

MedTech Europe Code of Ethical Business Practice

March 2022



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

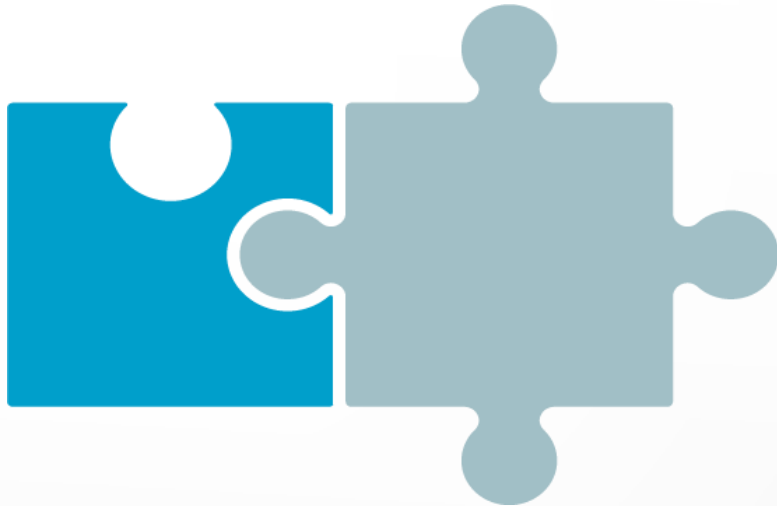
What does it cover?



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

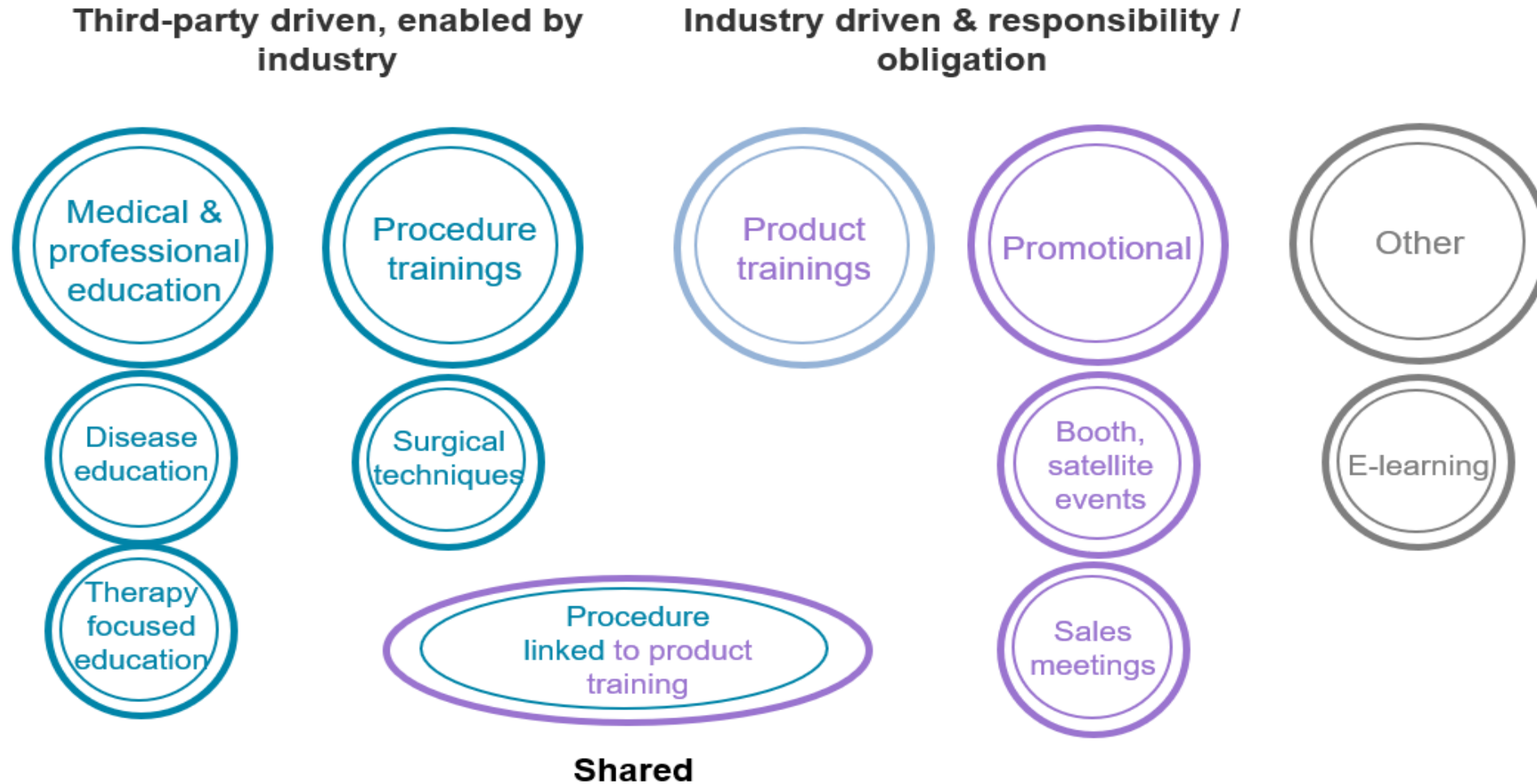


HCPs need to be trained on how to use technologies

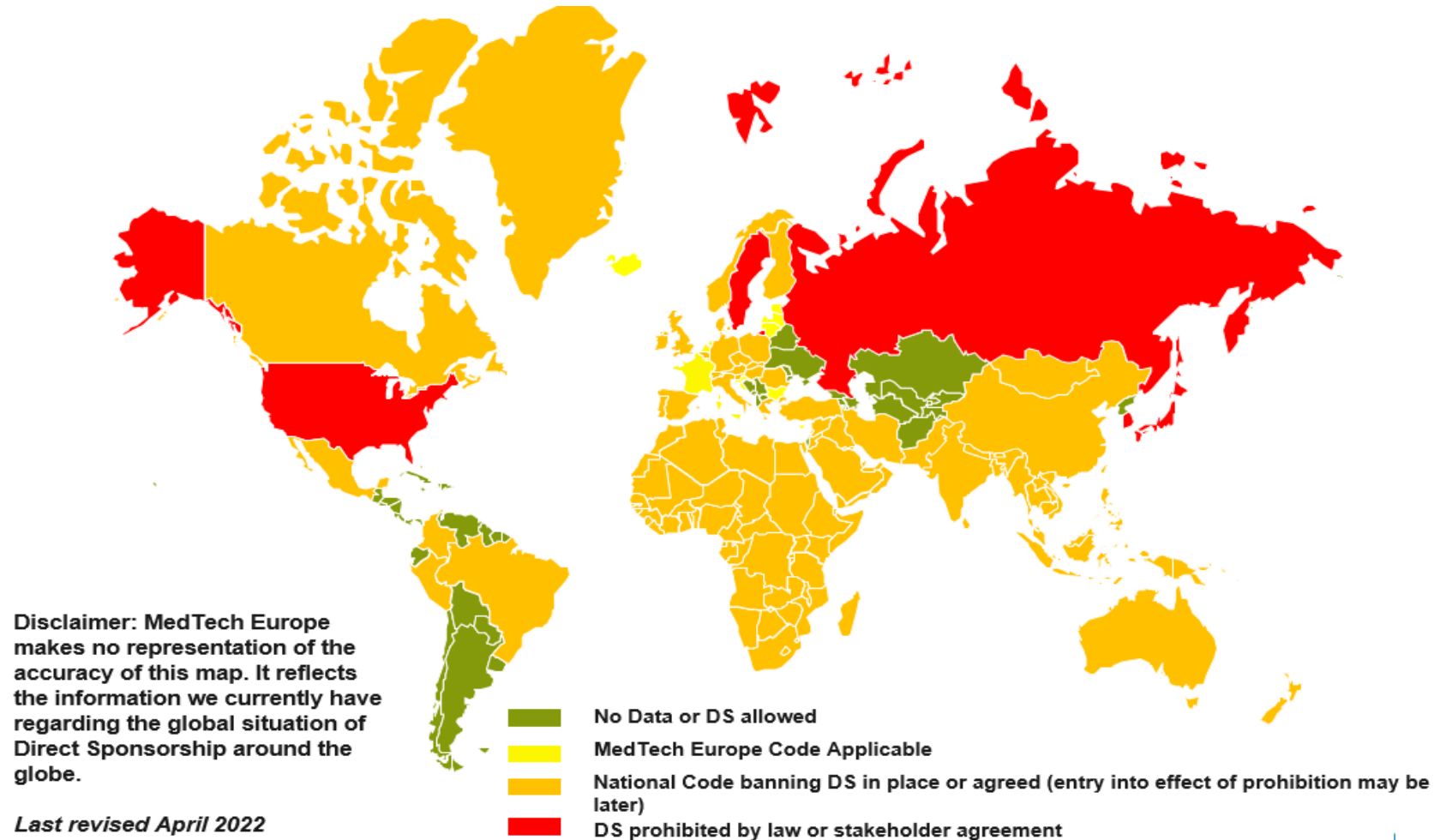


The industry liaises regularly with HCPs to ensure that the technologies are updated and maintained

Industry support to medical education is extensive



Phase out of DS: A global discussion



Industry's reputation at risk

The Telegraph

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

The New York Times

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

RTE

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

HSE suspends all payments to Eurosurgeon from all hospitals

THE INDEPENDENT



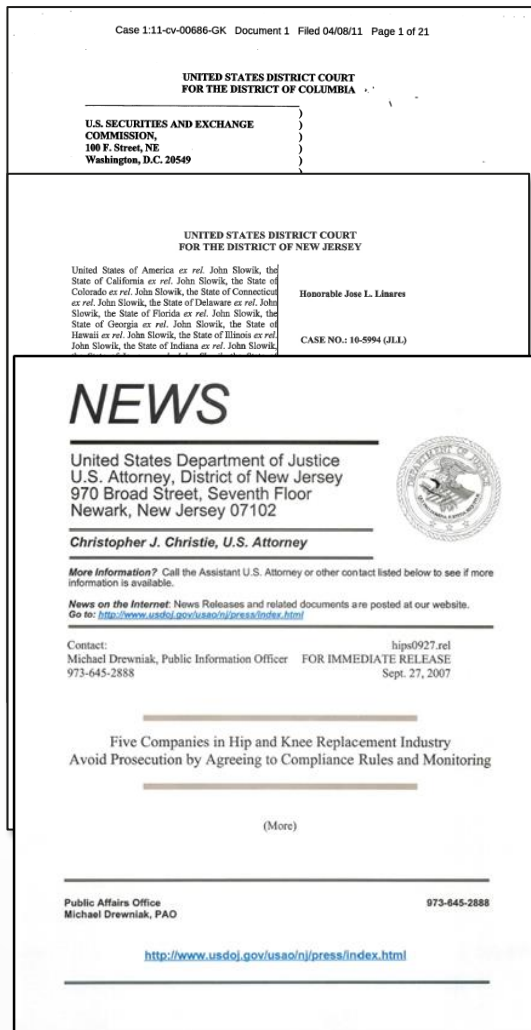
Whistleblower jailed over bribes to Greek
officials

Le patron de Mithra Pharmaceutical sous le
coup d'une instruction judiciaireLe Soir

Rédaction en ligne
Mis en ligne mardi 9 juin 2015, 18h26

LE SOIR

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.

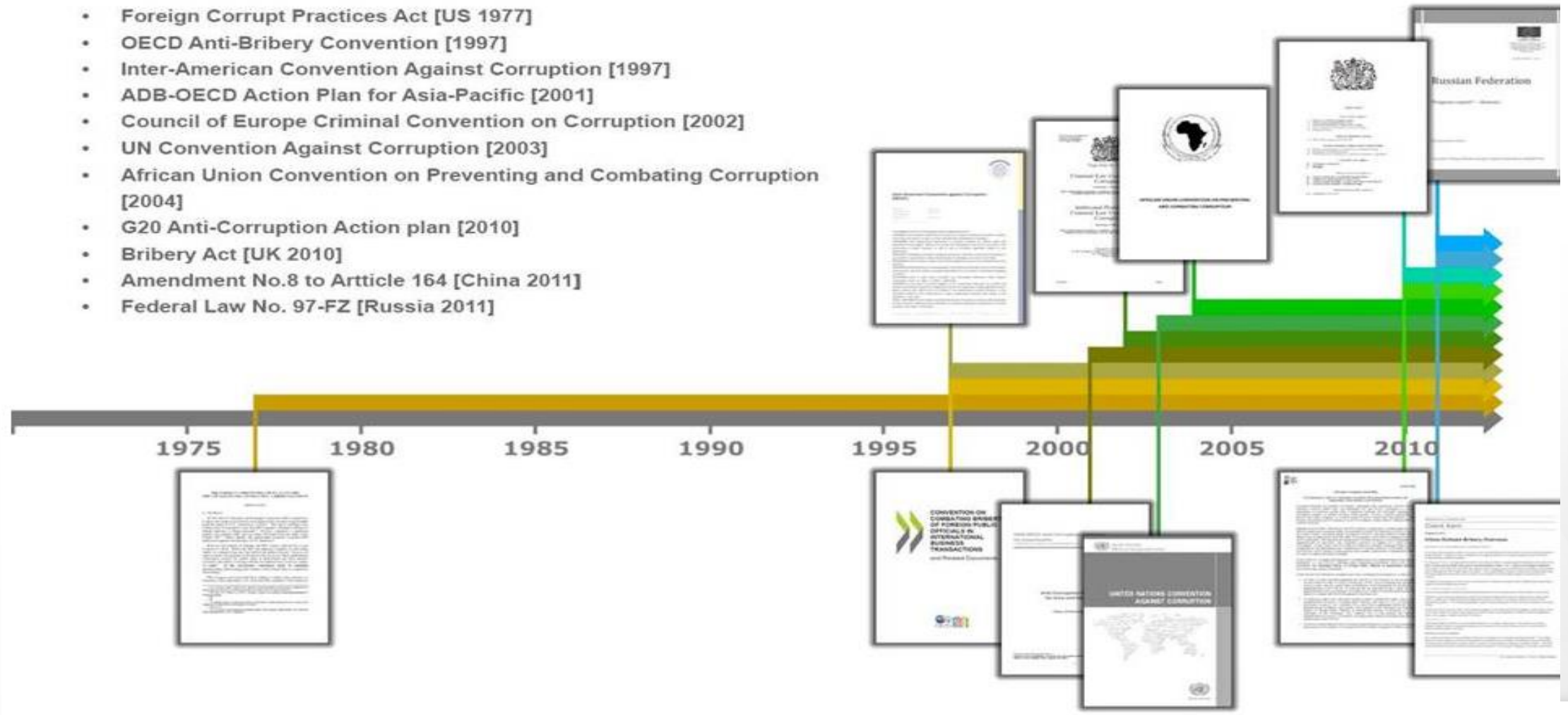
[Company] paid for doctors’ lavish meals, ballooning, winery tours, golf, and spa treatment at [a

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

- Foreign Corrupt Practices Act [US 1977]
- OECD Anti-Bribery Convention [1997]
- Inter-American Convention Against Corruption [1997]
- ADB-OECD Action Plan for Asia-Pacific [2001]
- Council of Europe Criminal Convention on Corruption [2002]
- UN Convention Against Corruption [2003]
- African Union Convention on Preventing and Combating Corruption [2004]
- 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]



Importance of doing the right thing



**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

Reminder: Transparency: What? When? Where?

Educational Grants to support Third Party Organised Events	Other Educational Grants to HCOs
<ul style="list-style-type: none">• Support for these Events• Support for HCP Participation	<ul style="list-style-type: none">• Scholarships & Fellowships• Grants for Public Awareness Campaigns
<ul style="list-style-type: none">• Yearly reporting of the previous year's data (uploading of the data from January to the end of June, publication end of August)	
MedTech Europe platform (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



Chapter 1: General Criteria For Events

Member Companies may invite Healthcare Professionals to Company Events and Third Party Organised Educational Events. The principles and criteria set out in this Chapter 1 shall apply to all such Events supported in any way by Member Companies, irrespective of who organises the Event.

1. Event Programme

The Event programme should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the Event or be sufficiently relevant to justify the attendance of the Healthcare Professionals. For Third Party Organised Educational Events, the agenda should be under the sole control and responsibility of the third party organiser. A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should 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. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

2. Event Location and Venue

The Event location and venue should not become the main attraction of the Event. For the location and the venue, Member Companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented, or that of an Entertainment venue.
- The Event location and venue should be centrally located when regard is given to the place of residence of the majority of invited participants.
- The need for ease of access for attendees.
- The Event location and venue should be in or near a city or town which is a recognised scientific or business centre, suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of knowledge.
- Member Companies must take into account the season during which the Event is held. The selected time of year must not be associated with a touristic season for the selected geographic location.

Q5 What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?

A5 Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.

Q6 Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or ski/water sports? (Amended in June 2017)

A6 In principle no. It is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities such as golf, private beach or ski/water sports. Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party Organised Event venue might be required for compliance. Where an exception is considered, the Event's promotional material should not feature the on-site leisure aspects of the conference venue as a key attraction and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

Definitions are aligned and in the Glossary of the new Code

MedTech Europe Code of Ethical Business Practice Part 3:

Glossary and Definitions



MEDTECH EUROPE – CODE OF ETHICAL BUSINESS PRACTICE

- **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: <http://www.ethicalmedtech.eu>.

New chapter on distributors

MEDTECH EUROPE – CODE OF ETHICAL BUSINESS PRACTICE

Chapter 10: Third Party Intermediaries



Member Companies must be mindful of the fact that they may be liable for the activities of Third Party Intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products and/or services.

Accordingly, where such arrangements are entered into, and provided local laws and regulations allow it, Member Companies shall ensure that the relevant contractual documentation imposes obligations upon the Third Party Intermediary to comply with provisions set out in the Code and other applicable guidelines, as well as appropriate oversight to ensure this is duly implemented.

Risk Assessment

Member Companies should evaluate the risk profile for proposed and utilised Third Party Intermediary arrangements, including, for example, assessing:

- Risk in the relevant country, as well as specific risk profiles of planned or utilised Third Party Intermediaries;
- Information concerning local market legal and ethics requirements;
- Information from the Third Party Intermediaries for potentially unusual arrangements ; and
- Information available from public sources or employees for potential risks associated with the Third Party Intermediaries.

⇒ N.B.: No substantial changes, which came from the Eucomed/AdvaMed Third Party SMI guidance

For more information on the 2022 Code

Material	Audience	Channel
Crosswalk	Internal (ECC + NAC)	Sharepoint & ethicalmedtech
One pager	Internal & external (e.g., HCO & PCOs; GMTA members; pharma)	MTE website
PowerPoint	Internal (ECC + NAC)	Sharepoint
Full training material	Internal (ECC + NAC)	Sharepoint
Recorded training session (Q2)	Internal (ECC + NAC)	Sharepoint
Press release (28 March)	General public	MTE website
Clean Code version	ALL	MTE website
Podcast (Q2 or Q3?)	ALL	MTE website
Q&A document?	Internal & external	Sharepoint & ethicalmedtech

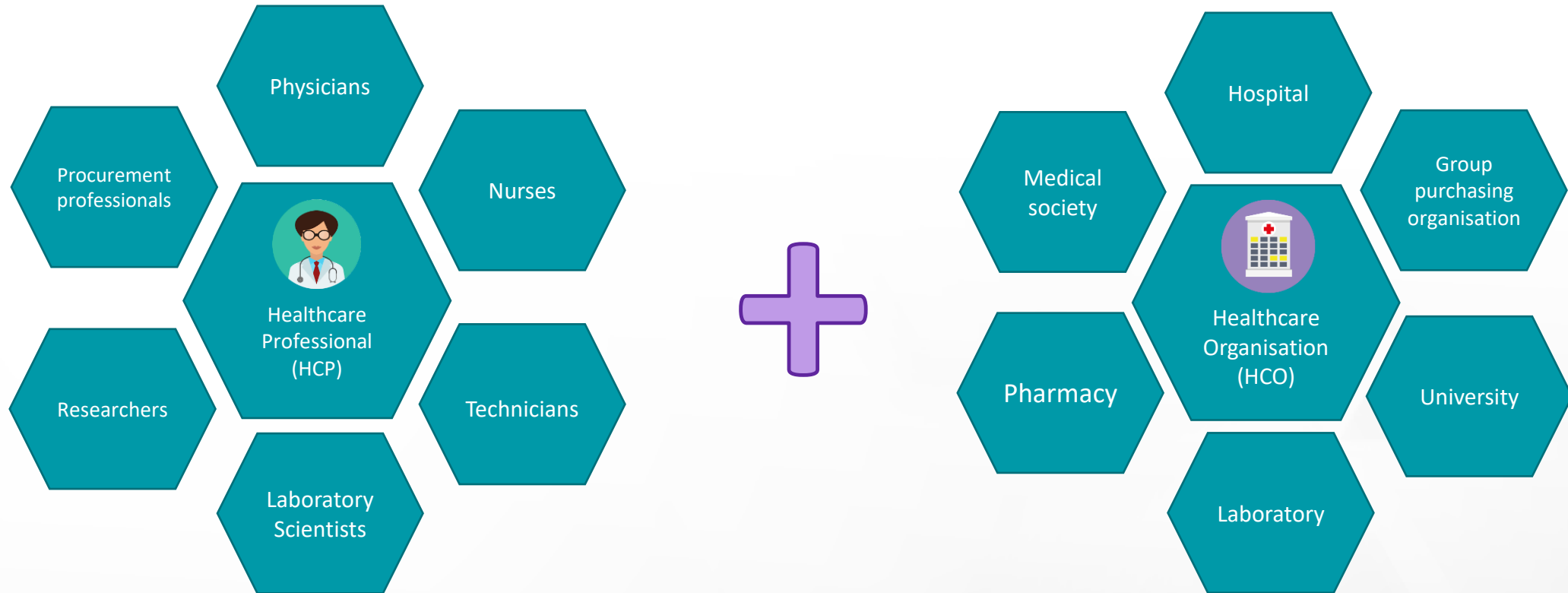
Code of Ethics: Content

Code: table of content

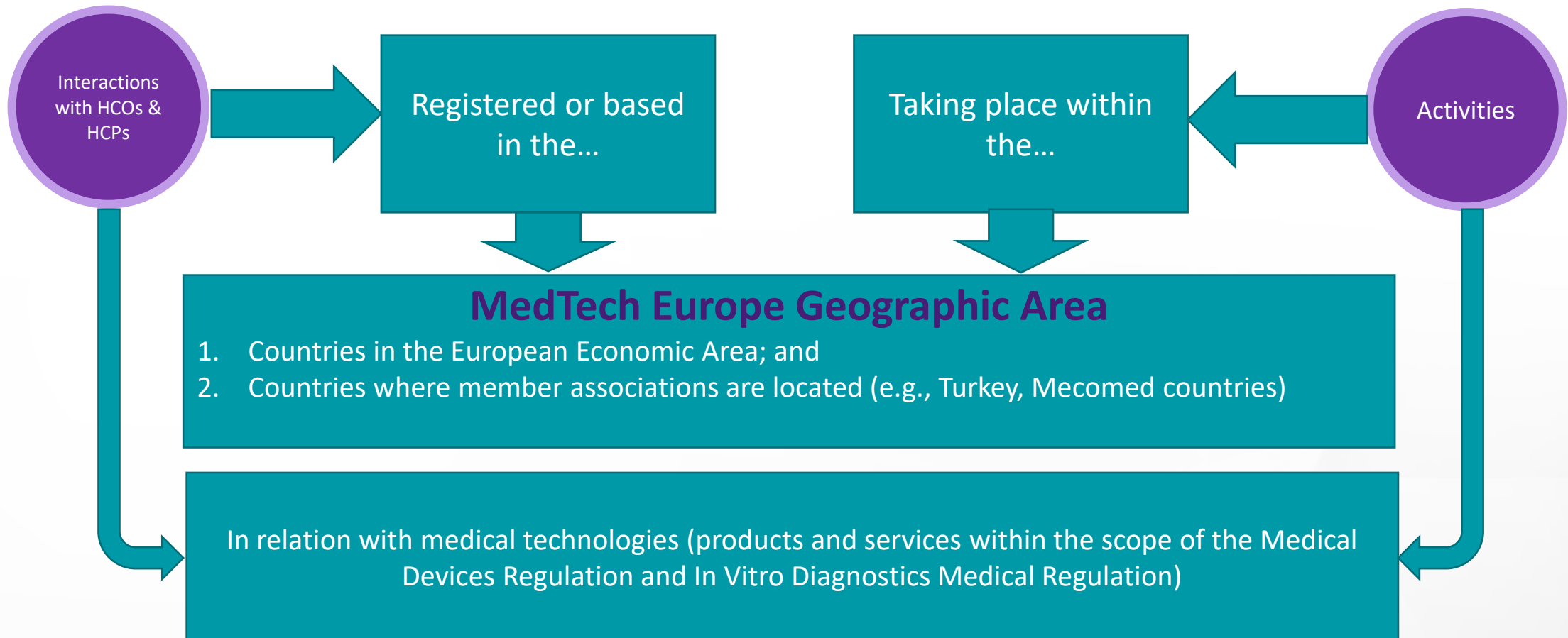
- Scope
- Administering the Code
- Introduction
- Chapter 1: General Criteria for Event
- Chapter 2: Third Party Organised Educational Events
- Chapter 3: Company Events
- Chapter 4: Grants and Charitable Donations
- Chapter 5: Consulting Arrangements
- Chapter 6: Research
- Chapter 7: Royalties
- Chapter 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?



Scope of the MTE Code



MedTech Europe Geographic Area

The MedTech Europe Geographic Area currently includes

Countries with National Associations:

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

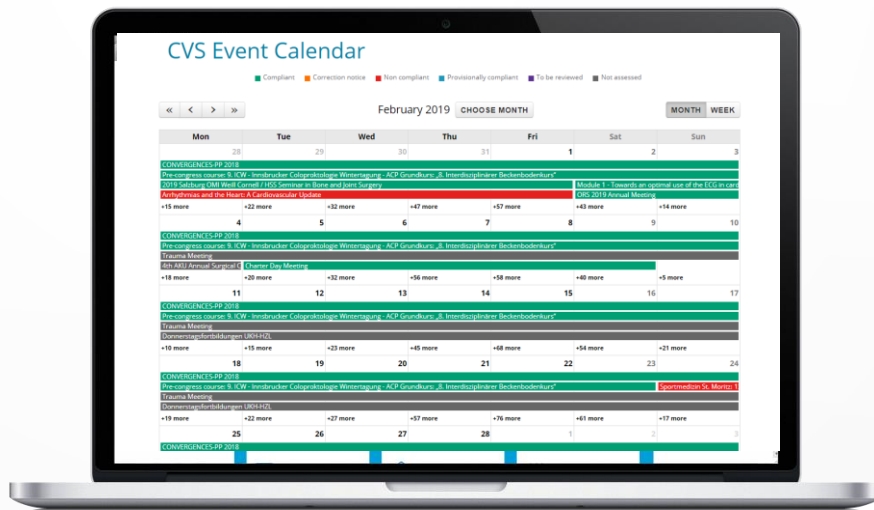


Recognised scientific or business centre

Near a city or town which is a recognized scientific or business centre, suitable for hosting an Event

The Conference Vetting System (CVS)

The **CVS** (Conference Vetting System) 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?

		PRIOR CVS SUBMISSION			
		IN MEDTECH EUROPE GEOGRAPHIC AREA		OUTSIDE MEDTECH EUROPE GEOGRAPHIC AREA	
WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?		NATIONAL Third Party Organised Educational Events attended by delegates which are local HCPs only)	INTERNATIONAL (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area ¹²⁾)	INTERNATIONAL (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area ³⁾)	INTERNATIONAL (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area attend, neither as speakers or delegates)
EDUCATIONAL GRANTS ⁴ PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grant to support the general running of a conference	Allowed ⁵ .	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code ⁶
	Educational Grants that includes funds to support HCP attendance to the conference	Allowed	Subject to CVS decision	Subject to CVS decision	N/A
	Educational Grants that includes funds to support Faculty	Allowed	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
COMMERCIAL ACTIVITIES	Consultancy agreement for speakers in satellite symposia	Allowed	Subject to CVS decision	Allowed. Not subject to CVS decision	N/A
	Booths/advertising	Allowed	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code
DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN THE MEDTECH EUROPE GEOGRAPHIC AREA	Direct sponsorship of HCPs as delegates (passive participation)	Not allowed	Not allowed	Not allowed	N/A
	Direct sponsorship of HCPs as Faculty (active participation)	Not allowed	Not allowed	Not allowed	N/A

CVS: Assessment criteria

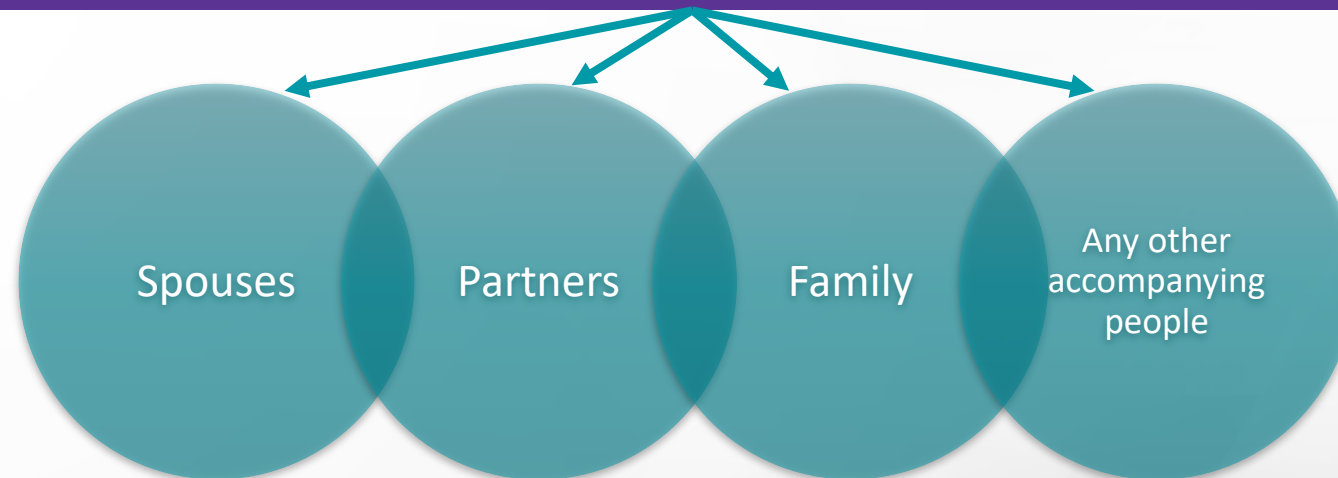


No guests

- 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



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.

Case study: TPOE

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.

Case Study: Company Event

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.

Hospitality: What is required?

- **Meals + accommodations = hospitality**

- **Any hospitality offered must be:**

- Subordinate in time
- Focus to the Event purpose
- Reasonable

Not considered as reasonable



Appropriate standard for the given location

Complying with the national laws, regulations and professional codes of conduct

Reasonable hospitality



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?

Not appropriate



Business class for flights shorter than 5 hours

Flight class

Appropriate



Economy or standard class

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)

			Direct Support for HCP attendance	
Event	Setting		Faculty /Speaker	Delegates
Third Party Organised Educational Conference	Main Event / Independent Scientific Program		Not allowed	Not allowed
	Satellite Symposium		Allowed (consulting agreement required)	Not allowed
	Booth		Allowed (consulting agreement required)	Not allowed
Third Party Organised Procedure Training meeting*			Allowed	Allowed
*The criteria for a Third Party Organised Procedure Training meeting can be found in Q&A 18				
Company Events	Product and Procedure Training and Education Event	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Allowed
		Taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Not allowed
	Sales, Promotional and Other Business Meeting	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed (consulting agreement required)	Not allowed (except for demonstration of non-portable equipment)
		Taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Not allowed

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

Requirements	Third Party Organised Educational Conference	Third Party Organised Procedure Training
Compliance with general criteria for Events (Chapter 1)?	YES	YES
CVS * approval?	YES	YES
Is direct Sponsorship of HCPs allowed?	NO	YES

* 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 1st 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.

Case Study: Support to TPOE

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 still 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



What is Product Training and Education Event?

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

What is Sales, Promotional and Other Business Meeting?

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?

			Direct Support for HCP attendance	
Event	Setting		Faculty /Speaker	Delegates
Company Events	Product and Procedure Training and Education Event	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Allowed
		Taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Not allowed
	Sales, Promotional and Other Business Meeting	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed (consulting agreement required)	Not allowed (except for demonstration of non-portable equipment)
		Taking place at or about the same time as a Third Party Organised Educational Event	Allowed	Not allowed

Requirements for Company Events? (con't)

Requirements	Product and Procedure Training and Education Events	Sales, Promotional and Other Business Meetings
Compliance with general criteria for Events (Chapter 1)?	YES	YES
CVS approval?	NO	NO
Is direct sponsorship of HCPs allowed?	YES	NO (unless demonstrations of non-portable equipment are necessary)

Case Study: Company Events; Business and Sales meetings

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

Requirements	Charitable Donations	Educational Grants	Research Grants
Can be provided to individual HCPs?	NO	NO	NO
Can be provided to HCOs?	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)	YES	YES
An independent decision-making/review process implemented by the company?	YES	YES	YES
Provided on “restricted basis” (i.e. control over the final use of funds)?	NO (except to ensure that the funds are applied for charitable/philanthropic purposes)	YES	YES
Written agreement and other documentation?	YES	YES	YES
Financial support publicly disclosed?	NO	YES	NO

Types of Educational Grants?

Support for Third Party Organised Educational Events:

- *Support for HCPs participation*
- *Event support*

Scholarship and fellowships

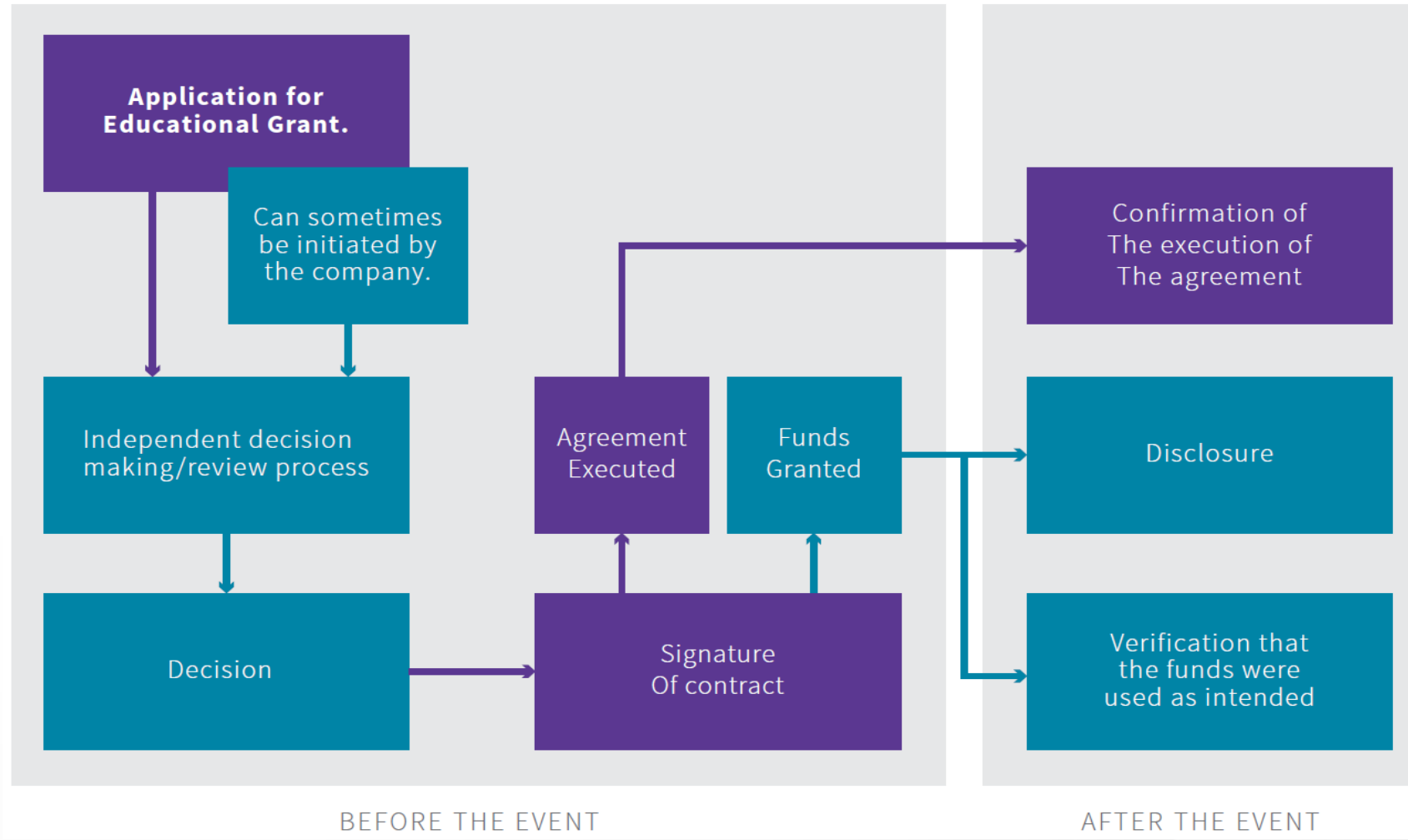
Grants for public awareness campaigns

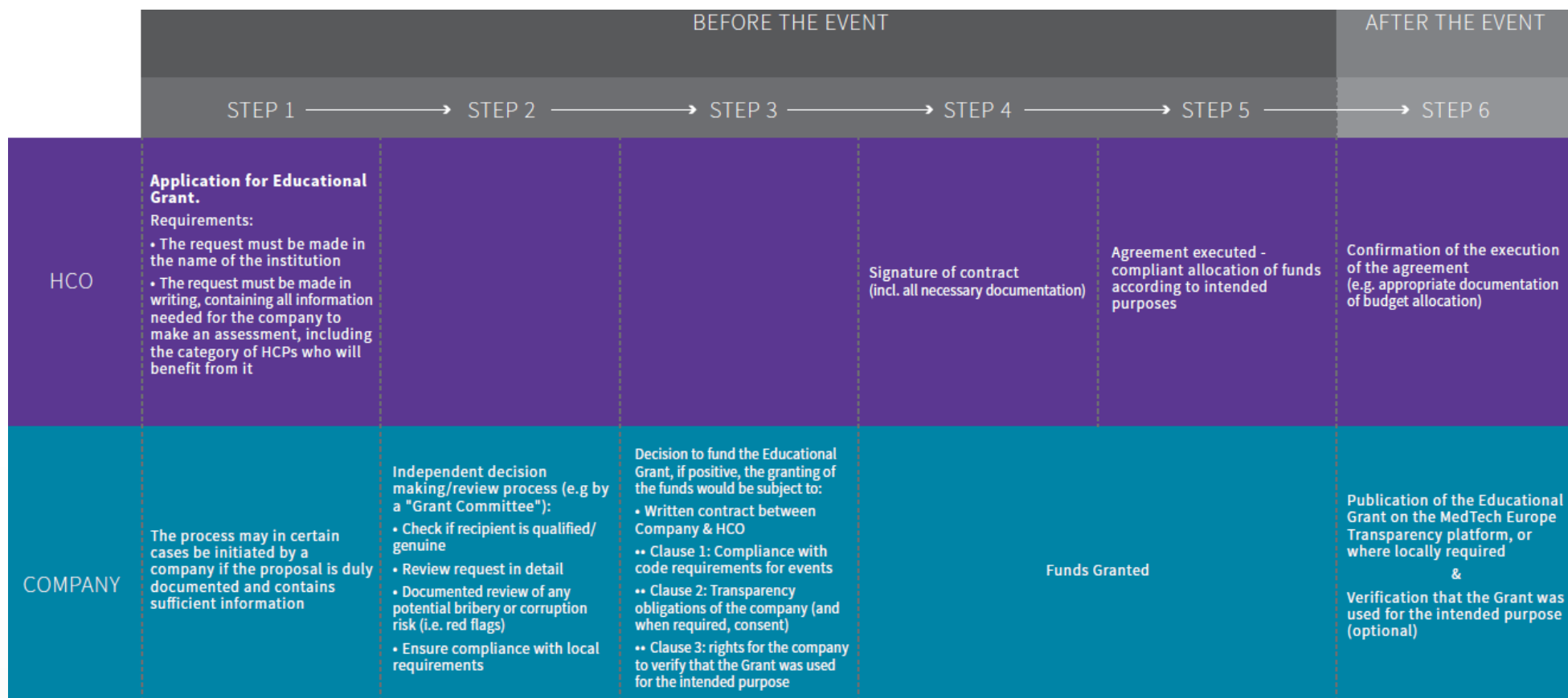
Educational Grants for general medical educational topics

Can only be
provided to
HCOs

List not
exhaustive

■ HCO ■ COMPANY





Requirements for Educational Grants

Requirements	Support for Third Party Organised Educational Events	Scholarships & fellowships	Grants for public awareness campaigns
Financial support publicly disclosed?	YES	YES	YES
Can be provided to individual HCPs?	NO	NO	NO
Written agreement and other documentation?	YES	YES	YES
An independent decision-making/review process implemented by the company?	YES	YES	YES
Provided on “restricted” basis?	YES	YES	YES
Compliance with general criteria for Events (Chapter 1)?	YES	N/A	N/A
CVS approval?	YES	N/A	N/A

Case Study: Educational Grants

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.)

Case Study: Educational Grants

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?



N.B.: Clarification of scope in the 2022 Code version: Consulting Arrangements can be arranged with an HCP OR an HCO

Quiz: Written agreement

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 are 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

Code requirements for [Company] Post Market Product Evaluation

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



Quiz: Royalty arrangements

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

Appropriate royalty arrangements



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

Not appropriate royalty arrangements

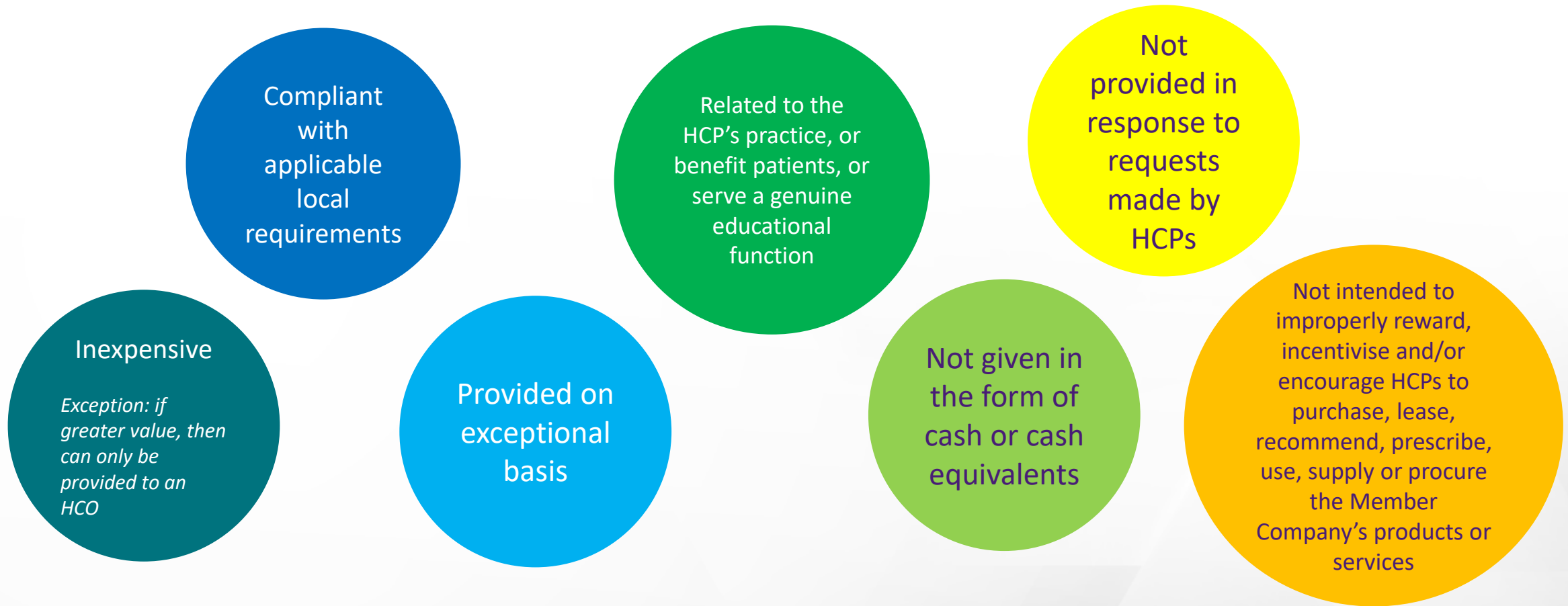


Royalties paid are conditioned on a requirement that the HCP recommends products or services of the company

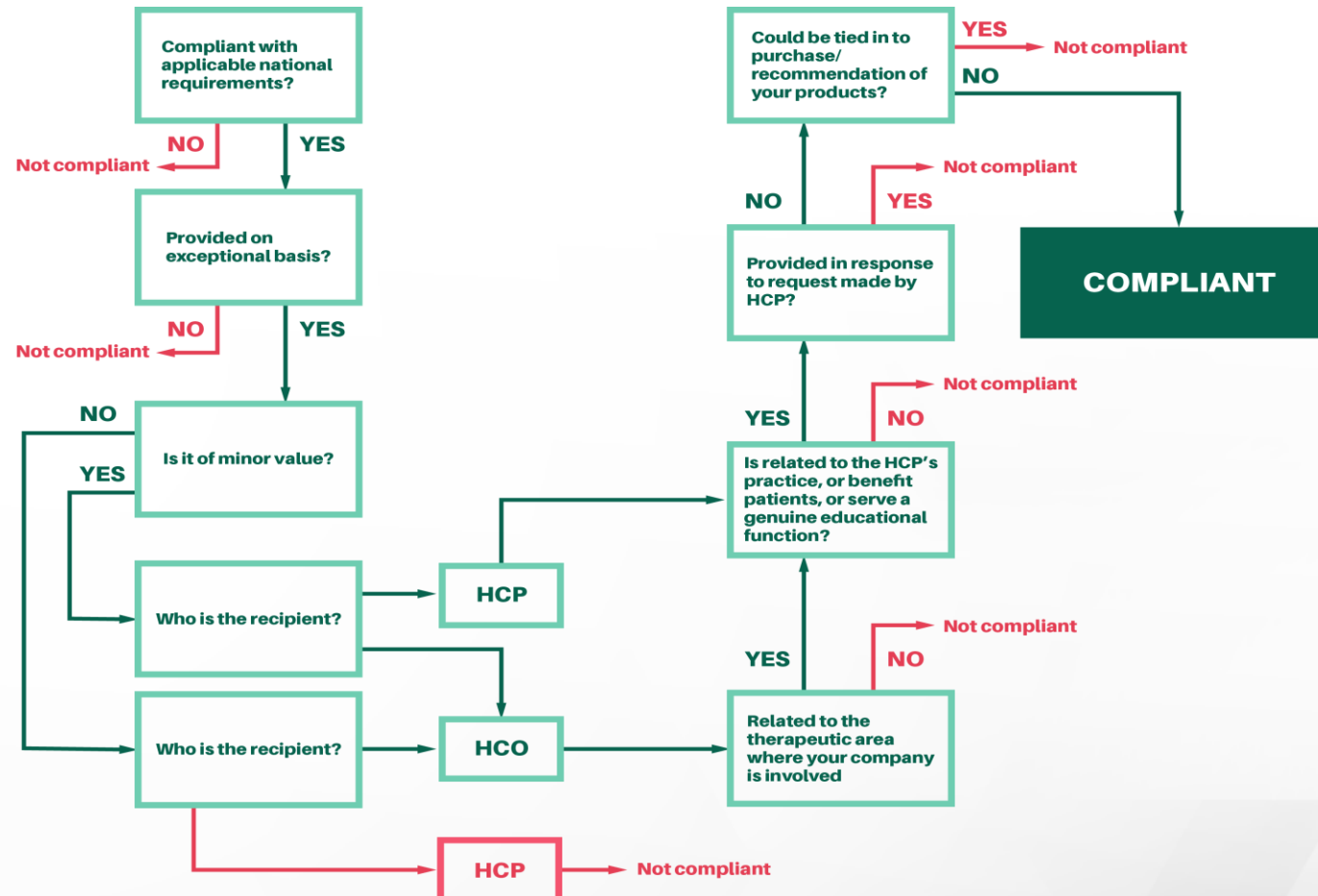
Chapter 8: Educational Items and Promotional Items



Requirements: Educational items or Promotional items



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

Quiz: Educational/Promotional items

Q: 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.

NO



a. 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.

NO



b. 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.

YES



c. 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.

Case Study: Educational/Promotional items

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:

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

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

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)

Demonstration Products	Samples
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	Provided in order to enable HCPs to familiarise themselves with the products in clinical use
	Single-use Samples: <ul style="list-style-type: none">- Quantity not exceeding the amount reasonably necessary to acquire adequate experience in dealing with the products
	Multiple-use Samples: <ul style="list-style-type: none">- Specific length of time (depending on the frequency of anticipated use, duration of the training, the number of HCPs etc.)- Company to retain title to Samples- Process in place to remove Samples at the conclusion of the period

**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

Country	National Association
Austria	Austromed
Belgium	BeMedTech
Cyprus	SAIEEK
Czech Republic	CzechMed
	CZEDMA
Denmark	Medicoindustrien
Finland	Sai Lab - MedTech Finland
France	SNITEM
	SIDIV
Germany	BV Med
	VDGH
Greece	SIEV
Hungary	AMDM
	ETOSZ
	HIVDA
Ireland	HealthTech Ireland
	Irish Medtech Association
Italy	Confindustria Dispositivi Medici
Middle East - Africa	Mecomed

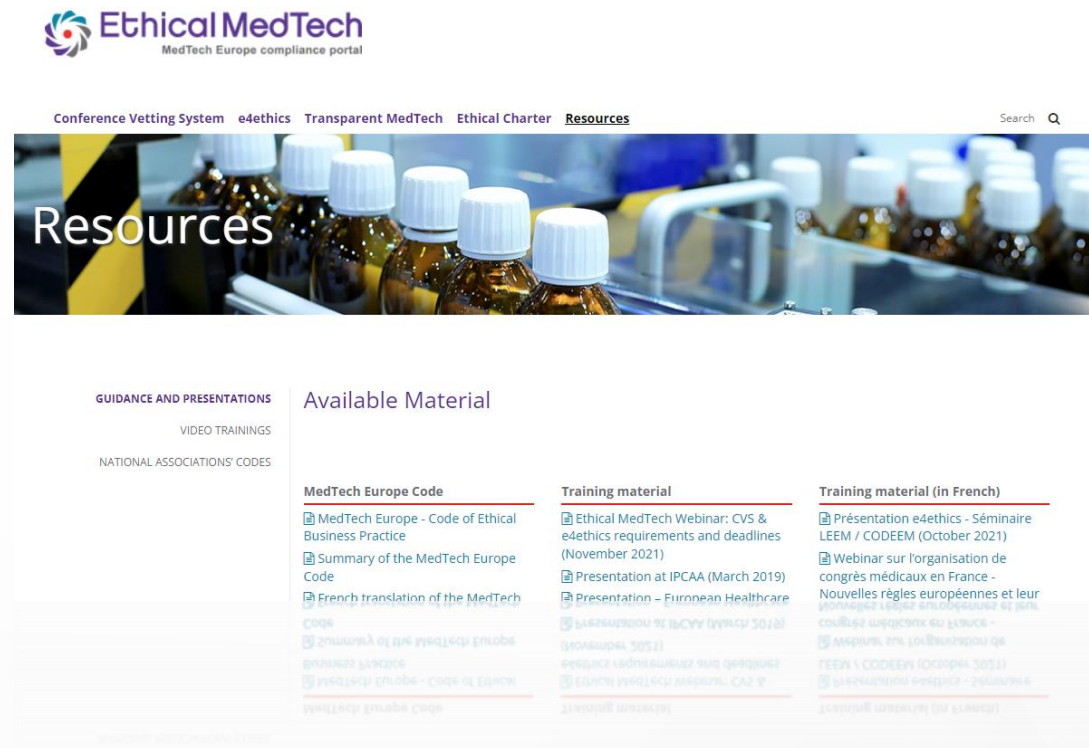
Norway	Melanor
Poland	Polmed
	MedTech Polska/ Poland
Portugal	Apormed
	Apifarma
Romania	AFPM
Russia	IMEDA
Slovakia	SK-MED
	SEDMA
Slovenia	SLO-MED and SIEDMA
Spain	FENIN
Sweden	Swedish Medtech - Labtech
Switzerland	Swiss MedTech
The Netherlands	NEFEMED – FHI - DIAGNED
Turkey	ARTED
UK	ABHI
	BIVDA



For additional information

For more information

- [MedTech Europe website](#)
- [Members' SharePoint](#)
- [Ethical MedTech website](#)



For more information (con't)

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