of 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 expose the following:

- . Gadgets of negligible value relating to the professional activity of doctors and pharmacists. On gadgets of medicines with a valid Marketing Authorisation in Countries of the European Union and in all other countries, 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. With respect to international conferences only can be distributed gadgets with 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 in other countries.

- During congresses and meetings the Pharmaceutical Companies can use the panels and distribute visual inside their own stands to deliver information provided they abide to the following criteria:

  - ❖ 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.

  - ❖ 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 in the stand. The display of any form of illustrative materials relating to the medicinal product (images of the packaging) is not allowed.

  - ❖ 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 the informative material above mentioned must be previously submitted to AIFA and may be utilised only after a 10 day negative clearance system and available in the venue where the meeting is held. In particularly:
    a) Every time this material is update it must be submitted again to AIFA.
    b) The date of last submission must be reported on this material..

- 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 and regularly submitted to AIFA.
  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.

- Regarding molecules under investigation information referring exclusively to their mechanism of action without mentioning any therapeutic indications not yet authorised can be provided.

Rome, 11/02/2010