New standards from MedTech Europe for industry-supported medical education

9th Annual European CME Forum Amsterdam
11th November 2016

www.medtecheurope.org
New MedTech Europe Code of Ethical Business Practice

1. WHY IS ETHICS IMPORTANT?

2. THE KEY CHANGES

3. FUTURE SUPPORT TO MEDICAL EDUCATION
Part 1

WHY IS ETHICS IMPORTANT?
The MedTech industry and HCPs **collaborate closely** throughout several stages of the development and use of medical technologies.

**HCPs actively participate in the research to develop new technologies**

This close collaboration is key to develop innovative technologies to treat patients.

**HCPs are trained on how to use technologies**

The industry liaises regularly with HCPs to ensure that the technologies are updated and maintained.

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Industry’s behaviour must respect high ethical standards & values

- Reduce compliance risk
- Safeguard integrity and industry reputation
- Uphold value and promote responsible industry image
Five principles

- **Image & Perception**: No luxury hotels, luxurious dinners etc.
- **Transparency**: Informing institution/superior of any interaction
- **Equivalence**: Setting the fee for service on strict FMV methodology
- **Separation**: Decision-making is not primarily sales-driven
- **Documentation**: Signing the contract & documenting expenses
Part 2

KEY CHANGES
Key changes - Main focus for today

1. Phase-out of direct sponsorship
2. Educational grants: Stronger rules & Transparency
3. Common chapter on general criteria for all events (whoever organises the event)
4. New chapter on demonstration products and samples
5. Clear definitions at the end of the Code (Glossary and Definitions)
6. Independent enforcement mechanisms (= dispute resolution)
1. Phasing out of direct sponsorship

2018

“Direct sponsorship”

“Educational grants”

Stronger rules
2. Sponsorship Changes / Educational Grants

1. Grants will be **publicly disclosed**

2. Conferences will still need to **comply with specific requirements**

3. Grants can only be provided to legal entities **never individuals** and will require a **written contract**

4. Companies can define the **recipients type not individual recipients**

5. Companies use internal & indep. process with **objective criteria**
2. Transparency platform

www.ethicalmedtech.com

Welcome to Europe’s MedTech Conference Vetting System

About Us

EthicalMedTech is a platform, supported by Eucomed, dedicated to ethics and compliance projects in the European MedTech industry.

The Ethical MedTech platform hosts the Conference Vetting System (CVS), a unique initiative in the healthcare industry. This independently managed system reviews the compliance of third-party educational conferences with the Eucomed Code of Ethical Business Practice (the “Code”) to determine the appropriateness for companies which are members of Eucomed or members of the national associations affiliated with Eucomed to sponsor Healthcare Professionals to participate in such conferences.

CVS aims to simplify and centralize decision-making for Eucomed members by establishing a single assessment procedure based on a set of criteria provisioned in the Eucomed Code of Ethical Business Practice. It also aims to harmonize the interpretation of the Code across the European medical technology industry with the goal of greater consistency and transparency in industry behavior.
3. Common Chapter on general criteria for all events

- Programme
- Geographic Location and Venue
- Guests
- Reasonable Hospitality
- Travel
- Transparency
Part 3

HOW MAY THE NEW RULES AFFECT MEDICAL EDUCATION?
Challenge: Raising awareness of all parties

MedTech Europe

- HCOs
- Companies & N.A.
- PCOs

Individual HCP

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ELEMENTS TO KEEP IN MIND ABOUT THE GRANTS

- Can only be given to an HCO – not an individual HCP
  
  - Only restricted grants in the future
  
  - Compliance with CVS (Conference Vetting System)
    
    - Records of everything should be kept
    
    - Need to be made public by companies
    
    - Should not be primarily sales-driven
For more information

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Closing remarks

THANK YOU!