



HELLENIC REPUBLIC
MINISTRY OF HEALTH & SOCIAL SOLIDARITY
NATIONAL ORGANISATION FOR MEDICINES
The President's Office

Cholargos, September 30, 2010
Ref No. 66500

CIRCULAR ON SCIENTIFIC EVENTS
I. INTRODUCTION

According to Article 31 paragraph 3 of Law 1316/83 “the organization or sponsorship of seminars or conferences or any other equivalent means of information **within EOF's (National Organization for Medicines) competence** by pharmaceutical industries or enterprises or via any advertising or other enterprise rendering services can be allowed after prior approval of EOF”.

For the exercise of such powers, EOF has decided to implement a new circular following public consultation.

The new circular intends to:

- a) Exercise EOF's competence in accordance with the law in force.
- b) Respect the rules of ethics among health professionals and the enterprises for products within EOF's competence.
- c) Contain pharmaceutical expenditure and other costs for products within EOF's competence.
- d) Validate the scientific nature of the events, and control sound training and execution of their budgets.

The new circular intends to reform, and not to limit scientific events. Reform is necessary because, due to the doubling of requests for scientific events during last year, there was an increase in events lacking documented scientific content and whose budgets didn't meet fair trade practice.

The circular refers to type A events according to the definitions below. The sponsoring of events to inform patients and citizens, on issues related to prevention, treatment and rehabilitation, of various diseases or disease categories and which are organized by patient associations, is not subject to the provisions concerning conferences and therefore the approval of EOF is not required. Holding of events for the provision of information to patients by pharmaceutical enterprises is not allowed according to the legislation in force.

II . DEFINITIONS

A. Scientific Content Conferences

The term, “scientific content” refers to conferences, seminars and similar events of continuous education, organized by governmental bodies, including universities and state hospitals (clinics, laboratories, State services, bodies and health units of the Social Insurance); non-profit scientific associations and non-profit scientific entities, both state and private entities, associations of health professionals and scientific associations of any legal nature, including private hospitals. These are held in Greece or abroad and the entire program has exclusively scientific content (medical/dental/pharmaceutical/healthcare/public health- health services).

All relevant events held in Greece or abroad by foreign organizations sponsored by enterprises whose products are within EOF’s competence are also included.

B. Scientific Information Events

The term refers to conferences, seminars and similar events intending to provide scientific information, which are organised by pharmaceutical enterprises or other enterprises of products within EOF’s competence, in collaboration with the entities of type A, so as to ensure the participation of any interested scientist. They are held in Greece and their program has exclusively scientific content on issues within EOF’s competence.

C. Scientific Information Events on medicinal or other products

This refers to workshops, seminars and similar events aiming to provide information on medicinal or other products within EOF’s competence in the context of their promotion. They are organized by enterprises with products within EOF’s competence, they are held in Greece and the main part of their program is designed to inform health professionals on products within EOF’s competence. For events of types B and C, EOF will issue a separate circular.

D. Products within EOF’s competence

Type A scientific events which require EOF’s approval according to Law 1316/83 are those whose organizing scientific entity, and/or subject, and/or majority of participants are related to the following products within EOF’s competence:

- medicinal products for human and veterinary use
- medicated animal food and food additives
- special diet food and nutritional supplements
 - biocides
- medical devices
- cosmetics

E. Promotional Expenses of medicinal products

According to E.U. Law (article 86 of Directive 2001/83/EU, as amended by Directive 2004/27/EU) promotional activities sponsored by promotional expenses of pharmaceutical enterprises are only addressed to people authorised to prescribe or supply medicinal products (article 94, paragraph 1).

In accordance with the legislation in force the promotional expenses of pharmaceutical and other enterprises within EOF's competence include sponsorships for the organization of events by scientific entities whose area of activity is exclusively (or in its greatest part) related to the provision or promotion of medicinal and other products within EOF's competence (according to Definitions in D.) These expenses must concern the promotion of specific products via exhibitions, shows, leaflets, exhibition stands, e.t.c.

Promotional expenses also include the expenses to organise events (renting of venues, congress material and audiovisual equipment, hospitality offered to the organizers and guests, participants' meals).

Travel and participation expenses of health professionals in scientific events type A organized in Greece and abroad as well as sponsorship for events organised by bodies whose discipline is **not related** with the supply and prescription of medicinal and other products within EOF's competence. (e.g. Pan-Hellenic Congress of the Greek Company of Promotion and Health Education) are not considered to be promotional expenses.

III. CIRCULAR

1) A Special Scientific Committee composed of 9 members is established with the participation of a representative from the Central Health Council (from the Education Committee of the Central Health Education) and the Pan-Hellenic Medical Association (PHMA) (responsible for quota attribution of the A.P.T.). In the committee also participate seven physicians and other health professionals specified by EOF. The Committee assesses requests for the organization of scientific events of type A as per their scientific content taking into account the current scientific developments, the dynamics and the interest of the proposed subjects, the scope, the originality and overall quality of the programs submitted, the accountability and responsibility of the organizing body, and the scientific group to which it is addressed, and finally the number of medical specialists. In cooperation with EOF's competent directorate, which will control the organizational and financial content, the Committee will suggest to EOF's Management the approval or rejection of the relevant requests.

2) All the entities rightfully authorized and interested in organizing Type A conferences should submit an application to EOF, in September, January and May, accompanied by the following:

- a) the name of the scientific entity
- b) the name of the scientific project coordinator
- c) the title and the basic subjects
- d) the time and the venue

e) the initial budget (revenue and expenditure, sources of revenue and expenditure)

In case of cycle of events taking place in a 12 month period, an application for the whole number of events has to be submitted.

3) EOF will announce and publish on October, February and June each year the approval of events for the next 12 months for congresses held in Greece and for a time period of up to 5 years for international events.

4) After the end of a type A scientific event, and within 4 months, the organizer shall submit to EOF the final program of the event, the financial report of the event, the declaration of conflict of interest submitted by Greek and foreign speakers and the speakers who are remunerated, the list with the names of sponsors and the amounts of sponsorship, the number of participants, according to registration and copies of the invoices of the expenses. At the end of each year, EOF shall publish on its website the title of the event, the organizing scientific entity, the height of the expenses and the source of sponsorship.

5) For the organization of type A events abroad by Greek scientific entities or international bodies based in Greece, EOF grants approval only if there are sound scientific reasons (e.g. international obligations) and if there is a co-organiser abroad who participates in at least 50% of the expenses, excluding travel expenses and accommodation costs for the Greek scientists.

6) Sponsorships shall be deposited into an account held by the beneficiary scientific entity mentioned in A of the definitions or in the Special Account for Research and Development (ELKEA) of the relevant Y.PE (Health Region), if clinics and state hospitals laboratories are concerned, or in the Special Account University Research (ELKE), if universities and higher education colleges are concerned, with the issuance of the relevant documents to the sponsor.

In case the scientific organizer does not have an organized accounting department or the legal person due to its nature cannot issue the relevant documents, it may, under a contract signed with the contractor PCO (Congress Organiser), who should be explicitly mentioned in the EOF approval, delegate to the PCO the collection of sponsorships, the invoicing of the sponsors and the overall financial management of the conference and the issuance of the relevant tax documents for the sponsors. The PCO contractor must proceed to the accounts settlement after the event, give a report and return any surplus to the scientific entities involved.

7) The coverage of hospitality expenses of physicians or other health professionals participating in type A scientific events organized by pharmaceutical enterprises and other enterprises with products within EOF's competence, is allowed following EOF's approval. To obtain approval for physicians' participation to these scientific events abroad, the sponsors inform EOF on the number of participants in the congress, citing the cost of participation per person and their expertise. As a final accounting report they submit the list of the participants' names, stating the final cost of participation per participant and their specialty.

For the participation to scientific events held in Greece, the sponsors submit to EOF a final accounting report within 2 months after the holding of the event including the list of the names and the specialty of the guests and the final cost of participation per person.

Hospitality costs include only the costs of registration in the relevant event, costs of accommodation and meals during the event and travelling expenses of participants from their place of practice to the venue of the event. They must be reasonable both as per their level and as per their value, if compared to market prices in relation to the main scientific objective of the event.

EOF sets limits, in cooperation with the representatives of the sponsoring enterprises, to the costs of participation and the number of A-type events in Greece and abroad, which an enterprise can sponsor for each health professional per year.

8) The pharmaceutical and other enterprises are allowed to deposit remuneration (honorarium) in favour of the speakers and people chairing the meetings of type A scientific events, provided that the organizers inform EOF about the full name, specialty, professional body and amount of the award fee per speaker. If no award fee is paid to the speakers, this should be explicitly stated in the accounting report. In case the speaker is physician of the NHS or a University physician, any award fee shall be deposited to ELKEA or ELKE respectively, who attribute it to the beneficiary after the appropriate deductions, and at the end of the year they will issue a relevant tax certificate for the beneficiary. Physicians and other health professionals who receive honorary fees for their speech must mention it in a declaration of conflict of interest to the Organizing Committee of each event and for a period of two years a) at the beginning of their speech and b) in any subsequent publication, which may be related to the enterprise's products in Greek or international journals.

9) EOF may carry out controls during conferences or events through its bodies or in cooperation with the competent tax authorities and in cases of no compliance with what has been approved, EOF will not give approval to the responsible body for future events for a period of 2 years. The same applies in the cases of serious surplus (over 25%) of the financial report in comparison to the documents submitted. In these cases appeals may be submitted in accordance with the existing procedures.

10) It is mandatory for meetings and scientific events (not conferences) organized by departments of the NHS or University faculties to have free entrance for all. The above should take place within the regional boundaries of their seat.

11) For each application filed at EOF a fee will be paid, the amount of which will be determined depending on the type of event and in accordance with the legislation in force. No fee is submitted with an application regarding hospitality costs.

12) A number of issues, as in Article 7 hereof, and any other matters not specified in this circular will be decided by EOF's administration following a justified opinion of the Special Scientific Committee referred to in Article 1 of the present circular and of the competent EOF's Directorate.

The present circular enters into force on October 1st 2010. Applications submitted before October 1st for Type A events will be evaluated according to No. 6434/28-1-2010 circular, which is repealed from 01/10/2010 on. As regards the provisions of paragraph 2, new applications for type A events may be submitted up to October 31, 2010. For type B and C events the circular in force applies until a newer version is issued.

The President of EOF's Board

J. Tountas