MEETING INTERNATIONAL COMPLIANCE
What Your Medical Meeting Needs to Know for 2018 and Beyond

Davide Veglia, ABTS Convention Services & Christine M. Sainvil, Ethical MedTech
Meeting International Compliance-
What Your Medical Meeting Needs to Know
for 2018 and Beyond

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HCEA Connect
Healthcare Convention & Exhibitors Association

Meet • Learn • Experience

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What is MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries.

MedTech Europe was created with via joint venture between EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medical devices industry and promotes a balanced policy environment that helps the medical technology industry meet Europe’s growing healthcare needs and expectations.
Background

- Stryker to pay $13.2 mln to settle civil bribery charges
- Inquiry Into Foreign Bribes at Biomet Hangs Over $13 Billion Merger
- Medtronic Agrees to $23.5 Million Settlement in Kickback Case
- Le patron de Mithra Pharmaceutical sous le coup d’une instruction judiciaire

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The Industry self regulating actions

To regulate interactions between MedTech Europe members and healthcare professionals
  - **Code of Ethical Business Practice (2008), revised in 2015**

To have a practical implementation of the Code

To address MedTech Europe members’ divergent interpretation of the Code

To reduce risk associated to industry sponsorship of HCPs to third-party educational events
  - **The Conference Vetting System (2012)**
Respecting Ethical Standards - FIVE PRINCIPLES

1. IMAGE & PERCEPTION - No luxury hotels, luxurious dinner, resorts, etc.

2. TRANSPARENCY - Informing institutions / superior of any interaction.

3. EQUIVALENCE - Setting fees for services following strict FMV Methodology.

4. SEPARATION - Decision-making is not primarily sales-driven.

5. DOCUMENTATION - Signing the contract and documenting expenses.

- Reduce compliance/bribery risks – unilateral transfer of value
- Uphold value and promote responsible industry image – Key priority
- Harmonization of requirements worldwide
- Potential prevention of new laws – stringent self-regulation
- Transparency will not end DS challenges by media and judicial authorities
Six big changes

- **Phasing out of direct sponsorship**
- **Transparency of educational grants**
- **Common chapter on general criteria for events**
- **New chapter on demonstration products and samples**
- **Agreed definitions**
- **Common independent enforcement mechanism**
**"Direct sponsorship"**
Companies select individual HCPs and financially support their participation to Third Party Organised Events.

Such financial support typically covers some or all of the travel, lodging and registration costs of the HCP.

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**"Educational grants"**
Companies provide educational grants to hospitals, medical societies and other third parties to support genuine medical education.

These include educational grants provided to support HCP participation to Third Party Organised Event. HCPs are selected by the receiver of the grant.

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The new Code is a clear message from the medical technology industry that we want to safeguard and protect our relationship with healthcare professionals by adopting a clear and strict self-regulation.
Conference Vetting System (CVS)

- **A centralised decision-making system**: CVS is a unique system in the Medical Device industry used by all MedTech Europe members, Professional Conference Organisers and Scientific Societies.

- CVS **reviews the compliance of third-party educational events with MedTech Europe Code of Ethical Business Practice** and **Mecomed Code of Business Practice** (the “Codes”) to determine the appropriateness for companies which are members of MedTech Europe and Mecomed to provide financial support to such events in the form of educational grants or commercial activities (booths, advertising, satellite symposium). CVS renders a binding decision for MedTech Europe and members of the national associations affiliated with MedTech Europe as to whether or not they can financially support healthcare professionals to attend such events.

- The system **operates independently** to ensure objectivity in events assessments.

- **Separate website & visual identity**: [www.ethicalmedtech.eu](http://www.ethicalmedtech.eu)

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Conference Vetting System (CVS)
**Conference Vetting System (CVS)**

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What type of support for which type of event?

- Educational grants
  - To support general running of the event
  - Includes funds to support HCPs
  - Includes funds to support Faculties
- Commercial Activities
  - Speakers consultancy
  - Satellite symposia
  - Booths/advertising

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The Ethical Charter

- Voluntary certification system displaying HCOs/PCOs’ engagement to comply with MTE’s Code when organising conferences

- Online Process

  **STEP 1**
  - CEO submits expression of interest
  - CEO identifies who needs to take the test (internally)

  **STEP 2**
  - Selected candidates follow online training

  **STEP 3**
  - Trained candidates take the online test
    - Pass rate: 85%

  **STEP 4**
  - CEO signs Ethical Charter (2 years)
  - Organisation gets logo

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MedTech industry is still fully committed to support independent medical education. However it will be done at arms’ length through independent third-parties. The independent third-party will decide which HCPs receive the funding.
The Current Process

International delegations attending US medical meetings are usually sponsored by either a Pharmaceutical or a Medical Device Company. This means that groups of international attendees are invited and all their travel and meeting expenses are paid by the sponsoring company.
As of 2018, MedTech Europe will require all meetings to be vetted through its Conference Vetting System. Only vetted meetings will be eligible to receive funds from MedTech Europe member companies, — and only through educational grants.

The most important change for the US Medical Meeting Industry is that MedTech Europe member companies will not be able to directly sponsor an HCP, neither as a delegate nor as a speaker.
The Old vs. the New – Adding to the Workload!

The new educational grant system adds a significant amount of work onto the shoulders of Healthcare Organizations.
The Old vs. the New – Adding to the Workload!

1. Conferences supported by medical device companies will need to apply and be in compliance with the Conference Vetting System.

2. Healthcare Organizations will need to write and submit grant requests to each medical device company that sponsors delegations to their medical meeting.

3. Once awarded the grant, Healthcare Organizations will be responsible for choosing the HCPs that will receive support, following the guidelines as set forth on the grant requested.

4. Healthcare Organizations will be responsible for the management of the sponsored HCPs, including figuring out how to contact them, gather their information, manage their travel requirements, etc.

5. Medical Device Companies will need to submit reconciliation and disclosure reports to MedTech Europe transparency platform.

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The CME provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.
Healthcare Organizations MUST APPLY for grants from Medical Technology Companies to fund travel, hospitality, and registration for international attendees to attend the medical meeting.

Healthcare Organizations ARE NOT ALLOWED to use funds received from Medical Technology Companies to fund travel and hospitality of attendees without jeopardizing their ACCME Accreditation.

SOLUTION

A third-party non-profit may apply for grants from the Medical Technology Company and use funds to fund travel, hospitality, and registration for international attendees to attend the Healthcare Organization’s medical meeting without jeopardizing the Healthcare Organizations ACCME Accreditation.

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A seamless process that will allow effortless grant requests for the healthcare organization, as well as targeted selection of health-care professional recipients within the market of the international sponsor.

The NEW Process

3rd Party Healthcare Organization requests and is awarded grant from Medical Device Company

3rd Party Healthcare Organization assigns a grant manager to provide services

HEALTHCARE ORGANIZATION Medical Meeting
Create and submit the application to The Conference Vetting System
The 3rd-party Healthcare Organization prepares the educational grant. Grants are submitted to each Medical Technology Company individually, following their preferred grant request format. Grants will detail how they meet requirements not only to the EthicalMedTech guidelines, but also to any local law and regulations in effect based on location of Medical Technology Company and/or origination of proposed HCP beneficiaries.
The 3rd-party Healthcare Organization requests and is awarded grant from Medical Device Company.

Funds from the Medical Device Companies are transferred to the 3rd-Party Healthcare Organization to execute the contracts.

The Healthcare Organization assigns a grant manager to provide services.
Grant Manager & 3rd Party Healthcare Organization chooses international healthcare professionals that will attend the annual meeting, meeting the grant guidelines- will provide an online Grant Application process adhering to all grant guidelines, via an approved event website.

HCPs may apply to participate as a grant beneficiary and, if they meet the criteria as specified in the grant, are chosen and invited on a first-come, first-served basis.
Grant Manager oversees the secretariat process and airline arrangements through partner travel agencies.

Grant Manager engages and pays Healthcare Organization/Medical Meeting for registration, housing, and travel arrangements through current international housing process.
Grant Manager prepares and provides grant reconciliation reports to all Healthcare Organizations and a grant disclosure reports for each Medical Device Company, following requirements based on EthicalMedTech guidelines.

Grant Manager will also provide any reports needed based on required laws as per the location of Medical Device Sponsor grant office of origin of HCP beneficiary.
# MedTech Corporate Members

| 1WorldSync | 3M | Abbott | Acelity | Alcon | Alere | Ansell | Artsana | Ascensia | Astute Medical | B Braun | Baxter | BD | Beckman Coulter | Bellco | Binding Site | Biocartsis | bioMérieux | Bio-Rad | Biosystems | Biotronik | Boston Scientific | BTG |
|------------|----|--------|---------|-------|-------|--------|---------|---------|--------------|---------|---------|---|---------------|-------|-------------|-----------|-----------|---------|-----------|---------|-----------------|------|-----------------|------|
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Thank You

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