MedTech Europe’s Code –
Back to basics: "Understanding Fundamental Principles"

15 September 2023, 10.30am CET
Agenda

1. Compliance basics
2. Legal framework
4. Roles & responsibilities
5. Additional resources & references
6. Q&A session
A blast from the past...
## Benefits of Refresher Training

<table>
<thead>
<tr>
<th>Benefits</th>
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<tbody>
<tr>
<td>Creating level playing field in knowledge across the medtech sector</td>
</tr>
<tr>
<td>Fostering a culture of continuous learning</td>
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<tr>
<td>Promoting excellence</td>
</tr>
<tr>
<td>Helping to identify training needs and skills gaps</td>
</tr>
<tr>
<td>Reduced mistakes</td>
</tr>
<tr>
<td>Achieving compliance – doing the right thing</td>
</tr>
</tbody>
</table>
Compliance basics
Industry’s reputation at risk

Industry’s relationship with HCPs

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.**
- **The industry liaises regularly with HCPs to ensure that the technologies are updated and maintained.**
- **HCPs need to be trained on how to use technologies.**
- **This close collaboration is key to develop innovative technologies to treat patients.**
Legal framework
Key legislation: anti-corruption & anti-bribery

- OECD Anti-Bribery Convention [1997]
- Inter-American Convention Against Corruption [1997]
- Council of Europe Criminal Convention on Corruption [2002]
- UN Convention Against Corruption [2003]
- G20 Anti-Corruption Action plan [2010]
- Bribery Act [UK 2010]
- Amendment No.8 to Article 164 [China 2011]
- Federal Law No. 97-FZ [Russia 2011]
MedTech Europe Code of Ethical Business Practice
Scope & principles
Scope of the MTE Code

Interactions
with HCOs & HCPs*

In relation with medical technologies
(products and services within the scope of the Medical Devices Regulation and In Vitro Diagnostics Regulation)

Activities

registered or based in the ...

taking place within the ...

MedTech Europe Geographic Area*

MedTech Europe from diagnosis to cure
Definitions: **HCPs & HCOs**
Definitions: **MedTech Europe Geographic Area**

- Countries in the **European Economic Area**; and
- Countries *where member associations are located*, i.e. ARTED (Turkey), FASMED (Switzerland), Mecomed® (Africa and Middle East)
Definitions: *MedTech Europe Geographic Area*
The Code’s core principles

Image & Perception
No luxury hotels, luxurious dinners, etc.

Transparency
Disclose any interaction

Equivalence
Fair Market Value of any fee for service

Separation
Decision-making is not primarily sales-driven

Documentation
Contract & documentation expenses
Key elements
General Criteria for Events

⇒ All apply to both Third Party Organised and Company Organised Events
Promoting an ethical industry

- Banning direct sponsorship (2015)
- Transparency of Educational Grants (2015)

**“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” (Indirect sponsorship)**

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.
# Type of Support allowed under the Code (ref. Annex VI)

<table>
<thead>
<tr>
<th>Event</th>
<th>Setting</th>
<th>Faculty / Speaker</th>
<th>Delegates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Third Party Organised Educational Conference</strong></td>
<td>Main Event / Independent Scientific Program</td>
<td>Not allowed</td>
<td>Not allowed</td>
</tr>
<tr>
<td></td>
<td>Satellite Symposium</td>
<td>Allowed (consulting agreement required)</td>
<td>Not allowed</td>
</tr>
<tr>
<td></td>
<td>Booth</td>
<td>Allowed (consulting agreement required)</td>
<td>Not allowed</td>
</tr>
<tr>
<td><strong>Third Party Organised Procedure Training meeting</strong></td>
<td>NOT taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Allowed</td>
<td>Allowed</td>
</tr>
<tr>
<td><em>The criteria for a Third Party Organised Procedure Training meeting can be found in Q&amp;A 18</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Company Events</strong></td>
<td>Product and Procedure Training and Education Event</td>
<td>Allowed</td>
<td>Allowed</td>
</tr>
<tr>
<td></td>
<td>Taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Allowed</td>
<td>Not allowed</td>
</tr>
<tr>
<td></td>
<td>Sales, Promotional and Other Business Meeting</td>
<td>NOT taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Allowed (consulting agreement required)</td>
</tr>
</tbody>
</table>
## Requirements for [Event] support

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Third Party Organised Educational Conference</th>
<th>Third Party Organised Procedure Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance with general criteria for Events (Chapter 1)</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>CVS * approval</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Direct Sponsorship of HCPs allowed</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>

* CVS is required for the following types of funding: Educational Grants, Promotional Activity (e.g., booths) and Satellite Symposia
### Requirements for Company Events [con’t]

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Product and Procedure Training and Education Events</th>
<th>Sales, Promotional and Other Business Meetings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance with general criteria for Events (Chapter 1)</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>CVS approval</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Direct sponsorship of HCPs allowed</td>
<td>YES</td>
<td>NO (unless demonstrations of non-portable equipment are necessary)</td>
</tr>
</tbody>
</table>


## Requirements for Company Events

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<tr>
<td><strong>Company Events</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Product and Procedure Training and Education Event</td>
<td>NOT taking place at or about the same time as a Third Party Organised Educational Event</td>
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<td>Allowed</td>
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<tr>
<td></td>
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<td>Not allowed</td>
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<td></td>
<td>Taking place at or about the same time as a Third Party Organised Educational Event</td>
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</tr>
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</table>
## General requirements for Grants and Donations

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Charitable Donations</th>
<th>Educational Grants</th>
<th>Research Grants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be provided to individual HCPs</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Can be provided to HCOs</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>(unless it is a charitable organisation/other non-profit entity; or for non-profit hospitals in case of demonstrated Financial Hardship under certain conditions)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent decision-making/review process implemented by the company?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Provided on “restricted basis” (i.e. control over the final use of funds)</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>(except to ensure that the funds are applied for charitable/philanthropic purposes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written agreement and other documentation</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Financial support publicly disclosed</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>
Types of Educational Grants

- Support for Third Party Organised Educational Events
  - Support for HCPs participation
  - Event support
- Scholarship and fellowships
- Grants for public awareness campaigns
- Educational Grants for general medical educational topics

Can only be provided to HCOs

List not exhaustive
Application for Educational Grant.

Can sometimes be initiated by the company.

Independent decision making/review process

Decision

Agreement Executed

Funds Granted

Signerable Of contract

Disclosure

Verification that the funds were used as intended

Confirmation of The execution of The agreement

BEFORE THE EVENT

AFTER THE EVENT
<table>
<thead>
<tr>
<th><strong>BEFORE THE EVENT</strong></th>
<th><strong>AFTER THE EVENT</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>STEP 1</strong></td>
<td><strong>STEP 6</strong></td>
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</tbody>
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**HCO**

Application for Educational Grant.
Requirements:
- The request must be made in the name of the institution
- The request must be made in writing, containing all information needed for the company to make an assessment, including the category of HCPs who will benefit from it

**STEP 2**

**STEP 3**

**STEP 4**

Signature of contract (incl. all necessary documentation)
Agreement executed - compliant allocation of funds according to intended purposes

**STEP 5**

Confirmation of the execution of the agreement (e.g. appropriate documentation of budget allocation)

**COMPANY**

The process may in certain cases be initiated by a company if the proposal is duly documented and contains sufficient information

**STEP 6**

Independent decision making/review process (e.g. by a "Grant Committee"):  
- Check if recipient is qualified/genuine  
- Review request in detail  
- Documented review of any potential bribery or corruption risk (i.e. red flags)  
- Ensure compliance with local requirements

Decision to fund the Educational Grant, if positive, the granting of the funds would be subject to:
- Written contract between Company & HCO
- Clause 1: Compliance with code requirements for events
- Clause 2: Transparency obligations of the company (and when required, consent)
- Clause 3: Rights for the company to verify that the Grant was used for the intended purpose

Funds Granted

**STEP 7**

Publication of the Educational Grant on the MedTech Europe Transparency platform, or where locally required & Verification that the Grant was used for the intended purpose (optional)
Specific requirements for Educational Grants

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Support for Third Party Organised Educational Events</th>
<th>Scholarships &amp; fellowships</th>
<th>Grants for public awareness campaigns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial support publicly disclosed</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
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<td>NO</td>
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<td>YES</td>
<td>YES</td>
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<td>Compliance with general criteria for Events (Chapter 1)</td>
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<td>N/A</td>
<td>N/A</td>
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<td>CVS approval</td>
<td>YES</td>
<td>N/A</td>
<td>N/A</td>
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Roles & responsibilities
MedTech Europe roles & responsibilities

- General Assembly of Members
- Board of Directors
- Compliance Panel
- National Association Council
- Regulatory
- Other committees...
- Env. & Sustainability
- Legal & Compliance
- Code Committee
Roles & responsibilities within MTE membership

- Maintaining policies & SOPs is labor-intensive
- Compliance training is a never-ending task
- Enforcement, audits & managing complaints are “tricky business”
Additional resources & references
For more information

- MedTech Europe website
- Members’ SharePoint
- Ethical MedTech website
Q&A session
Conclusions
For more information [con’t]

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Thank you!