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Protocol No. 81867

SUBSTITUTION OF CIRCULARS FOR SCIENTIFIC EVENTS WITH PROTOCOL NUMBER 66500/1.10.2010 - 82205/3.12.2010 - 14660/25.2.2011-47558/4.7.2012

CIRCULAR FOR SCIENTIFIC EVENTS

I. INTRODUCTION

Pursuant to article 31 par. 3 of Law 1316/83 “organising or funding conferences or seminars and any respective means of information on issues concerning the competencies of EOF from pharmaceutical industries or undertakings or through any advertising or other company rendering services, may be permitted only with EOF’s prior approval“.
For the exercise of this jurisdiction, EOF has decided to apply a new circular which was formed following open discussions.
The new circular aims at:
a) EOF exercising its jurisdiction in accordance with applicable laws.
b) Observing the code of ethics between health professionals and the companies with products under EOF’s jurisdiction.
c) Retaining pharmaceutical expenditure and other expenditure for the products under EOF’s jurisdiction.
d) verifying the scientific nature of the approved events and inspecting the due preparation and performance of their budget.
Setting this targets, the new circular aims at reforming and not restricting the scientific events. This reformation is rendered necessary because, due to the over-doubling of demands for scientific events in the last year, there was an increase of the events with no documented scientific content and with budgets for expenses that did not correspond to transacting morals.

Funding of events for informing the patients and in general citizens for issues that relate to prevention, treatment and rehabilitation in separate diseases or nosologic categories organised by unions of patients, are not subject to the provisions on scientific events/seminars and therefore the approval by EOF is not required.
Events for informing patients by pharmaceutical companies are not allowed in accordance with the applicable legislation.

II . DEFINITIONS

A. Conferences with scientific content (Type A)
Scientific are the conferences, seminars and similar events of on-going training, which are organized by the State agencies, which include universities and state hospitals (clinics, laboratories, health clinics, health agencies and units of Social Insurance), unincorporated scientific unions, as well as unincorporated scientific foundations, Public Law or Private Law Legal Entities, from associations of healthcare scientists and scientific unions, of any legal form, including private practices. They are conducted in Greece or abroad and their programme consists in whole exclusively of scientific content (medical/dental/pharmaceutical /inpatient /public health – health services).
The same category includes all respective events organised in Greece or abroad from foreign agencies and are sponsored by companies with products under EOF's jurisdiction.

B. Scientific Update Events (Type B)
Conferences, seminars and similar events for scientific update are those organised by pharmaceutical undertakings or other undertakings with products under EOF's jurisdiction, in co-operation with the beneficiaries of Type A category, so as to ensure that any interested scientist will be able to participate, are held in Greece and their programme consists in whole in exclusively scientific context of the issues under EOF's jurisdiction.

C. Scientific update events of pharmaceutical or other products (Type C)
Daily events, seminars and similar events for update on pharmaceutical products or other products under EOF's jurisdiction in the context of the promotion thereof, are the events organised by undertakings with products under EOF's jurisdiction, they are held in Greece and the main part of their programme aims at informing healthcare professionals for the products under EOF's jurisdiction.

D. Scientific Update Events (Type D)

Scientific events (Type D) in Greece are organized by pharmaceutical companies with registered offices outside of Greece, without having promotional purposes, on the contrary, these are solely of training or research nature, and constitute specialized fora, with a complete scientific programme, bringing together speakers of high caliber (e.g. training seminars for speakers and/or for writing scientific articles and/or theses, CMEs, research programmes, etc.. participation of up to 5 healthcare professionals per company per event (application form Type D).

E. Granting of access to scientific events/conferences and/or research events via the internet

Pharmaceutical companies and other companies with products under EOF's jurisdiction may support financial healthcare professionals (personally or in groups), by providing access codes for the continuance of training through the use of technology.
For group attendance via the internet, the expenses for the premises and facilities are covered by the pharmaceutical company.
Only the offer of coffee/ refreshment drinks is permitted in group attendance.

F. Products under EOF's jurisdiction

Type A scientific events that require EOF's approval in accordance with law 1316/83 are those which the scientific organizing agency and/or the object thereof and/or the majority of the participants therein are related to the following products under EOF's jurisdiction.

- pharmaceutical products for use in humans and animals
- medicine-containing forage and forage additives
- special nutrition food and supplements
- biocides
- medical technology products
- cosmetics

Z. Expenses for the promotion of pharmaceutical products

Pursuant to EC Law (article 86 on Directive 2001/83/EC, as amended by Directive 2004/27/EE), the recipients of promotional activities financed from the promotion expenses of pharmaceutical companies are only the persons authorised to issue the relevant prescriptions or to supply medicines" (article 94, par. 1).
Based on applicable law, the promotion expenses of pharmaceutical companies and other companies under EOF's jurisdiction include sponsorships for the organising events from scientific agencies whose object is exclusively associated or to its largest part with the administration or promotion of medicines and other products under EOF's jurisdiction (according to D of the definitions hereof). These expenses must concern the projection of specific produts via exhibitions, demonstrations, forms, stands etc..
The promotion expenses also include the organising expenses for the events (rental of space, conference material, audio & visual equipment, accommodation of organisers and guests, sustenance of participants).
The promotion expenses do not include the coverage of transportation costs and participation of health professionals in Type A scientific events both in Greece and abroad, as well as sponsorships for events organised by agencies whose object is not associated with the administration or promotion of medicines and other products under EOF's jurisdiction (e.g. Hellenic Conference of the Greek Company for Promotion and Aid of Health).

H. Accommodation Expenses

Accommodation expenses exclusively include the expenses for the entry for participation in the respective event, stay and sustenance during the event until the place the event is held and must be reasonable both as to their level and as to their cost, compared to the market prices and in relation to the main scientific goal of the event.

I. Formation of the Special Scientific Committee

A nine-member Special Scientific Committee is formed in EOF with the participation of the representative of KESY (from the Training Committee of KESY) and of PIS (who is responsible for granting the S.I.E. points), as well as seven physicians and other health professional appointed by EOF, which will evaluate the requests for the organising of Type A scientific events as to their scientific content, co-assessing the current scientific developments, the dynamics and the interest of the suggesting scientific topics, the range, the originality and in general the quality of the programmes filed, the validity and responsibility of the organising agency, as well as the scientific group which it addresses and the number of the specialized physicians thereof. In co-operation with EOF's competent directorate, which will control the organising and financial content of the events, it will suggest to EOF's management the approval or rejection of the relevant applications.

III. PROCEDURES FOR ORGANISSCIENTIFIC EVENTS/ CONFERENCES

III. A. Domestic Scientific Events/ Conferences (Type A)

1. All beneficiary agencies who are interested in organising Type A conferences, must file their request to EOF in September, January, May and November, submitting:
a) the name of the scientific agency
b) the name of the scientific supervisor
c) the title and the relevant topics
d) time and place the conference will beheld
e) original budget (income, expenses, sources of income-expenses)
If it concerns a series of events in a 12-months period, then one request is filed for all events.
EOF will announce each October, February, June and December the approved events for the following 12 months.
EOF will make public at its website the title of the event, the scientific organising agency and the amount of the budget.

2. The annual number of participations in Type A scientific events/conferences held in Greece of the health professionals sponsored by pharmaceutical companies and other companies with products under EOF's jurisdiction, cannot exceed the number five (5) per health professional.

3. Exception: cases where a health professional actively participates as the "speaker", "chairman", "member" of the organising committee, 1st – 2nd and last "author" in a work (oral announcement or poster) which has been approved to be presented in the conference, with the necessary proof.

4. Training leave of Health Professionals

A necessary condition for the participation of the health professional, who is sponsored by pharmaceutical companies and other companies with products under EOF's jurisdiction, in scientific events/conferences, is to notify his/her participation to his/her employing agency in order to be granted a training leave based on the relevant law (Law 2889/2001) and a solemn declaration provided for by applicable law for the number of his/her participations during the current

year (the solemn declaration will be filed to the sponsor pharmaceutical company).
A physician of the NHS – Health Center by the Hospital, a University Clinic Physician by the supervising authority - a physician contracted with an Insurance Agency (waged relation) to the Directorate of the Insurance Agency.
In case of speech or work, the health professional will solemnly declare that the relevant employing agency has been informed of the contents of the speech or the work. If the scientific event/conference is held on a weekend, the health professional is obliged to inform his/her employing agency for his/her participation therein.
For the participation in scientific events held both in Greece and abroad as well as for the granting of a training leave to the physicians of the NHS – University, Military, EOPPY and all other Insurance Organisations of the State, the provisions of par. 18 article 11 of Law 2889/2001 (Gov. Gazette 37A/2001) apply.
The speakers participating in the scientific events/ conferences, are obliged, instead of the written declaration, in the beginning of their speech (in the 2nd slide after the title of the lecture), to refer any conflict of interest.

5. Verification of the presence of the physician in events held abroad

The conference organizer: has computers, lists with names and barcodes for each participant available.
Upon the entrance registration is effected, together with the delivery of the card (e.g. full name/ capacity/ country and barcode)
At the entrance of each hall there is a scanner that scans the card.
If there are CMEs, then these are credited to the participant respectively.
When the conference is concluded, he/she receives the certificate f attendance, after having completed 60% on the total programme hours and the CMEs that have been calculated based on the attendance/participation.
Daily events and scientific events with less than one hundred (100) participants are excluded.

6. Sponsorships of scientific events/ conferences

Support of scientific events/ conferences from pharmaceutical companies and other companies with products under EOF's jurisdiction, which are organised in Greece upon the approval of EOF, with showrooms, satellite conferences, lectures, advertisements as well as their general sponsorship cannot exclude per pharmaceutical company the following limits (VAT including):

- Worldwide/Pan-European up to €50,000 per pharmaceutical company
- Throughout the Greek State up to €30,000 per pharmaceutical company
- Regionally up to €20,000 per pharmaceutical company and
- Locally up to €10,000 per pharmaceutical company

Sponsorships/subsidies are deposited in an account maintained by the beneficiary scientific agency referred to A of the definitions or in the Special Account for Research and Development Funds (ELKEA) of the relevant Y.PE., if it concerns clinics or laboratories of state hospitals or Special Account for Research and Development Funds of Universities, if it concerns Universities and Higher Education Institutions, with the issue of the relevant vouchers to the sponsor.

In case the scientific organising agency is professionally inadequate or, in the context of the form of its legal entity cannot proceed with the issue of the relevant voucher, then it is able, in the context of the agreement it executes with the contractor PCO (Professional Conference Organiser), who must strictly be subject to EPF's approval, assign to the PCO the collection of sponsorships, the invoicing to the sponsors and the general financial management of the conference, as well as the issue of the relevant tax vouchers to the sponsors-companies.
The contractor PCO is obliged, following the conclusion of the event, to proceed with the clearance and review and deliver any surplus to the responsible scientific agencies.

7. No satellite conference, sponsored by pharmaceutical companies is graded (applies to the U.S.A. and the E.U. countries)

8. Cost-plus data

Following the conclusion of the Type A scientific event and within two (2) months, the organising agency files to EOF the final programme of the event, the financial review of the event, the list of names of the sponsors, the number of participants, as concluded from the entries made, as well as a solemn declaration pursuant to applicable Law, with which they will declare that the income-expenses data referred to in the review, are true and accurate.
They are also obliged to produce ratified copies of any voucher issued to EOF, if so requested.
Transgression over 25% of the original budget is prohibited, unless it is fully justified, based on the respective increases of the sizes of the scientific event.

III.B. Organising scientific events /conference (Type A) abroad by Greek scientific agencies in co-operation with foreign scientific agencies

For the organising by Greek scientific agencies, of Type A events in a foreign country, EOF shall grant its approval only if serious scientific reasons exist (e.g. international obligations) and if there is/are a foreign co-organiser(s) who participate, by at least 50% in the expenses, excluding the transportation and accommodation expense of Greek scientists.

III.C. Agreement with a Scientific Events/Conference Organisation office

In the context of the agreement executed between the two parties, the following must be included:
- Full details of the contracting parties (registered office, name, VAT Registration Number, Tax Office, legal form, legal representation etc.)
- True and accurate financial data (budget that corresponds to the data of the request, fee of PCO and any other data)
- In general, the agreement must be accurately presented and described.

III.D. Organising International and Worldwide scientific eventsin Greece, by foreign agencies

International or worldwide scientific events organised in Greece by foreign agencies, a) are not subject to any time limitation for the filing of the request.

b) The decisions approving the organising of these events, will be notified no later than one month from the date of filing.
c) As regards the cost-plus data, they will be filed to EOF, if scientific agencies are co-organisers from Greece and are sponsored by Greek pharmaceutical companies.

IV. (Honoraria)

1. The payment of an honorarium is permitted by pharmaceutical and other as above companies, to the invited speakers or chairmen of the meetings of Type A, B and C scientific events, with the obligation of the organisers of the event to inform EOF of the full name, specialty, professional agency and the amount of the honorarium for each speaker.

1. In case no honorarium is paid to the speakers, this must be expressly referred to in the financial review. If the speaker is a NHS or University physician, any honorarium is paid to ELKEA or ELKE respectively, who reimburse it to the beneficiary after making the relevant retentions (if any) and at the end of the year they issue a relevant certificate of wages to be used by the person receiving the fee for tax purposes.

2. Physicians and other health professionals being paid honoraria for a speech, are obliged to state it in the second slide presented upon the commencement of the event (conflict of interest). For a period of two years, the list of companies from which a speaker has been paid an honorarium must be referred a) in the beginning of his/her speech and b) in any future publication, which may be related with the products of the company, in Greek or international scientific magazines.

4. Payment of honoraria of the foreign invited speakers is not subject to the obligation of depositing them to the accounts of ELKE or ELKEA.

V. Events for updating the public

For the events held for updating the public, which are organised by scientific agencies, no approval of EOF is required, except if they are sponsored by pharmaceutical companies.

VI. Participation of health professional in Scientific events/ conferences held abroad

1. Pharmaceutical companies and other companies with products under EOF's jurisdiction are entitled to cover the participation expenses of a health professional for the transfer, registration, accommodation, sustenance thereof, subject to the approval of EOF and the approval of the employing agency of the said participant (University – Hospital – EOPPY- Insurance Organisation).
2. The number of times in one year, for which a health professional may be sponsored by pharmaceutical companies for participating in a Scientific event /

Conference held abroad, cannot be higher than three (3), with at least two (2) of them being held in Europe.

3. Participation in conference of the specialty or relevant specialties..
Clear prohibition of entertaining events or participation therein (e.g. excursions).
4. Clear prohibition of the presence of accompanying members who are not health professionals.
5. Pharmaceutical companies and other companies with products under EOF's jurisdiction file an application form (the EOF application form) for approval of the participation of the health professional to a scientific event/ conference to EOF, one month before the event is held and during the first fifteen days of each month (e.g. if the application is filed in January, then it will concern the events held from March 1 and during the remaining months of the year) where the following will be recorded:

- Full name
- Specialty
- Employing agency
- Social Security Number and
- Solemn declaration of the applicant for the number of his/her participations, for the current year, as well as notification of his/her participation to his/her employing agency
- Suggestive cost per health professional
- Subject -Place-Time –Organiser of the event

Following the filing of the application, the sponsor company will sent the details electronically (xl) to the following email address med_conf@eof.gr.

The database operated by EOF is updated by the pharmaceutical company on a cost-plus basis, with all the above details and the final cost.

6. Maximum number of participants per sponsor company in scientific events/ conferences held abroad (Type A)
In conferences held outside Europe, 30 health professionals/ conference, in N. America and Canada, 10 health professionals/ conference and in the remaining world, 5 health professionals/ conference, with the exceptions a, b and c referred to below in paragraph VII.

VII. Exceptions in the annual number of participating health professionals in scientific events held abroad (Type A and targeted training activities)

a. If the health professional is the "speaker", "chairman'', ''member" of the organising committee επιτροπής, 1st – 2nd – 3rd "author" in a work (oral announcement or poster) approved to be presented in the event.

b. The health professionals participating in international clinical trials approved by EOF (the head of the programme, the technician and the physician conducting the trial).

c. Ability to participate in targeted training activities without any restrictions e.g. participation in special workshops (learning of special endoscopic techniques or

operating techniques), research seminars, training Schools for one specific topic (e.g. European Respiratory School on monitoring airways diseases).

For all the above exceptions, the applicant health professional will fill in a special application form, in order to be granted a special permit (EOF's application form). The said application will record:

- The full name – specialty – employing agency – Social Security Number of the Health Professional
- The suggestive cost per health professional
- Subject – Place – Time – Organiser of the Event

In addition, the supporting documents that prove his/her participation as well as the solemn declaration provided for by the relevant law in force, that he/she has notified his/her participation in the scientific event to his/her employing agency will be attached. For participation in international clinical trials, the relevant approving decision of EOF will also be attached.

All the above will be filed to EOF by the pharmaceutical company undertaking to sponsor the applicant(s), with a supporting document.

Following the filing of the application, the sponsor company will sent the details electronically (xl) to the following email address med_conf@eof.gr.

Pharmaceutical companies must request, upon the conclusion of the event, by the health professional whose participation they sponsored, a copy of the participation certificate, in order to file it to EOF together with the cost-plus data.

VIII. Participation of health professionals in events held in Greece (Type A) which are sponsored by pharmaceutical and other companies with products under EOF's jurisdiction

For the participation of health professionals who are sponsored by pharmaceutical and other companies with products under EOF's jurisdiction, in scientific events in Greece, n preliminary approval is required (either the said companies are sponsors of the scientific events or they only cover the expenses of the participants).
In these cases, EOF's database will be updated on a cost-plus basis within two (2) months from the date the event is held by the pharmaceutical company with the following data: full name - specialty – Social Security Number – employing agency of the participants - final cost per participant– number of participations for the current year (for which (number) the sponsor company will obtain a solemn declaration provided for by the relevant law in force).

IX. SCIENTIFIC EVENTS TYPE B, C, D

1. All beneficiaries-agencies interested in organising Type B, or C events, must file their request for approval to EOF, one month before the event is held, within the first fifteen days of each two-months period (e.g. if the application is filed in

January, it will concern the events that will be held from March 1 and during the remaining months of the year).

1. Type B and C events must not exceed 5 events per company per period of applications filing (two months)
2. Type D events are not subject to any time limitation for the filing of the application
3. The application (EOF forms Type B, C, D) will include:

- Name of the company and data of the co-operating scientific agency for Type B events
- programme of the event
- time and place the event is held
- original budget

The approval procedure does not require the positive opinion of the scientific committee, as for Type A events.

A necessary condition for the approval of Type B and C events, is the organising of a training session of at least 4 hours, for each day of the event, if the participants stay overnight.

Type C events are approved only if their purpose is the promotion of medicines, in accordance with the provisions of the Joint Ministerial Decision (ΚΥΑ) ΔΥΓ3 (α) 85657 (ΦΕΚΒ΄59/2006).

4. The specialty or the object of work/ occupation of the health professionals must be related to the topics of the event
5. Pharmaceutical companies established in Greece are prohibited from organising Type B or C events abroad.
6. Accommodation of participants must not include clearly entertaining events, while the selection of the countries must be made with case and with regard to the conference facilities and not the recreation and entertainment.
7. Participation of NHS physicians and University physicians in Type C events is not permitted (law 2889/2001, article 11, par. 18)
8. Pharmaceutical companies are allowed to pay honoraria to the invited speakers or chairmen of the meetings of Type B and C scientific events in accordance with the terms stipulated in section IV of this circular.
9. Pharmaceutical companies must see to that the expenses for the promotion of Type B or C events do not negatively affect the sponsorships for Type A conferences.
10. After the end of the scientific events and within two (2) months, the pharmaceutical company files to EOF the final schedule of the event, the number of participants and the copies of the expenses vouchers, if requested. For Type D events, the cost-plus data are filed by the subsidiary with registered office in Greece or the respective representative.

X. Granting of access to scientific events/ conferences and/or research events via the internet

For group attendance via the internet, the expenses for the premises and facilities are covered by the pharmaceutical company.
Only the offer of coffee/ refreshment drinks is permitted in group attendance.

No preliminary approval or filing of cost-plus data is required for personal or group activities of this type.

XI. Objections

Objection against the rejecting decision for Type A, B and C events is filed by the applicant within 10 days from the date the rejecting decision is notified.

XII. INSPECTION OF SCIENTIFIC EVENTS/ CONFERENCES – PENALTIES

1. EOF is entitled to conduct inspections during the conferences or the events via its competent bodies or in co-operation with the competent tax authorities and in case the non-observance of the approved provisions is discovered, no approval shall be granted to the relevant agency for future events for a period of two (2) years. The same applies in the case of serious transgression (above 25%) of the budget from the supporting documents filed. In these cases objections can be raised and filed in accordance with applicable procedures.
2. In case the number of participations of health professionals in Type A events/ conferences held in Greece is exceeded (5 per health professional per year) and abroad (3 per health professional per year, of which 2 in Europe) then the health professional shall be excluded from any scientific event for one year.

XII. GENERAL

1. Beneficiary agencies interested in organising Type A conferences, as set out in this circular, will file their request four (4) times a year and specifically in September, November, January and May in order to be examined by the nine-member Scientific Committee which convenes in October, December, February and June respectively. The applications are not limited to the events of the forthcoming three months period, but may concern any other future date. Each agency must see to the timely filing of its application, so that an expedient period will elapse between the meeting of the Committee and the date the event will be held. By means of this procedure, financial loss and unnecessary preparation of speakers are avoided, in case EOF's approval is not granted.

2. Limits concerning accommodation of health professionals in scientific events held in Greece – abroad

   Accommodation of health professionals in scientific events/conferences held abroad must be in 4-star hotels and only in special occasions in 5-star hotels following justification (e.g. conduct of the conference in a 5-star hotel, inadequacy of beds etc.). For airplane transits, economy class tickets must be issued and only in case of transits exceeding 4 hours, business class tickets can be issued, if possible.

   The total cost (stay and sustenance) of the health professionals in scientific events/conferences held abroad, cannot exceed 400€ per day (70 maximum sustenance cost, VAT not included).

   The accommodation cost (stay and sustenance) of the health professionals in scientific events/conferences cannot exceed €250 per day (€70 maximum sustenance cost, VAT not included).

   These limits apply to Type A, B and C events.

Finally, accommodation must be strictly restricted to the main scientific goal of the event.

3. Pharmaceutical companies belonging to SFEE are obliged to ensure their compliance with the Code of Ethics and the restrictions of the accommodation expenses as for Type A events.

4. Pharmaceutical companies not belonging to SFEE are invited to adopt the relevant Code of Ethics.

5. Daily events or scientific events (not conferences) organized by the NHS departments or by Universities must have obligatorily free of charge entrance and must be held within the prefectural boundaries of their headquarters.

6. EOF's management will decide for any issue not specified in this circular, following the justified recommendation of the Special Scientific Committee referred to in section II hereof.

Documents attached:

Application forms type A, B, C and D and exceptions special application

This circular enters into force on 1.2.2013

Internal Distribution

Office of the president

1st Vice President Office

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THE PRESIDENT OF EOF

PROFESSOR I. TOUNTAS