Structure of the presentation

01 Ethics & Compliance
   Why is it important?

02 MedTech Europe Code
   What are the main changes in 2015 & 2022?

03 MedTech Europe Code
   What does it cover?
Why is ethics important?
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.
- This close collaboration is key to develop innovative technologies to treat patients.
- HCPs need to be trained on how to use technologies.
- The industry liaises regularly with HCPs to ensure that the technologies are updated and maintained.
Industry support to medical education is extensive

Third-party driven, enabled by industry

- Medical & professional education
- Procedure trainings
- Disease education
- Surgical techniques
- Therapy focused education

Industry driven & responsibility / obligation

- Product trainings
- Promotional
- Booth, satellite events
- Sales meetings
- Procedure linked to product training

Other

E-learning

Shared
Phase out of DS: A global discussion

Disclaimer: MedTech Europe makes no representation of the accuracy of this map. It reflects the information we currently have regarding the global situation of Direct Sponsorship around the globe.

Last revised April 2022

Legend:
- Green: No Data or DS allowed
- Yellow: MedTech Europe Code Applicable
- Light Yellow: National Code banning DS in place or agreed (entry into effect of prohibition may be later)
- Red: DS prohibited by law or stakeholder agreement
Industry’s reputation at risk

Jeremy Hunt: NHS bosses face jail over links to drug firms

Pursuit of Cash Taints Promise of Gene Tests

Inquiry Into Foreign Bribes at Biomet Hangs Over $13 Billion Merger

German government poised to tackle healthcare corruption

SEC Charges California-Based Bio-Rad Laboratories With FCPA Violations

HSE suspends all payments to Eurosurgical from all hospitals

Whistleblower jailed over bribes to Greek officials
Role of regulators & enforcement agencies

"Surgeons . . . were often lavished with trips and other expensive perquisites. . . Prior to our investigation, many orthopedic surgeons . . . made decisions predicated on how much money they could make — choosing which device to implant by going to the highest bidder. With these agreements in place, we expect doctors to make decisions based on what is in the best interests of their patients — not their bank accounts."

-SEC 2007 Press Release

"[Polish Company] also paid for public doctors and hospital administrators to travel to medical conventions in Poland and abroad in order to influence tender committee decisions in their favor. Sponsored doctors were taken on trips in exchange for influencing the doctors’ decisions to purchase [Parent Company’s] medical products or to award hospital tenders to [Parent Company]. Some of the trips were to the United States for conferences. Some of the trips were to tourist areas in Europe, and some included spouses and family members to what amounted to vacations."

-Government Complaint, U.S. Securities and Exchange Commission v. [Company]

"[Company] also sponsored physician vacations disguised as physician education. For example, [Company] sponsored an annual event called the Masters MIS forum. In 2009, the forum was held at the prestigious Colony Hotel in Kennebunkport, Maine on July 7-11."

-Complaint, United States of America v. [Company]

"It was a further part of the conspiracy that [Company] paid doctors’ expenses for travel, leisure, and recreation during programs requiring doctor travel, including week-long trips to Japan, to reward past purchases and induce future purchases of [Company] products. For example:

b. Every year from 2006 through 2009, [Company] treated the physician president of a prominent professional organization and (except for 2009) his or her spouse to a week-long trip to Japan and paid the physician a $10,000 honorarium to give one lecture during the trip.

[Company] paid for doctors’ lavish meals, ballooning, winery tours, golf, and spa treatment at [a]

c. [Company]-sponsored forum because it was ‘a great way to network, talk business, socialize without our competitors.’"

-Deferred Prosecution Agreement between U.S. Attorneys Office and [Company]
Example of key legislation

- 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 154 [China 2011]
- Federal Law No. 97-FZ [Russia 2011]
Importance of doing the right thing

- Reduce compliance/bribery risks – unilateral transfers of value (e.g. direct sponsorship)
- Uphold value and promote responsible industry image – Key priority
- Harmonisation of requirements worldwide
- Potential prevention of new laws – stringent self-regulation
- Transparency would not by itself end DS challenges by media and judicial authorities
What are the main changes in 2015 and in 2022?
Reminder: Six biggest changes in 2015

1. Phasing out of direct sponsorship
2. Transparency of Educational Grants
3. Common Chapter on general criteria for events
4. New Chapter on Third Party Intermediary
5. Agreed definitions
6. Common independent enforcement mechanism
Implications of the ban of direct sponsorship

“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.
Reminder: What are the rules for Educational Grants?

1. Grants are **publicly disclosed**, ensuring increased transparency of the funds allocated to medical education.

2. Conferences 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 require a **written contract** & other related documentation.

4. Companies can 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.

<table>
<thead>
<tr>
<th>Educational Grants to support Third Party Organised Events</th>
<th>Other Educational Grants to HCOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Support for these Events</td>
<td>• Scholarships &amp; Fellowships</td>
</tr>
<tr>
<td>• Support for HCP Participation</td>
<td>• Grants for Public Awareness Campaigns</td>
</tr>
<tr>
<td>• Yearly reporting of the previous year’s data (uploading of the data from January to the end of June, publication end of August)</td>
<td></td>
</tr>
</tbody>
</table>

**MedTech Europe platform**

([https://www.ethicalmedtech.eu/transparent-medtech/](https://www.ethicalmedtech.eu/transparent-medtech/))

* No double reporting where exceptions were granted to countries which have pre-existing & equivalent platforms (e.g., Belgium, France and Portugal)
Overview of the 2022 changes

- General clean-up, re-organization, look & feel
- No more reference to “gifts” – only “Promotional Items”
- New chapter on Distributors
- Clarification between Education Grants & commercial sponsorships
- New guidance in Annex for in-kind Grants
- New definitions in Glossary
- Virtual Events
- Addition of “collaborative research”
- Consulting Arrangements applicable to HCOs & HCPs
- End of the “Novo Nordisk exception”
New design & layout
Definitions are aligned and in the Glossary of the new Code

MedTech Europe Code of Ethical Business Practice Part 3:
Glossary and Definitions

- **Charitable Donations**: means provision of cash, equipment, Member Company product or relevant third party product, for exclusive use for charitable or philanthropic purposes and/or to benefit a charitable or philanthropic cause. Charitable Donations may only be made to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

- **Clinical Research**: a type of research that studies tests and treatments and evaluates their effects on human health outcomes. This includes clinical investigations or interventional and non-interventional clinical performance studies where people volunteer to take part in order to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.

- **Company Events**: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of Member Companies to fulfil a legitimate, documented business need of the Member Company, including but not limited to a legitimate business need to interact with customers including Healthcare Professionals and/or Healthcare Organisations.

- **Conference Vetting System (CVS)**: means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under the supervision of the MedTech Europe Compliance Panel. For more information see: https://www.ethicalmedtech.eu.
New chapter on distributors

⇒ N.B.: No substantial changes, which came from the Eucomed/AdvaMed Third Party SMIs guidance
# For more information on the 2022 Code

<table>
<thead>
<tr>
<th>Material</th>
<th>Audience</th>
<th>Channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crosswalk</td>
<td>Internal (ECC + NAC)</td>
<td>Sharepoint &amp; ethicalmedtech</td>
</tr>
<tr>
<td>One pager</td>
<td>Internal &amp; external (e.g., HCO &amp; PCOs; GMTA members; pharma)</td>
<td>MTE website</td>
</tr>
<tr>
<td>PowerPoint</td>
<td>Internal (ECC + NAC)</td>
<td>Sharepoint</td>
</tr>
<tr>
<td>Full training material</td>
<td>Internal (ECC + NAC)</td>
<td>Sharepoint</td>
</tr>
<tr>
<td>Recorded training session (Q2)</td>
<td>Internal (ECC + NAC)</td>
<td>Sharepoint</td>
</tr>
<tr>
<td>Press release (28 March)</td>
<td>General public</td>
<td>MTE website</td>
</tr>
<tr>
<td>Clean Code version</td>
<td>ALL</td>
<td>MTE website</td>
</tr>
<tr>
<td>Podcast (Q2 or Q3?)</td>
<td>ALL</td>
<td>MTE website</td>
</tr>
<tr>
<td>Q&amp;A document?</td>
<td>Internal &amp; external</td>
<td>Sharepoint &amp; ethicalmedtech</td>
</tr>
</tbody>
</table>
Code of Ethics: Content
Code: table of content

• Scope
• Administering the Code
• Introduction
• Chapter 1: General Criteria for Event
• Chapter 2: Third Party Organised Educational Events
• Chapter 3: Company Events
• Chapter 4: Grants and Charitable Donations
• Chapter 5: Consulting Arrangements
• Chapter 6: Research
• Chapter 7: Royalties
• Chapter 8: Educational items and Promotional Items
• Chapter 9: Demonstration Products and Samples
• Chapter 10: Third Party Intermediaries
• Part 2: Complaint handling and dispute resolution
• Part 3: Glossary and Definitions
Who is covered?

Physicians

Procurement professionals

Nurses

Researchers

Healthcare Professional (HCP)

Technicians

Laboratory Scientists

Hospital

Medical society

Group purchasing organisation

Pharmacy

Healthcare Organisation (HCO)

University

Laboratory

Who is covered?
Scope of the MTE Code

MedTech Europe Geographic Area

1. Countries in the European Economic Area; and
2. Countries where member associations are located (e.g., Turkey, Mecomed countries)

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

The MedTech Europe Geographic Area currently includes

Countries with National Associations:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom

Countries party to the European Economic Area agreement without a MedTech Europe National Association:

- Iceland
- Liechtenstein
- Luxembourg
- Malta

Countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.
The Code’s core principles

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

Equivalence
FMV of any fee for service

Transparency
Inform about any interaction

Separation
Decision-making is not primarily sales-driven

Documentation
Contract & documentation expenses
Chapter 1: General Criteria for Event
Chapter 1: General Criteria for Events

⇒ All apply to both Third Party Organised and Company Organised Events
The Event program

- Directly related to the specialty and/or medical practice of the HCPs who will attend the Event, or
- Sufficiently relevant to justify the attendance of the HCPs
- For Third Party Organised Educational Events the agenda should be under the sole control and responsibility of the third-party organiser

Not appropriate

- Organising Events which include Entertainment
- Supporting Entertainment elements where part of the Third Party Organised Educational Events
What is “Entertainment”?

- Entertainment:
  - Incidental, background music
  - Reasonable hospitality

- Does not include entertainment:
  - Examples: dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) etc.
Entertainment at TPOE should:

1. Be outside the educational programme schedule and paid for separately by the Healthcare Professionals.

2. Not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session.

3. Not be the main attraction of the Third Party Organised Educational Event.
Appropriate Event location & venue

- **Perceived image**: Must not be perceived as luxury, or tourist/holiday-oriented, or that of an Entertainment venue
- **Centrality**: Centrally located when regard is given to the place of residence of the majority of invited participants
- **Ease of access**: In close proximity to an airport and/or train station/ground transportation infrastructure
- **Selected time of year**: Selected time of the year outside a touristic season for the selected geographic location
  - Ski season: December 20 – March 31
  - Summer season: June 15 – September 15
- **Recognised scientific or business centre**: Near a city or town which is a recognized scientific or business centre, suitable for hosting an Event
The Conference Vetting System (CVS) reviews the compliance of Third-Party Organised Educational Events with the MedTech Europe Code of Ethical Business Practice.

It issues a binding decision on the appropriateness for Member Companies to financially support these events through Educational Grants, promotional activity (e.g., booths) or satellite symposia.
### When is a CVS decision required?

| Educational Grants/Provided to Support a Third Party Organised Conference | National (Third Party Organised Educational Events attended by delegates which are local HCPs only)
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Education Grants to support the general running of a conference</td>
<td>Allowed*</td>
</tr>
<tr>
<td>Education Grants that includes funds to support HCP attendance to the conference</td>
<td>Allowed</td>
</tr>
<tr>
<td>Education Grants that includes funds to support Faculty</td>
<td>Allowed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commercial Activities</th>
<th>National (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area)*&lt;sup&gt;9&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultancy agreement for speakers’ satellite symposia</td>
<td>Allowed</td>
</tr>
<tr>
<td>Booth/Advertising</td>
<td>Allowed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direct Sponsorship of HCPs (non-HCP delegates or non-local HCPs)</th>
<th>National (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area)*&lt;sup&gt;9&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct sponsorship of HCPs as delegates (passive participation)</td>
<td>Not allowed</td>
</tr>
<tr>
<td>Direct sponsorship of HCPs as Faculty (active participation)</td>
<td>Not allowed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior CVS Submission</th>
<th>In MedTech Europe Geographic Area</th>
<th>Outside MedTech Europe Geographic Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education Grants to support the general running of a conference</td>
<td>Subject to CVS decision</td>
<td>Allowed. Not subject to CVS decision</td>
</tr>
<tr>
<td>Education Grants that includes funds to support HCP attendance to the conference</td>
<td>Subject to CVS decision</td>
<td>Subject to CVS decision</td>
</tr>
<tr>
<td>Education Grants that includes funds to support Faculty</td>
<td>Subject to CVS decision</td>
<td>Allowed. Not subject to CVS decision</td>
</tr>
<tr>
<td>Consultancy agreement for speakers’ satellite symposia</td>
<td>Subject to CVS decision</td>
<td>Allowed. Not subject to CVS decision</td>
</tr>
<tr>
<td>Booth/Advertising</td>
<td>Subject to CVS decision</td>
<td>Allowed. Not subject to CVS decision</td>
</tr>
</tbody>
</table>

* Denotes the Code applies.
*<sup>9</sup> Denotes the Code applies in certain circumstances.
CVS: Assessment criteria

- Geographic location
- Conference venue
- Registration packages
- Program
- Website, Invitations, Brochures
- Hospitality
No guests

- Member Companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for Guests of HCPs

**Guests of HCPs**

Any person who does not have a *bona fide* professional interest in the information being shared at an Event

- Spouses
- Partners
- Family
- Any other accompanying people
Quiz question – HCPs’ guests

Q. A physician asks whether he can bring his wife to a company event organised to train cardiac surgeons. He sends proof that his wife is running a private dermatology practice and has been a practicing HCP for 25 years. Can the company allow him to bring his wife along and participate in the training as well as cover her costs for accommodation and travel?

a. Yes, the company can allow him to bring his wife as he has provided the necessary documentation that she is an HCP as well.

b. Yes, the company can allow him to bring his wife to participate in the trainings, if she only participates passively and the costs of her meals is paid by the HCP.

c. No, under the MedTech Europe Code it is not permissible to bring a spouse who does not have bona fide professional interests in the information being shared at the event.
Q: An HCP has asked you whether your company is going to provide Educational Grants to a medical congress she would like to attend. The medical congress in question is taking place in Majorca, Spain, in late June. What criteria shall apply?

A: The general criteria for events laid down in Chapter 1 of the Code apply to all Events, regardless of whether they are organised by a Member Company or by a Third Party.

Any support for a Third Party Organised Educational Conference (through Educational Grants, satellite symposia or promotional activity) requires prior approval via the Conference Vetting System.

Please check www.ethicalmedtech.eu to see if a particular congress has already been assessed.
Q: Your company would like to organise a product training meeting and one of the options is Estoril, Portugal, in January. Should the training be hosted there?

A: YES, provided the Event complies with the general criteria for events laid down in Chapter 1 of the Code apply to all Events. These criteria apply regardless of whether they are organised by a Member Company or by a Third Party.

The chosen geographic location should be in or near a city or town which is a scientific or business centre conducive to exchange of ideas and the transmission of knowledge.

For European and international events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question, but the Code does not automatically exclude any location based on it being known as a touristic destination.
Hospitability: What is required?

- Meals + accommodations = hospitality

• Any hospitality offered must be:
  - Subordinate in time
  - Focus to the Event purpose
  - Reasonable

- Reasonable hospitability
  - Appropriate standard for the given location
  - Complying with the national laws, regulations and professional codes of conduct

- Not considered as reasonable
  - Lodging at top category or luxury hotels
Travel costs: Requirements

- Any reimbursement/paid travel should:
  - Be reasonable
  - Be actual
  - Not cover a period of stay beyond the official duration of the Event

What is appropriate when it comes to reimbursement of air travel costs?

- Business class for flights shorter than 5 hours: **Not appropriate**
  - Flight class

- Economy or standard class: **Appropriate**
  - Business class for flights longer than 5 hours
Chapter 2: Third Party Organised Educational Events
What are Third Party Organised Educational Conferences (TPOE)?

- **Definition**: A genuine, independent, educational, scientific, or policy-making conference organized to promote scientific knowledge, medical advancement and/or delivery of effective healthcare

**Examples:**
- Conferences organized by national, regional, or specialty medical associations/societies
- Hospitals
- Professional Conference Organisers (PCOs)
- Patient organisations or accredited continuing medical education providers
Third Party Organised Procedure Training

Definition: A type of Third Party Organised Educational Event that is primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:

- Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
- Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment

For the avoidance of doubt, proctorship and preceptorship are not considered to constitute Third Party Organised Procedure Training
Third Party Organised Procedure Trainings (con’t)

Qualifying criteria:

• Stand alone training: Third Party Organised Procedure Trainings must stand alone

• Venue: The hands-on sessions of TPPT should be organised in either a clinical environment or in places suitable for or set up to simulate medical environment

• Size: The set up of the hands-on sessions should be the same as in operation conditions
## Type support allowed under the Code (ref. Annex VI)

<table>
<thead>
<tr>
<th>Event</th>
<th>Setting</th>
<th>Direct Support for HCP attendance</th>
<th>Faculty /Speaker</th>
<th>Delegates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Third Party Organised Educational Conference</td>
<td>Main Event / Independent Scientific Program</td>
<td>Not allowed</td>
<td>Not allowed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Satellite Symposium</td>
<td>Allowed</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>Allowed</td>
<td>Not allowed</td>
</tr>
<tr>
<td>Third Party Organised Procedure Training meeting*</td>
<td>*The criteria for a Third Party Organised Procedure Training meeting can be found in Q&amp;A 18</td>
<td>Allowed</td>
<td>Allowed</td>
<td></td>
</tr>
<tr>
<td>Company Events</td>
<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>
<td>Allowed</td>
<td>Allowed</td>
</tr>
<tr>
<td></td>
<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>
<td>Not allowed (except for demonstration of non-portable equipment)</td>
</tr>
<tr>
<td></td>
<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>
</tbody>
</table>
Type support allowed under the Code (ref. Annex IV)

Description:
Delegate: "Delegate" is any Healthcare Professional who is attending passively a Company Event or a TPOE and cannot be considered as "Faculty". For avoidance of doubt, poster- and abstract-presenters are considered to be Delegates.

Satellite Symposium: Common elements of Satellite Symposia are:
- It takes place at a Third Party Organised Event (TPOE) and it is part of the TPOE official programme (i.e. not focused on marketing of specific products);
- The Company is responsible for the content subject to review by the Organiser where required;
- It’s open to any Delegate, not only to selected individuals;
- It has Company branding and the Company can promote the Satellite Symposia to customers.

Speaker/Faculty: “Faculty/speaker” in this chart is someone who is considered a speaker at an Event, for example someone who gives a presentation whether at a Company Event or a TPOE; someone who moderates/chairs a session and therefore needs to prepare ahead of the presentation/moderation.

Guidance:
In order to determine whether an event is a TPOE or a Company Event, the following aspects should be taken into account:
- Open events (not only Company’s customers) are typical of a TPOE, and in this case, it is a third party chooses which HCPs attend or HCPs self-select;
- Who is the primary initiator of the Event: To what extent is the third party vs. the Member Company involved and who is determining the agenda?
- CME accreditation is an indication of a TPOE;
- TPOE generally have a broader focus than one or only a few products;
- Single-sponsored events are often Company Events.
## 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>Is 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
Case Study: Speaker agreements

Q. Your company would like to place systems at KOL laboratories so that they can work on the systems, publish results and speak of those results and the performance of the system at conferences. The work done/study undertaken is fully funded by your company. Is this arrangement still acceptable after 1\textsuperscript{st} January 2018?

A: YES. This arrangement would still be acceptable if it happens in the context of a satellite symposium of a conference. Member Companies can still invite HCPs to speak in these satellite symposia provided the speaker services are part of a consulting agreement.

If the HCP would be a speaker in the main event of the conference his or her support should be done through an Educational Grant to the organiser of the conference.

Please, note that participants in the satellite symposia cannot be sponsored.
Q. Your company has allocated a specific budget to support HCPs to attend Third Party Organised Educational Conferences and support medical education. You used to select individual HCPs to support their medical education, could you till do it?

A: NO. Member Companies shall not provide support directly to individual HCPs to cover costs of their attendance at Third Party Organised Educational Events. Consequently, companies can’t select individual HCPs.

You may support individual HCPs to attend Third Party Organised Educational conferences through Educational Grants provided to an HCO.
Chapter 3: Company Events
Primarily intended to provide HCPs with genuine education, including information and/or training on:

- Safe and effective use of medical technologies, therapies and/or related services, and/or
- Safe and effective performance of clinical procedures, and/or
- Related disease areas

In all cases the information and/or training directly concern a member company’s medical technologies, therapies and/or related services
Has the objective to affect the sale and/ or promotion of a Member Company’s medical technologies and/or related services, including meetings to discuss product features, benefits and conduct contract negotiations, or discuss sales terms.
## Requirements for Company Events?

<table>
<thead>
<tr>
<th>Event</th>
<th>Setting</th>
<th>Direct Support for HCP attendance</th>
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<tbody>
<tr>
<td><strong>Company Events</strong></td>
<td><strong>Product and Procedure Training and Education Event</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOT taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Faculty /Speaker: Allowed, Delegates: Allowed</td>
</tr>
<tr>
<td></td>
<td>Taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Faculty /Speaker: Allowed, Delegates: Not allowed</td>
</tr>
<tr>
<td><strong>Sales, Promotional and Other Business Meeting</strong></td>
<td>NOT taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Faculty /Speaker: Allowed (consulting agreement required), Delegates: Not allowed (except for demonstration of non-portable equipment)</td>
</tr>
<tr>
<td></td>
<td>Taking place at or about the same time as a Third Party Organised Educational Event</td>
<td>Faculty /Speaker: Allowed, Delegates: Not allowed</td>
</tr>
</tbody>
</table>
### 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>Is direct sponsorship of HCPs allowed?</td>
<td>YES</td>
<td>NO (unless demonstrations of non-portable equipment are necessary)</td>
</tr>
</tbody>
</table>
Q. My company would like to organise a new product demonstration in our factory in Frankfurt, can I still invite doctors from outside Germany?

A: YES, it is acceptable to invite HCPs from outside the country where the company event takes place provided the event complies with all the other requirements of the Code and if there is a legitimate business need.

If the participants are primarily of one country the venue should be in the specific venue involved, if the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected is the residence of at least some of the participants.

Chapter 3 of the Code provides that travel or accommodation support to HCPs can only be provided for demonstrations of non-portable equipment, so it shall be assessed whether the product that is going to be presented falls within this category or not.
Case Study: Company Events; Business and Sales meetings

Q. Your company would like to organise and pay a dinner for a few Healthcare Professionals, unrelated to any Event, as a thank you for key customers. Would it be compliant with the new Code?

A: No, Member Companies are generally not allowed to invite and pay for individual HCPs to come to a dinner, when this dinner is not connected to any Event.

For such a dinner to be considered as a Business and Sales meeting, and therefore potentially allowed, there must be legitimate business purpose and, in any case, it would not be appropriate to facilitate or pay for travel or accommodation support.
Chapter 4: Grants and Charitable Donations
## 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 (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>YES</td>
<td>YES</td>
</tr>
<tr>
<td>An 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 (except to ensure that the funds are applied for charitable/philanthropic purposes)</td>
<td>YES</td>
<td>YES</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
### BEFORE THE EVENT

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
<th>STEP 4</th>
<th>STEP 5</th>
<th>STEP 6</th>
</tr>
</thead>
</table>
| **HCO** | Application for Educational Grant.  
- 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 HCOs who will benefit from it | Signature of contract (incl. all necessary documentation) | Agreement executed - compliant allocation of funds according to intended purposes | 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

- **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**

**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)**
# 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>
</tr>
<tr>
<td>Can be provided to individual HCPs?</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Written agreement and other documentation?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>An 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?</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Compliance with general criteria for Events (Chapter 1)?</td>
<td>YES</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>CVS approval?</td>
<td>YES</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Q: Your company would like to sponsor an Educational Event related to a specific sector in which it is active. Your commercial department has decided to provide an Educational Grant to the local Hospital and identified in the draft Contract some HCPs belonging to the relevant sector. Is this process compliant with the new Code?

A: NO:

1. According to the principle of Separation, an independent decision making/review process shall be implemented by Member Companies. Sales’ function shall not decide upon and/or approve a decision to provide a Grant or a Charitable Donation. For example, such independent process could be led by a Member Company’s Legal, Finance or Compliance functions, according to clear, transparent decision making process.

2. Member Companies shall only provide Educational Grants, meaning that companies shall only specify the intended purpose of the Educational Grant, and not select individual HCPs. They can, however, indicate types or categories of potential recipients (area of practice, expertise, etc.)
Q: A medical society has approached your company asking for support to their annual medical conference. In particular, they would like your company to support the attendance of young physicians. In the past, your company used to select the HCPs individually, is this still possible?

A: NO. Member Companies are no longer able to provide support directly to individual HCPs to cover costs of their attendance at Third Party Organised Educational Events. Consequently, companies will no longer be able to select individual HCPs.

However, you may provide Educational Grants specifying the category of HCPs that would benefit from it. You may for instance specify that the Educational Grant is intended to cover the attendance costs for young physicians.
Case Study: Educational Grants

Q: Your company supports the attendance of HCPs to a Third Party Educational Conference. You would like to tell an HCP that your company has provided an Educational Grant to the HCO organising the conference, is this allowed?

A: **YES**, you may inform the HCP that such Educational Grant is supported by your company. However, you shall not contact directly or indirectly the HCO in charge of the selection of HCPs who will benefit from the Educational Grant.
Chapter 5: Consulting Arrangements
Requirements for Consulting Arrangements?

- Written agreement and documentation of the services
- Decision-making/review process Plan
- Selection criteria directly related to the identified business need
- Adequate number of consultants
- Fair Market value
- Meetings with consultants: general criteria for events
- Legitimate business need
- Employer notification
- Principle of separation

**N.B.:** Clarification of scope in the 2022 Code version: Consulting Arrangements can be arranged with an HCP **OR** an HCO
Q: An employee of a in vitro diagnostics company wants to engage an HCP to provide specific consulting services. The employee's superior told him that a written contract is required for such services. Which rules apply as far as contracts for consulting services are concerned?

- **NO**
  - a. Consulting services may only be provided on the basis of a written contract that precisely describes the services (nature, time, benefit for the company, etc.), whereas the remuneration may be agreed upon orally.

- **YES**
  - b. A written agreement must be in place before the services are rendered. Such agreement should describe, in detail, the nature of the services to be provided and the basis for payment of these services.

- **NO**
  - c. A written contract is needed only for multiple consulting services, whereas an agreement by telephone or e-mail is fully sufficient for a single service, in particular when the services is for free.
Case Study: Consulting agreements

Q: Your company concluded a consultancy agreement with an HCP to conduct post-market research. The HCP asks you if, within the framework of this agreement, it would be possible to cover his costs for travel and accommodation as he will attend a Third Party Organised Educational Conference as speaker in the main program. Is this compliant with the new Code?

A: NO. After 31 December 2017, Member Companies shall no longer provide support directly to individual HCPs to cover costs of their attendance at Third Party Organised Educational Events.

There are two exceptions to this rule:

• Third Party Organised Procedure Training meetings,
• Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium pursuant to a consulting agreement.
Chapter 6: Research
Requirements for Member Company-Initiated Research

Legitimate Business need for data, e.g.,
- Medical needs; e.g., patient safety
- Research and development
- Scientific purposes, e.g. performance indicators
- Regulatory, e.g., post-market surveillance, vigilance, safety and cost-effectiveness data

Documentation of any arrangements to procure research-related services
- Written agreement referencing written research protocol
- Written schedule of work
- Required consents, approvals and authorisations

Compliance with applicable Good Clinical Practice guidelines, if relevant

Appropriate clinical trial transparency
- Appropriate disclosure of information about company’s clinical trials, e.g., in external public registries
Legitimate business need to obtain evaluation/feedback from HCPs and HCOs in relation to the evaluation products

Evaluation products may be provided on a no charge basis in return for the requested user feedback

Documented in a written protocol or questionnaire forming part of the contract

Provision of evaluation products must not improperly induce and/or encourage HCPs/HCOs to purchase, lease, recommend etc. companies’ products or services
Chapter 7: Royalties
A Member Company and an HCP may enter into royalty arrangement where the HCP is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the HCP would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations.

**Quiz: Royalty arrangements**

A written agreement on royalty arrangements providing appropriate and reasonable remuneration in accordance with applicable laws and regulations.

Royalties paid are conditioned on a requirement that the HCP recommends products or services of the company.
Chapter 8: Educational Items and Promotional Items
Requirements: Educational items or Promotional items

- Compliant with applicable local requirements
- Related to the HCP’s practice, or benefit patients, or serve a genuine educational function
- Provided on exceptional basis
- Not provided in response to requests made by HCPs
- Not given in the form of cash or cash equivalents
- Not intended to improperly reward, incentivise and/or encourage HCPs to purchase, lease, recommend, prescribe, use, supply or procure the Member Company’s products or services

Inexpensive

Exception: if greater value, then can only be provided to an HCO
Educational or Promotional items – Decision tree
Quiz: Educational or Promotional items

Never allowed

- Cash or cash equivalents
- Food (e.g., fruit basket; chocolate), alcohol and items which are primarily for use in the home or car
- Gifts to mark significant life events e.g., marriage, birth or birthday
An employee of a MedTech company has been working with an HCP for several years. It is early December and Christmas is coming. Furthermore, the HCP celebrates the 25th anniversary of her practice in January. The company employee wonders what kind of gift he can give the HCP and for what occasion.

- The employee can give a bottle of wine to the HCP for the 25th anniversary of her practice, but not for the occasion of Christmas, as this is a general holiday.
- The employee can give a calendar or diary for the 25th anniversary of her practice and clinical items such as wipes, nail brushes or surgical gloves for Christmas.
- The employee cannot offer a gift of modest value that relates either to the 25th anniversary of the HCP’s practice or for the occasion of Christmas.
Q: Your company wants to run a raffle at a congress and the prize would be a bottle of champagne. Is this allowed under the new Code?

A: NO. Although raffles are allowed under the new Code, they need to comply with all the requirements of Chapter 8 on Educational Items and Promotional items.

Therefore, this raffle would not be compliant with the new Code as:

1. The prize is not related to the Healthcare Professionals practice or benefit patients, or serve a genuine medical education function.

2. Educational/Promotional items must not encourage Healthcare Professionals to recommend, prescribe, use, supply or procure the Member Company’s products or services.

3. It would not be compliant with the Principle of Perception and Image.
Chapter 9: Demonstration Products and Samples
Demonstration Products and Samples

- Member companies may provide Demonstration Products and/or Samples at no charge in order to:

  1. Enable HCPs/HCOs to evaluate/familiarise themselves with safe and appropriate use/functionality of the product/related service

  2. Determine if to use, order, purchase etc. the product and/or service in the future

  3. Provision of such products must not improperly reward, induce and/or encourage HCPs/HCOs to purchase, lease, recommend, prescribe, use, supply or procure Member Companies’ products or services
Requirements: Demonstration Products and Samples

- Maintaining appropriate records, e.g.:
  - Proof of delivery for any Demonstration Products/Samples provided
  - Receipt of return for multiple-use products

- Documenting the no-charge basis and other applicable conditions no later than the time of the supply:
  - Clear record in the Member Company’s records
  - Clear disclosure in writing to HCPs/HCOs
## Requirements: Demonstration Products and Samples (con’t)

<table>
<thead>
<tr>
<th>Demonstration Products</th>
<th>Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provided solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer</td>
<td>Provided in order to enable HCPs to familiarise themselves with the products in clinical use</td>
</tr>
<tr>
<td><strong>Single-use Samples:</strong></td>
<td><strong>Multiple-use Samples:</strong></td>
</tr>
<tr>
<td>- Quantity not exceeding the amount reasonably necessary to acquire adequate experience in dealing with the products</td>
<td>- Specific length of time (depending on the frequency of anticipated use, duration of the training, the number of HCPs etc.)</td>
</tr>
<tr>
<td></td>
<td>- Company to retain title to Samples</td>
</tr>
<tr>
<td></td>
<td>- Process in place to remove Samples at the conclusion of the period</td>
</tr>
</tbody>
</table>
MedTech Europe Code of Ethical Business Practice Part 2:

Complaint handling and dispute resolution
Enforcement

**Procedural Framework**
Disputes are generally best handled by national panels subject to certain exceptions

**Independent body**
MedTech Europe Compliance Panel
Enforcement mechanism – only new composition (not structure)

Independent MedTech Europe Compliance Panel

Jean-Claude Najar
(Chair)

Willy Vanbuggenhout

Suzanne Logstrup
Enforcement complexity: the role of National Associations

<table>
<thead>
<tr>
<th>Country</th>
<th>National Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Austromed</td>
</tr>
<tr>
<td>Belgium</td>
<td>BeMedTech</td>
</tr>
<tr>
<td>Cyprus</td>
<td>SAIÉEK</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>CzechMed</td>
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<td>CZEDMA</td>
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<tr>
<td>Denmark</td>
<td>Medicoindustrien</td>
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<tr>
<td>Finland</td>
<td>Sai Lab - MedTech Finland</td>
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<tr>
<td>France</td>
<td>SNITEM</td>
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<tr>
<td>France</td>
<td>SIDIV</td>
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<tr>
<td>Germany</td>
<td>BV Med</td>
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<td>Greece</td>
<td>SIEV</td>
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<td>ETOSZ</td>
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<td>Ireland</td>
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<tr>
<td>Italy</td>
<td>Irish Medtech Association</td>
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<tr>
<td>Middle East - Africa</td>
<td>Mecomed</td>
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<tr>
<td>Norway</td>
<td>Melanor</td>
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<td>The Netherlands</td>
<td>NEFEMED – FHI - DIAGNED</td>
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<td>Turkey</td>
<td>ARTED</td>
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<td>UK</td>
<td>ABHI</td>
</tr>
<tr>
<td>Middle East - Africa</td>
<td>BIVDA</td>
</tr>
</tbody>
</table>
For additional information
For more information

- MedTech Europe website
- Members’ SharePoint
- Ethical MedTech website
For more information (con’t)

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