



HELLENIC REPUBLIC
MINISTRY of HEALTH
DIRECTORATE GENERAL FOR HEALTHCARE SERVICES
DEPARTMENT OF PHYSICIANS, OTHER
SCIENTISTS & HEALTH PROFESSIONALS
DEPARTMENT A

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RE: CONFERENCES, SCIENTIFIC EVENTS, EDUCATIONAL ACTIVITIES

Pursuant to Article 164(4) ("Central Health Board - "KESY") of Law 4600/2019 "Modernization and Reformation of the Institutional Framework governing Private Clinics; Establishment of a National Organisation for Public Health; Establishment of a National Institute for Neoplasms and other provisions" (Government Gazette Series A, Issue no. 43) and the provisions of Ministerial Decision No. Γ5α/ΓΠοικ.46340/18-6-2019, the competence of the National Organisation for Medicines ("EOF") relating to the organisation and financing of conferences and seminars by pharmaceutical industries and commercial enterprises or by advertising firms or other service providers is transferred to KESY.

The implementation of the above regulations is thoroughly analysed below:

A. AUTHORISATION AND ALLOCATION OF SCIENTIFIC EVENTS / EDUCATIONAL ACTIVITIES

1. Authorisation for each type of educational event / activity shall be granted on the basis of a request to be filed to that effect to ESYE/KESY by the organising body [Scientific Association (SA) or Scientific Healthcare Structure (SHS)]. Such request shall essentially indicate: the form of the event (conference, workshop, two-day workshop, seminar, clinical tutorial, intra-clinical lesson, interdisciplinary course, annual series of postgraduate courses, Webinar), as well as its geographic scope (international event conducted in Greece, national / local / regional event), term and frequency, any accreditation to be awarded to the participants (CME -CPD) and the event's budget.
2. The authorisation criterion for all educational events / activities will be their scientific content, taking into account the current scientific developments, the dynamics and importance of the agenda, the breadth, originality and general quality of the programs, the prestige of the organising body,

the educational experience of the speakers and the scientific group the event will be addressed to.

3. Cost limits for each scientific event / activity shall be primarily defined on the basis of the event category. According to the above classification, the organisation costs of each event and the registration fees to be charged to health professionals for attendance will be determined by means of a special decision of ESYE, following a recommendation by the Board of Directors of the organising body. The registration fees for trainee physicians will be 50% of those applicable to licensed physicians in the relevant category of activity. Any details pertaining to reimbursement of health professionals for registration fees shall also be thoroughly regulated.

KESY shall monitor the preparation and implementation of the budget of each event/activity as well as compliance with the rules of ethics between SHSs, health professionals and manufacturers/traders of EOF-regulated products.

4. The compulsory attendance hours by scientific event / educational activity per year shall be determined for each specialisation/ area of expertise by the corresponding Scientific Medical Society/ Scientific Dental Society (SMC/SDC) and shall be validated by the KESY Committee for Ongoing Education (“ESYE”).

5. The term (duration) of the scientific program of Pan-Hellenic Conferences is two (2) to four (4) days; the minimum number of participants is one hundred (100); the sponsorship limit is thirty thousand Euros (EUR 30,000.00) per company / sponsor, net of the registration, transportation and accommodation costs of the participants. Each SA shall guarantee for the accuracy and validity of its representations.

6. The term (duration) of the scientific program of Scientific Days / Workshops is one (1) or two (2) days respectively, irrespective of the number of participants. The sponsorship limit is five thousand Euros (EUR 5,000.00) and ten thousand Euros (EUR 10,000.00) per company / sponsor, net of the registration, transportation and accommodation costs of the participants.

7. The term (duration) of the scientific program of local/ regional Conferences is one (1) or two (2) days, irrespective of the number of participants. The sponsorship limit is fifteen thousand Euros (EUR 15,000.00) per company / sponsor, net of the registration, transportation and accommodation costs of the participants.

8. Save in justified situations, if a budget is exceeded by over 25%, the organizing SA may not file a request for a similar event in the following calendar year.

9. Satellite symposia organised by sponsors in the context of conferences may not exceed in total duration 20% of the total duration of the relevant conferences, and are subject to the following conditions:

- a.** The names and fees of the sponsor's speakers at the event and of the speakers at the satellite symposia shall be officially announced to KESY by the body responsible for organising the event.
- b.** No certificates of attendance shall be furnished to the participants.
- c.** A Health Professional (HP) may not serve as Chairman, Coordinator or Speaker in more than six
(6) symposia per year.

d. The scientific program of satellite symposia shall be prepared by care of the sponsor in direct consultation with the organising SA.

10. In respect of the organisation of scientific events / educational activities of all categories, a contract shall be executed between the SA/SHS and the sponsors, with explicit reference to the amount and the terms of the sponsorship, including any details pertaining to the organisation of satellite symposia by the sponsors. Exclusively responsible for the financial management of sponsorships and any revenues deriving from registrations shall be the relevant SA/SHS.

Each SA/SHS may assign the organisation of educational activities to a Conference Planner, by decision of its Board of Directors. In this context, a contract shall be executed between the SAs/SHSs and the conference planner/ travel agent, whereby the latter shall undertake all transportation, accommodation and board services for the participants. These services shall be invoiced by the planners/ travel agents directly to the sponsors, as per the instructions of the SAs/SHSs. All contracts shall be notified to ESYE / KESY.

11. Social & cultural events are not allowed to take place outside the conference venue, except for any events concerning exclusively the speakers and the chair persons.

12. Scientific events may not be organized (a) at tourist destinations during the relevant tourist periods, i.e. during the summer season (15/6 - 31/8) or the winter season (15/12 - 28/02).

13. The cash reserve to arise from the proceeds shall remain at the treasury of the SAs/SHSs, by decision of its Board of Directors, which is validated by the General Meeting and notified to KESY. Such reserve shall be posted on their web sites and shall be allocated to grant scholarships and to finance research activities and scientific publications.

14. Any conferences organised in Greece exclusively by International Scientific Societies / Organisations (without the involvement of a Greek Scientific Association (SA) or a Scientific Healthcare Organisation (SHO) as a co-planner) shall be simply notified to KESY. The organisation costs of such conferences shall be fully covered by the foreign scientific organisations concerned. Greek sponsors may participate in these conferences by covering the participation costs of Greek

HPs or through advertising sponsorships. No numerical restrictions shall apply to the participation of HPs in these conferences.

15. In the case of events jointly organised with a Greek SA/ SHS, the foreign organisation shall contribute by 50% to the budgeted costs and the speakers' expenses, through sponsorships deriving from companies abroad.

16. Any events organised by Greek SAs/ SHSs with the participation of foreign speakers shall not be considered as international, but rather, as domestic events with international participation, and will be subject to the sponsorship limits applicable to the category of the event.

17. For scientific events organised abroad by Greek SAs/ SHSs, authorisation shall only be granted for serious scientific reasons, following an assessment on a case-by-case basis.

18. No authorisation from KESY shall be required in respect of events organized by SAs / SHOs and patient associations, for public awareness purposes. For any events other than those financed by manufacturers/traders of EOF-regulated products, authorisation from ESYE-KESY is required. In these events, the speakers must essentially be Health Professionals and the events shall be under the auspices of SMCs/SDCs.

19. Events intended for public awareness purposes may not be organised by manufacturers/traders of EOF-regulated products.

20. Honorarium fees may be paid [Article 11(18) of Law 2889/2001 (GG A, 37), as amended by Article 36 of Law 4272/2014 (GG A, 45)]

by manufacturers/traders of EOF-regulated products to speakers and round-table chair persons. Such fees shall be essentially declared along with the relevant participation requests to be filed by HPs, as per the applicable regulations. Honorary fees shall be paid to the HPs of the NHS (National Healthcare System) or Universities (being employed by clinics established in NHS hospitals or University Hospitals) through ELKEA (Special Account for Research and Development Funds) or ELKE (Special Account for Research Funds).

Lists with the details of all authorised scientific events (name of the SA/ SHS organising the event, topic, venue, date and time of the event, budget and estimated number of participants) shall be posted on KESY's website.

SAs/SHSs shall post on their websites, prior to their annual general meeting, lists with: a) the names of all HPs that participated in every event organised by them; b) the sponsorships they received for each event and the respective sponsors (event planning sponsorship & HP participation sponsorships).

B. ORGANISATION OF SCIENTIFIC EVENTS BY CATEGORY

1. Each SMC / SDC may organise one (1) pan-Hellenic conference per year, with or without international participation. It may also organise one (1) other pan-Hellenic activity per year with a specific subject and activities addressed to young physicians, up to a total of three (3) events,

such as: conferences /workshops, seminars, clinical tutorials and annual series of postgraduate or post-degree courses.

2. Each SMC/SDC Branch may organise up to one (1) local / regional conference, workshop and/or seminar per year. Every three (3) years it may organise a pan-Hellenic educational activity, subject to prior authorisation by the relevant Ongoing Education Committee. If a pan-Hellenic Conference is organised by a Branch, no similar conference may be organised by the SMC/SDC in the same year.

3. Interconnected Scientific Societies (ISSs)

Other KESY-certified medical associations may organise one (1) educational activity of any form every year. They may also organize round tables on their area of expertise as part of any larger, certified, pan-Hellenic conferences of their interconnected SMCs.

4. The Medical Societies of: Athens, Thessaloniki, Western Greece and the Peloponnese, and Heraklion, Crete may organise one (1) educational activity of any kind every year.

5. All categories mentioned above (1, 2, 3 and 4) may organise scientific events consisting in e-learning and skill practising activities. Such activities shall be validated by ESYE-KESY and shall not be subject to numerical restrictions.

6. Public Healthcare Structures

Educational activities organised by Medical / Dental Schools, University Hospitals, University Clinics and Laboratories may organise one (1) scientific event every year, of any geographic range. Sponsorships by manufacturers/traders of EOF-regulated products shall be assessed on a case-by-case basis and may not exceed the limit applicable to pan-Hellenic Conferences, net of the transportation and accommodation costs of the participants. NHS Clinics and Laboratories may organise one (1) scientific event of regional/local range per year. Sponsorships by manufacturers/traders of EOF-regulated products shall be subject to the limits applicable to regional / local sponsorships, net of the transportation and accommodation costs of the participants. No registration fees shall be charged for these educational events. When these events are conducted at a Hospital or University auditorium, no stands or other advertisements of pharmaceutical companies may be placed on the premises. These events may not exceed two (2) days in duration. Other public structures (Health Centres) may organise one (1) daily educational event with a maximum budget of ten thousand Euros (EUR 10,000.00).

7. The Scientific Medical Organisation of the Armed Forces may organise one (1) educational event of any kind every year.

8. The costs and revenues of the events shall be paid/collected through ELKE or ELKEA, in respect of all categories of scientific events / educational activities.

9. Private Healthcare Structures

Educational activities organised by Private Structures such as hospitals, clinics and laboratories, may not exceed three (3) per year as follows: one (1) local / regional Conference, two (2) Workshops / two-day Workshop without registration fees.

10. Patient Associations may organise scientific events for the public once a year, in collaboration with the SA responsible for the scientific program.

C. PHARMACEUTICAL COMPANIES / MEDICAL EQUIPMENT COMPANIES

1. Pharmaceutical Companies / Medical Equipment Companies shall essentially declare to ESYE-KESY twice a year any scientific events they intend to support in the relevant time period through direct financial sponsorships to the organising bodies, as well as the number of physicians and other health professionals whose attendance will be supported in each event, including in any conferences to be held abroad.

2. Pharmaceutical Companies / Medical Equipment Companies may organise corporate informational meetings with HPs in Greece, for promotional purposes. Such informational meetings shall be essentially concluded in a single day, may not exceed five (5) hours in duration and may not involve any overnight stays. Events organised by manufacturers/traders of EOF-regulated products may not exceed in total forty-eight (48) per year. The informational activities organised by each sponsor shall be notified to ESYE-KESY and to EOF. Events organised by manufacturers/traders of EOF-regulated products may not be held on the premises of any Universities or Hospitals.

3. Pharmaceutical Companies / Medical Equipment Companies may organise meetings between advisory bodies with a strictly scientific agenda, by filing relevant requests to ESYE-KESY.

4. Pharmaceutical Companies / Medical Equipment Companies are liable to notify to EOF any sponsorships they intend to offer to SHSs to cover the costs of each scientific event, including any sponsorships for participations in the events.

5. The physicians, nurses and all scientific staff of NHS and university physicians employed in clinics established in NHS or University Hospitals are not eligible to participate in conferences or seminars

organised in Greece or abroad by pharmaceutical companies / medical equipment companies for reasons of promotion of their own products.

D. SUBMISSION OF APPLICATIONS FOR AUTHORISATION OF SCIENTIFIC EVENTS

1. Twice a year, i.e. in November and May every year, the SAs/ SHSs shall submit electronically to ESYE-KESY for validation, through a special electronic database, a plan of any events / activities they intend to organise in the relevant time period.

2. Any SAs/SHSs interested in organising scientific events / activities shall submit electronically each application to ESYE-KESY at least six (6) months prior to the starting date of the event / activity concerned. Each body is liable to ensure timely submission of its own applications. Late applications shall be rejected by the database automatically. Any applications missing any of required completed documents / attachments shall be also rejected automatically.

3. Pharmaceutical companies / medical equipment companies may submit applications for their corporate informational meetings and for the participations of HPs therein, including the advisory bodies organising each meeting, at least thirty (30) days prior to the commencement date of each event / activity.

4. Requests for Changes to Scientific Events shall be submitted to the online database with an indication of the requested change added in the “comments” field. The date of an event may be modified no later than one (1) month prior to the commencement date of the event.

5. Reporting data: Within two (2) years from the end of each Scientific Event / Activity, the organising SA / SHO is liable to submit **essentially online**:

- a financial report of the event (revenues - expenses),
- a nominal list of the sponsors
- the amount of each sponsorship and
- the number and names of the participants, based on the registrations.

E. PARTICIPATION OF HPs IN SCIENTIFIC EVENTS / EDUCATIONAL ACTIVITIES

1. Following a recommendation by the respective Educational Committee, each SMC/SDC shall define the minimum annual attendance (in hours) of educational activities by trainee and licensed physician, and shall monitor and make recommendations on the matter to ESYE-KESY, in order for KESY to render an opinion on the matter in accordance with the applicable laws and regulations.

2. Any HPs interested in attending a scientific event in Greece or abroad and wishing to obtain financial support from sponsors for their registration, transportation or board and accommodation, shall file online applications exclusively to the SA/SHS concerned no later than two (2) months prior to the event. At the same time, after the recording process is updated, HPs are liable to submit, in the form of attachment, the number of hours / points of ongoing education they are required to complete according to the validated ongoing medical education program. The Boards of Directors of the SAs shall review the applications of HPs and the number of HPs who wish to attend the event through sponsorships and shall authorise their participation, taking into account (if the applications outnumber the sponsorships), the following criteria, in the following order of priority:

(a) presentation of a work paper

or speech; (b) participation in the chairing committee;

(c) hours of attendance required and the capacity of the physician is a licensed, trainee or specialising physician. The decisions of the SAs/ SHOs on the applications for participation shall be posted their websites and shall be notified to ESYE-KESY. Any decisions rejecting applications may be appealed before ESYE/KESY. Appeals shall be reviewed within ten (10) working days.

3. Each HP shall be personally responsible for the accuracy of all submitted information and the validity of his/her educational leave.

4. The SA/ SHS shall forward electronically to ESYE / KESY all information concerning HP participations in scientific events in Greece or abroad and shall notify such information to EOF. HP applications shall be submitted online on a monthly basis, throughout the term of each month, through completion of the relevant fields on the online database.

5. HPs can participate in scientific events or specialised seminars of high scientific profile and international participation organised abroad by the respective SMCs/ SDCs. Such events may consist in:

- International Congresses
- European Congresses
- Conferences in North America and Australia
- Events relating to rare diseases, as same are defined in Article 24 of Law 4213/13 (GG A, 261), organised by, rather than under the auspices of, scientific organisations.

6. In assessing applications for participation / attendance in educational activities, due regard shall be paid to any proposals by sponsors of Pharmaceutical Companies and Medical Equipment Companies. Applications accepted on the basis of such proposals may not exceed 50% of the total number of HPs sponsored by each sponsor, with due regard to the criteria set out in points a, b and c above. Participations / registrations in the above events shall be invoiced by the planners/ travel agents directly to the sponsors, as per the instructions of the SAs/ SHSs concerned. All contracts shall be notified to ESYE / KESY.

7. In any case, the trainee physicians / licensed physicians ratio must be at least 1 to 6.

8. Participations by HP may not exceed

- three (3) per year, for events organised abroad, and
- four (4) per year, for events organised in Greece.

Any active participation of HPs (as speakers or members of chairing committees) in scientific events of any kind shall be considered in addition to, rather than within, the above limits. Such calculation shall be carried out based on the participation of HPs in events by calendar year. Non-utilised participations may not be carried forward to the next year.

9. SAs/SHSs are liable to update *ex post* all information concerning HP participations in scientific events / educational activities in Greece or

abroad, including final costs information, within two (2) years after the end of each event.

10. Applications for participation in webinars or other educational activities shall be assessed online and shall be submitted and reviewed on a case-by-case basis. HP participations in online scientific events are not subject to any numerical limitations. Webinars are not subject to any limitations as to the number of applications or HP participations or to any time limitations and shall not be considered when establishing compliance with the numerical limits set forth herein. Training and skill practising seminars are not subject to any numerical limitations.

F. EXPERT COMMITTEES

1. HPs are allowed to participate in meetings of advisory committees with a strictly scientific agenda, taking place in Greece or abroad and being organised by pharmaceutical companies / medical equipment companies, against remuneration or otherwise, subject to prior permission by their employer.

2. To participate in such meetings in Greece or abroad, HPs are liable to file applications to KESY, as in the case of any other event, by filing electronically the relevant set of applications bearing the indication "Expert Committee".

3. Each HP shall be personally responsible for the accuracy of all submitted information and for the validity of his/her educational leave.

4. Each manufacturer/trader of EOF-regulated products may file an unlimited number of applications for participation in Expert Committees abroad.

5. In respect of domestic Expert Committees, each manufacturer/trader of EOF-regulated products may submit up to twenty (20) applications **in total** per year for medicines and therapies already approved or currently reviewed. Each delegation may comprise up to ten (10) experts.

6. The participation of any HPs licensed to write prescriptions shall be notified to the Committee for Evaluation of Medicinal Products for Human Use.

7. Payments of the relevant remuneration amounts, where applicable, shall be effected

through ELKE or ELKEA. Ex post reporting is also required in respect of the Advisory Committees.

Z. DEFINITIONS

1. SMC- Scientific Medical Community
2. SDC - Scientific Dental Community
3. SMC/SDC- GD - Scientific Medical Society/Scientific Dental Society subject to Geographic Definition
4. ISS - Interconnected Scientific Societies
5. SA - Scientific Associations
6. SHS - Scientific Healthcare Structures
6. HP - Health Professionals
7. ESYE
8. The term “EOF-regulated products” refers to medicinal products for human use and medical devices.

THE MINISTER of HEALTH

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