

Professional Conference Organisers (PCO) Guidance Document

March 2018

Introduction

MedTech Europe (MTE) represents In-Vitro Diagnostics and Medical Device manufacturers operating in Europe. MedTech Europe strives to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of stakeholders. As part of this mission, the [MedTech Europe Code of Ethical Business Practice](#) (the Code) regulates all aspects of the industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), to ensure that all interactions are ethical and professional and to maintain the trust of all stakeholders, including regulators and patients alike.

In the framework of the Code, there is one stakeholder—Professional Conference Organizers (PCOs) —which plays a key role in the organisation of independent medical conferences. Although PCOs do not fall directly within the scope of the Code, they can and may indirectly influence how MedTech Europe Members set up their compliance with this same Code when supporting medical conferences.

Therefore, MedTech Europe drafted the following guidance document in an attempt to address some of the PCOs' most frequently asked questions. This guidance document is meant to assist PCOs in their interactions with MedTech Europe Member Companies, as well as to suggest best practices that MedTech Europe believes would help level the playing field and ensure compliance by its Members.

For the avoidance of doubt, please note that according to the Code, PCOs can either act on behalf of Healthcare Organisations and therefore collect Educational Grants or act independently of any HCO, in which case they are not eligible to receive Educational Grants. They may however receive funds earmarked for educational purposes, which need to comply with the same rules as Educational Grants.

This document is aimed at and intended for use by PCOs; however, the same recommendations could also be made to HCOs.

1. Conference Vetting System (CVS)

CVS decisions are rendered by the [Compliance Officer](#) and are binding on MedTech Europe and Mecomed members. Members of MedTech Europe cannot support events that have not been assessed as compliant by the Conference Vetting System.

CVS reviews compliance of Third Party Organised Educational Events with the General Criteria for Events laid down in Chapter 1. Any changes related to [criteria assessed by CVS](#) to an Event with a CVS positive decision will require the re-submission of the Event.

An appeal of a CVS decision may be filed by the Third Party Educational Event Organiser with the Compliance Panel provided that [certain requirements](#) are respected.

2. Educational Grant Recipients

a) Names of recipients: Can a PCO share the names of the Healthcare Professionals benefiting from the Educational Grant provided by a specific company?

One of the guiding principles in the Code is that companies should not receive or be able to determine the names of the ultimate HCP beneficiaries. This means that a Member Company should not proactively seek to receive the names of the Healthcare Professionals benefiting from its Educational Grant. Generally, when a Third Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which Healthcare Professionals have benefited from a particular Member Company's Educational Grant.

However, where required by law (e.g. France, Turkey), a Member Company may, in accordance with the applicable legal requirements, request and obtain, before the Event, the names of the Healthcare Professionals participating in the Event, who are benefiting from that Company's Educational Grant. For purposes of auditing, compliance and monitoring by relevant Company functions, as well as to comply with transparency obligations that require disclosure of the final recipient by the Member Company (France, Portugal, Belgium) it may be necessary for a Member Company to request and receive the names of the Healthcare Professionals who have benefited from the Educational Grant provided by the Member Company after the Event has taken place.

In either of the above cases, unless required by law, these names of Healthcare Professional should never be received by the Member Company until the Educational Grant agreement has been signed and the independent selection process of the Healthcare Professionals has been completed.

b) Criteria for determining recipients: Examples of criteria for selecting Educational Grant Recipients

Examples of criteria for selecting Educational Grant Recipients are Healthcare Professionals' speciality, years of practice, educational needs, country, city/region of practice and/or academic criteria such as number of publications, participation to clinical trials in a given pathology.

There is no *per se* prohibition in the Code on including a criterion specifying an individual hospital or hospital department. However, one of the guiding principles in the Code is that companies should not receive or be able to determine the names of the ultimate HCP beneficiaries. Therefore, PCOs should bear in mind that the smaller the hospital or department the greater the risk of companies being able to make such a determination and therefore making the use of such a criterion not possible.

3. Grant donor & transparency

The PCO is free to set up a webpage listing the grant donors. However, some societies and in certain countries, PCOs and HCOs, allow applying HCPs to indicate from which company's Educational Grant they would like to benefit.

This practice could well facilitate and may encourage companies to conclude gentlemen's agreements for specific HCP sponsorships through financial support agreements to PCOs, and the same HCPs may then be encouraged to apply for sponsorship by the company of which they are a customer. This practice should therefore be avoided as it would constitute an infringement of the Code.

4. Grant Agreements

MTE encourages PCOs and HCOs to take advantage of the MTE Educational Grant Agreement template as well as the MTE Medical Education Financial Support Agreement template as this will ensure both increased efficiency in the negotiation process, as well as compliance with the MTE Code. The MTE Educational Grant Agreement and Medical Education Financial Support Agreement templates are publicly offered by MTE to help all stakeholders, but it is in no way mandatory to use them. PCOs and companies may adjust the MTE templates to fit any specific need or national legal requirement. There are however legal requirements, including, but not limited to data protection requirements that the PCO will need to comply with.

- Multi-year “Grant” Agreements: The MTE Code does not regulate the duration of Medical Education Financial Support Agreements. Therefore, any such agreement should be agreed upon, on a case-by-case basis, between the PCO and the company.
- Selection criteria: See Point 1b) above for examples. Any criteria should be included in the agreement, following a discussion between the PCO and the company.
- Overhead costs: The MTE Code does not regulate this aspect and each company makes its own determination whether to support such costs at all and to what extent. Any overhead costs should be reasonable and Fair Market Value. Furthermore, in some countries in Europe there are limits on these amounts, therefore, local codes and laws should be consulted (e.g. FENIN established a threshold of max. 10%).
- Faculty support: If a company provides an Educational Grant for Support for Third Party Organised Educational Events, which includes Faculty support, such support covers all aspects, including honoraria, if any. Therefore, PCOs should not require or suggest an additional charge for Faculty to participate in the main portion of the Third Party Organised Educational Event.
- Service packages offered to companies: Cost estimations for registration, travel and accommodation need to be discussed with the individual companies, but limitations included in the Code still apply (e.g. no luxury hotel; no entertainment/leisure activities, business travel for air travel for flight time under is of a duration of greater than 5 hours including connection flights).
- Verification rights: Member Companies may be under the legal obligation to ensure the funds they provide to certain types of organisations are used for the intended, approved purposes. Internal procedure rules may also require that the use of the funds provided through a particular Educational Grant need to be verified. For these and other reasons the Code requests that Member Companies include verification rights in their contracts with HCOs and PCOs.

5. Grant Process

- Regardless of who initiates the grant process, it needs to be documented. A PCO may be asked by a company to file a written request.
- HCOs and PCOs concerned with potential timing issues regarding the collection of Grants for their events, may consider applying for the [Ethical Charter](#). This Ethical Charter logo demonstrates to companies a HCO/PCO's commitment and willingness to abide by the MTE Code. Moreover, the Ethical Charter logo provides HCOs/PCOs with priority assessment of their events in the [Conference Vetting System \(CVS\)](#). Ultimately, this allows PCOs to approach companies earlier in order to request and obtain funding for their events.
- Companies, **not** HCOs/PCOs, are responsible for the disclosure of Educational Grants on [Transparent MedTech](#). In France, disclosure obligations can be delegated to a PCO, but companies will ultimately remain liable for legal compliance.