

## **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