EthicalMedTech

Strategy for US Health Care Organizations

A Guide to Understanding MedTech Europe's EthicalMedTech and Its Effect on the US Medical Meetings Industry.

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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.

Common Code of Ethical Business Practices

The new MedTech Europe Code of Ethical Business Practice sets strict, clear and transparent rules for the industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs), including company-organized events, arrangements with consultants, research and financial support to medical education.

Renewed Commitment to Support Education

The new Code is a clear message from the medical technology industry to safeguard and protect the relationship with healthcare professionals by adopting clear and strict self-regulations.

The industry is still fully committed to support independent medical education at arms' length through medical education grants requested and managed by independent third-parties. The independent third-party will decide which HCPs receive the funding.

Code in Brief

Separation: Interactions between Healthcare Professionals (HCPs) and Medical Device Companies should be independent from sales transactions, use or recommendation of members' products.

Transparency: Medical Device Companies will ensure that the HCP's employer or superior is made aware of any interaction or collaboration between them and the HCP.

Documentation: Any interaction between Medical Device Companies and HCPs must appear in written agreement.

Changing the Playing Field

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.

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. As of 2018, MedTech Europe will require all meetings to be vetted through its Conference Vetting System, only these meetings will be eligible to receive funds from MedTech Europe member companies, — and only through educational grants.

Healthcare Organizations should brace themselves for an impact and will need to plan for a loss in revenue **from any international** delegation sponsored by Medical Technology Companies in Europe. From the ABTS portfolio of clients, we expect about 30 percent of delegations to be at risk for 2018 unless there is an overhaul of the current process to meet the Common Code requirements.

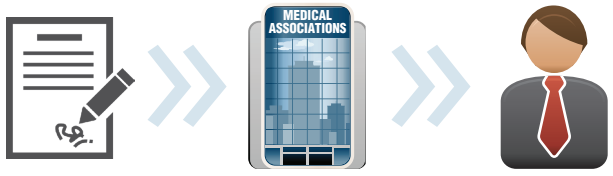
"Direct sponsorship"

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.

"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.**

The Old vs. the New – Adding to the Workload!

The largest change coming from the new educational grant system is that it adds a significant amount of work onto the shoulders of the Healthcare Organization.

1. Conferences supported by medical device companies will need to apply and be in compliance with the Ethical 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. Healthcare Organizations and Medical Device Companies will need to submit reconciliation and disclosure reports to MedTech Europe.

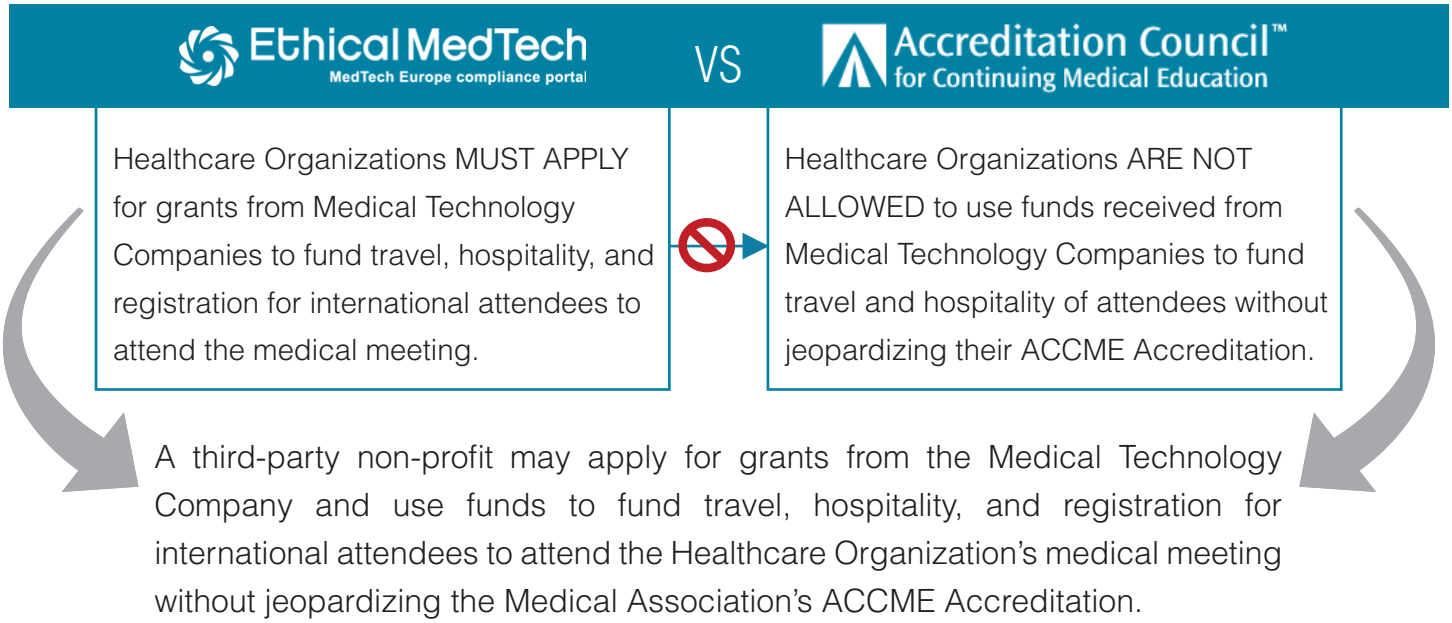
How the rules will change

1. Grants will be **publicly disclosed**, ensuring increased transparency of the funds allocated to medical education.
2. Conferences will still need to **comply with specific requirements** and with the Conference Vetting System
3. Grants can only be provided to legal entities but **never individuals** and will require a **written contract** & other related documentation
4. Companies will be able to define the **type of recipients** which should be eligible for the grant but **not individual recipients**
5. Companies must have an internal & independent process based on **objective criteria** to assess the grant requests

EVEN MORE COMPLEXITY

ACCME STANDARDS FOR COMMERCIAL SUPPORT

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.



YOUR SOLUTION

With 22 years of experience managing international delegations and unique ongoing relationships with international sponsors, ABTS is focusing efforts on creating 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.

ABTS has submitted application and is under review as "Trusted Partner" under the MedTech Europe Ethical Charter initiative (launched July 4, 2017). As part of the Ethical Charter, ABTS will extend an official commitment, signed by the president, to abide by the principles of the MedTech Europe Code and will be provided a license to use the Trusted Partner logo.

The ABTS Process

1. ABTS Convention Services creates and submits the application to The Conference Vetting System- The Vetting System reviews the compliance of medical conferences against the MedTech Europe Code of Ethical Business Practice and issues a binding decision on the appropriateness to financially support the meeting through educational grants, promotional activity (e.g. booths) or satellite symposia.

2. Please note that this process will be repeated with each Medical Device Company, as each is expected to have their own strategic targets and grant processes. ABTS and a third party Healthcare Organization prepare the educational grant. Grants will need to be submitted to each Medical Technology Company individually, following their preferred grant request format and detailing 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.

3. The third party Healthcare Organization requests and is awarded grant from Medical Device Company. Funds from the Medical Device Companies are transferred to the third party Healthcare Organization to execute the contracts.

4. The third party Healthcare Organization assigns ABTS Convention Services grant manager to provide services. Grant funds are transferred to ABTS for management.

5. ABTS Convention Services and/or the Medical Association choose international healthcare professionals that will attend the annual meeting, meeting the grant guidelines. ABTS Convention Services 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.

6. ABTS Convention Services manages the secretariat process and airline arrangements through partner travel agencies.

7. ABTS Convention Services engages and pays Medical Association for registration, housing, and travel arrangements through current international housing process.

8. ABTS Convention Services prepares and provides grant reconciliation reports to third party Healthcare Organization and Medical Association and a grant disclosure report for each Medical Device Company, following requirements based on EthicalMedTech guidelines. ABTS 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.

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Information obtained from www.medtecheurope.org