

Guidance for AO Educational Events supported by Educational Grants

Edition for Faculty

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General principles & introduction

The AO Foundation (AO) confirms its commitment to support surgeon education, improve efficiencies in the healthcare system, and drive better outcomes for patients globally. Industrial partners might support AO Educational Events through grants, for the provision of financial, material, and in kind support.

More than 200,000 Health Care Professionals (HCPs) are expected to participate in AO Educational Events globally over the next five years.

Compliance environment changed significantly over the last few years and is further evolving. Health Care Compliance rules and guidelines have been actively driven and established by governmental authorities and followed by industry associations (AdvaMed, Eucomed, APACMed) accordingly.

If the rules are not adhered to it might endanger the position of AO Educational Events to be CME accredited education.

The fact that on some occasions, staff members of an industrial partners are seconded to the AO, and its clinical divisions, to support AO Educational Events is not considered to be an issues in this context.

Health Care Compliance

Cooperation between industry and practitioners is guided by Health Care Compliance (HCC) rules set in national and international laws, as well as applicable professional codes of conduct and industry codes. Such laws and codes may differ from one country or region to another but HCC rules are subject to general common principles outlined below in this document.

HCC rules apply to all AO Educational Events globally where a faculty, guest speaker, and participant would be attending. Guest speakers are to be treated as faculty.

Aims of the HCC rules are:

- Advancement of medical technologies: the development of innovative medical devices and technology requires collaboration between industry and HCPs and Health Care Organizations (HCOs)
- Safe and effective use of medical technology: requires that industry offers HCPs and HCOs appropriate instruction, education, training, service and technical support
- Research and education:

industry support to medical research and education serves to enhance HCPs' clinical skills

Principles behind the HCC rules are:

- Image and perception: the industry should always consider the image and perception projected to the public when interacting with HCPs and HCOs
- Principle of separation:

any funding or payment from industry to HCPs and/or HCOs must never be conditioned on the current or anticipated future purchasing or prescribing of industry's products • Principle of transparency:

interactions between industry and HCPs/HCOs must be transparent and comply with national and local laws, regulations or professional codes of conduct

• Principle of equivalence:

any compensation paid by industry to HCPs/HCOs must be fair market value for the services provided or the nature of the work performed

• Principle of documentation:

services or arrangement between industry and HCPs/HCOs must be properly documented in a written agreement and maintained along with supporting documentation by industry

What are the HCC rules and general criteria to be considered for AO Educational Events?

The following criteria apply to all AO Educational Events supported by educational grants:

1. Program

All communication materials (eg, flyers, brochures and websites) should be consistent with the educational nature of the program content.

The event program should:

- Be medical or scientific in nature
- Include a clear schedule with reasonable breaks
- Identify the faculty and guest speaker (if any), or selection criteria should be provided
- Indicate any course dinner/banquet/reception
- Indicate general criteria of the targeted audience of the specific AO Educational Event
- NOT include social, sporting and/or leisure activity or other forms of entertainment

2. Location and venue

The location and venue should:

- Be centrally located and easily accessible for participants.
- Be in a recognized scientific, medical or business center, suitable for hosting an educational event.

But must:

- NOT be luxurious, or tourist/holiday-oriented, or an entertainment venue, such as a golf, casino, ski, or watersports resort, even if the negotiated price is attractive, bearing in mind perception and image of location and venue.
- NOT be associated with a touristic high season for the selected geographic location.

Question:

Why is Davos appropriate for an AO Educational Event when it is known as tourist/holiday-oriented location?

Answer:

Davos is the AO's headquarters with its research facilities and has served for over 50 years as the host location for this flagship educational event.

3. Guests

Question:

Who is considered to be a personal guest?

Answer:

All persons accompanying a faculty, guest speaker, participant, be it spouses, partners, family or colleagues, not participating on invitation of the Chairperson to add value to the AO Educational Event.

Participants dinners are included in the fee of the AO Educational Event. Faculty dinners are part of the preparation and therefore meant to be for all those contributing to the quality of the educational event.

This means:

- Costs of guests actively contributing to the educational event such as meals, travel, accommodation and related costs, will be handled by the event organizer and covered by the respective budget of the AO Educational Event.
- Costs of personal guests participating in events related

to the AO Educational Event are expensed to their personal hosts.

4. Reasonable hospitality

- Should not cover a period of stay before or after the official duration of the AO Educational Event.
- Include reasonable meals and accommodation.
- "Reasonable" refers to the appropriate standard for the given location and must comply with national laws and regulations as well as professional codes of conduct. Be aware that some countries additionally have their national rules which are applicable for their HCPs even outside these countries; ie, France, Belgium.

Question:

What if a personal guest shows up at an AO Educational Event faculty dinner or reception?

Answer:

The AO actively promotes interaction between faculty and participants therefore participation in the educational event and related activities are addressed to these two groups. Persons accompanying a faculty or participant are considered personal guests. According to compliance rules the AO cannot facilitate or pay for any meals, travel or accommodation of personal guests. Costs of personal guests participating in such events related to the AO Educational Event will be expensed to their personal hosts.

5. Travel

Question:

Can a HCP prolong his/her stay after the AO Educational Event?

Answer:

The HCP can do this at his/her own expense. Organization of rebooking of travel, accommodation and meals can be done by the AO support Staff.

Question:

Are there exceptions to the arrival rule and to the rule of business class flight to be of a duration of more than 5 hours including connecting flights?

Answer:

Exceptions can be granted if it is a 'night flight' and the faculty having to perform an early morning session during an AO Educational Event (red-eye flight). There might be other exceptions that have to be evaluated on a case by case basis. • Reasonable and actual travel can only be covered and paid for faculty, guest speakers and participants. Faculty, guest speakers and participants have to arrive not earlier than the day before the AO Educational Event begins (arrival rule) and leave not later than the day after the AO Educational Event finishes.

• However, where additional AO business related activities are planned for faculty or in cases where faculty, guest speakers or participants are involved in other AO Educational Events before or after the AO Educational Event, or in exceptional circumstances, extended travel arrangements may be appropriate. In all other cases, only travel that is linked to the attendance in an AO Educational Event will be covered.

5. Travel

For air travel, the following fares can be covered:

- Economy or standard class.
- Business class if overall scheduled flight time is of a duration of more than 5 hours including connecting flights (as an exception according to AO Travel and Expense Policy for non-employees).

• Faculty/guest speakers travel: travel reimbursement by AO to faculty/guest speakers is only possible upon submission of the original receipt proving the travel schedule per rule indicated above and will be limited to the maximum amount a benchmark ticket price between home town and place of the AO Educational Event. If the ticket is issued by the official AO travel agency, travel schedule changes can be requested by the faculty/guest speaker but these will be done at faculty/guest speaker's own costs.

Question:

Can travel reimbursement for faculty be combined with other events?

Answer:

No, travel reimbursement is only possible for travel with arrival date not earlier than the day before the AO Educational Event begins and departure date not later than the day after the AO Educational Event ends and upon presentation of an official receipt confirming such travel. However, where additional AO business related activities are planned for faculty or in cases where faculty, guest speakers or participants are involved in other AO Educational Events before or after the AO Educational Event, or in exceptional circumstances, extended travel arrangements may be appropriate.

6. Material support

Any material provided by industrial partners to support an AO Educational Event may only be used for training purposes and within the framework of the AO Educational Event. As soon as the AO Educational Event finishes, any remaining material should be returned to industrial partners.

7. Transparency

AO must ensure full compliance with national laws with regard to visa (such as Belgian MDEON), employer approval (such as German requirements for government employees) or disclosure requirements (such as French requirements) associated with financial support to AO Educational Event faculty/guest speaker. Local staff organizing the AO Educational Event must also ensure full compliance with these requirements.

8. Additional Requirement for International Events in EMEA

For international AO Educational Events, and this includes AO Educational Events where one or more participants are from a country other than the country where the AO Educational Event takes place, a submission to and approval from the MedTech Conference Vetting System (CVS) is also required. If industrial partner is sponsoring a HCP originating from EMEA for participation in an international AO Educational Event, such an AO Educational Event needs to also be submitted to the CVS. The respective contact person will undertake the submission for AO Educational Events.

CVS is a centralized decision-making process which reviews the compliance of third party organized educational events with the code and which is managed independently of MedTech Europe under the supervision of the Med-Tech Europe Compliance Panel (for more information, see: www.ethicalmedtech.eu). CVS evaluation outcomes are binding. AO Educational Events with a negative CVS evaluation outcome are not supported by DPS.

Supervision by the Joint Cooperation Board (JCB) and the Joint Working Group (JWG)

AO and industry have established a JCB, whose objective is to give guidance on this cooperation between industry and AO, and to improve communication between the respective groups. Any issue that cannot be solved locally or regionally between the two parties can be elevated to the JCB for resolution. However, the first point of contact is the JWG, which tries to resolve day-to-day problems brought to its attention before referring them to the JCB.

Industry HCC rules apply to all activities of AO where industry funds are directly used, in particular in education and AOTK. For the avoidance of doubts, in case funds are mixed or cannot be clearly attributed to AO funding, industry HCC rules shall apply.

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