

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

15 September 2023, 10.30am CET

MedTech Europe
Code of Ethical
Business Practice

March 2022



Agenda







Reminder of
the
principles

- 1 Compliance basics
- 2 Legal framework
- 3 MedTech Europe Code of Ethical Business Practice
- 4 Roles & responsibilities
- 5 Additional resources & references
- 6 Q&A session

A blast from the past...



Benefits of Refresher Training

	Creating level playing field in knowledge across the medtech sector
	Fostering a culture of continuous learning
	Promoting excellence
	Helping to identify training needs and skills gaps
	Reduced mistakes
	Achieving compliance – doing the right thing

Compliance basics

Industry's reputation at risk



Latest news

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



NOV 16, 2020

Heart doctors more likely to implant devices from manufacturers that pay them, new study finds



OCT 20, 2020

Implant Files reporters win partial release of medical device information in France

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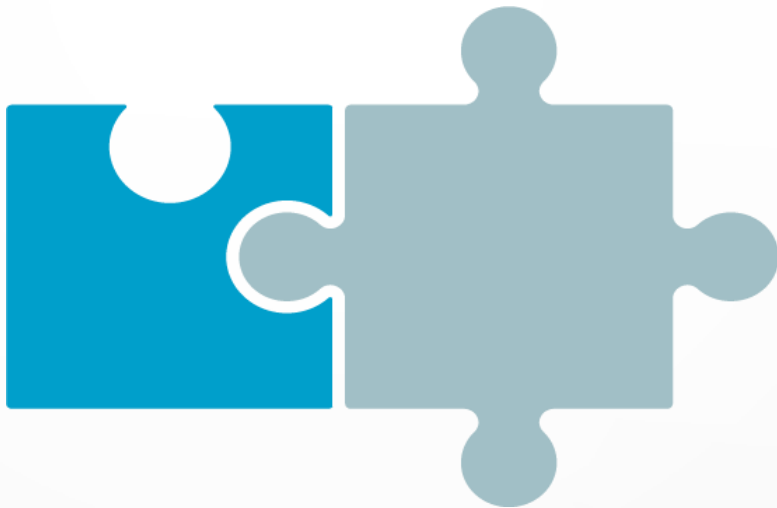
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Healthcare	38
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Consumer Goods	29
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Real Estate	3
Non-profit Organization	2

Source: [Stanford Law School – Foreign Corrupt Practices Act Clearinghouse](#).

Industry's relationship with HCPs

The MedTech industry and HCPs collaborate closely throughout several stages of the development and use of medical technologies



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



HCPs actively participate in the research to develop new technologies



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



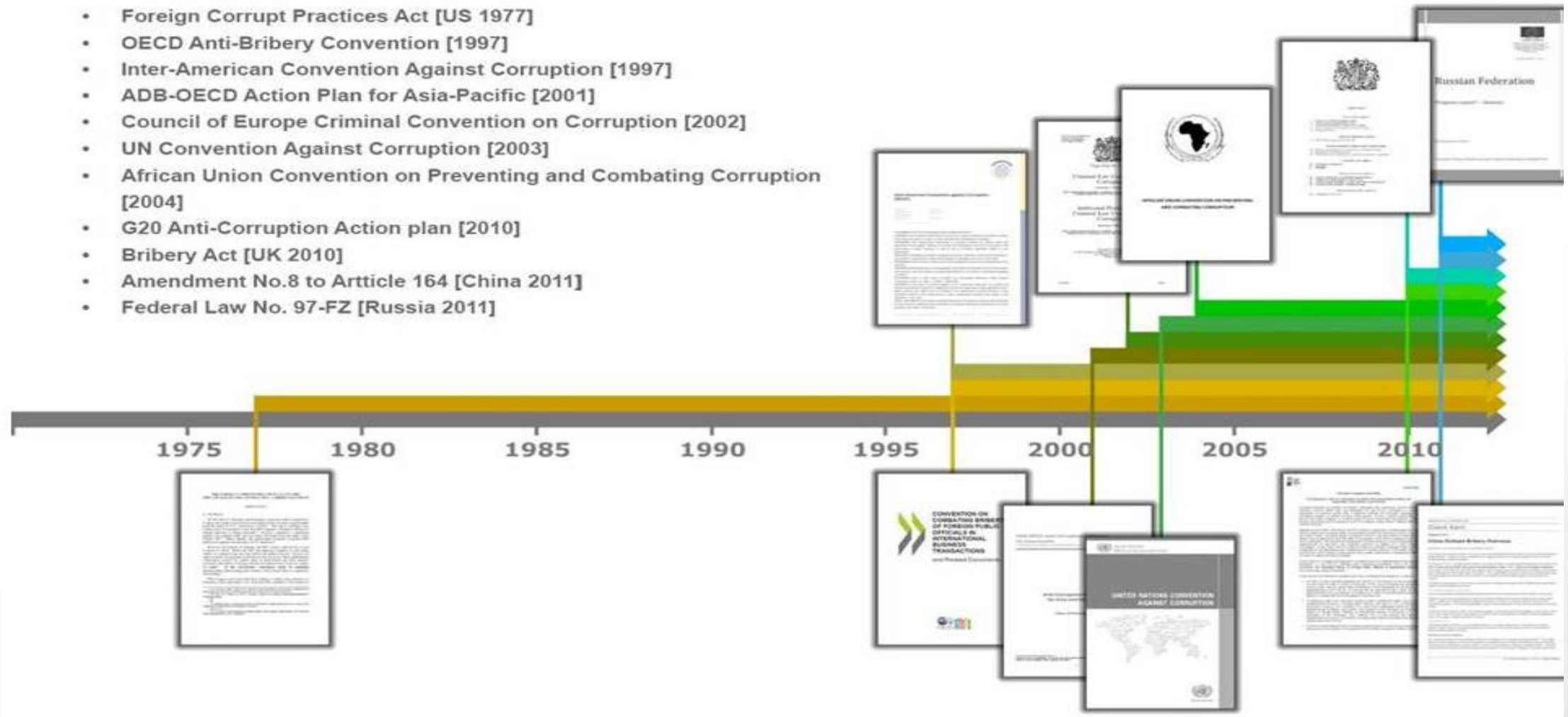
HCPs need to be trained on how to use technologies



Legal framework

Key legislation: anti-corruption & anti-bribery

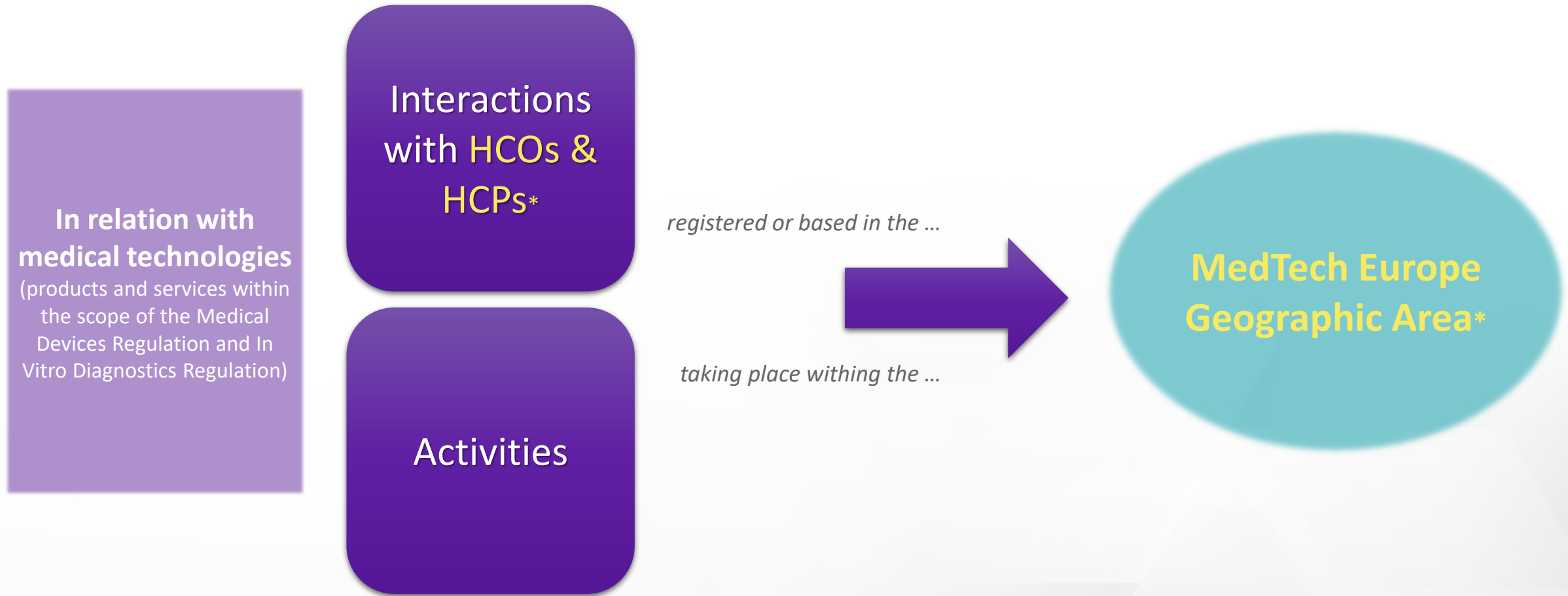
- Foreign Corrupt Practices Act [US 1977]
- OECD Anti-Bribery Convention [1997]
- Inter-American Convention Against Corruption [1997]
- ADB-OECD Action Plan for Asia-Pacific [2001]
- Council of Europe Criminal Convention on Corruption [2002]
- UN Convention Against Corruption [2003]
- African Union Convention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



MedTech Europe Code of Ethical Business Practice

Scope & principles

Scope of the MTE Code



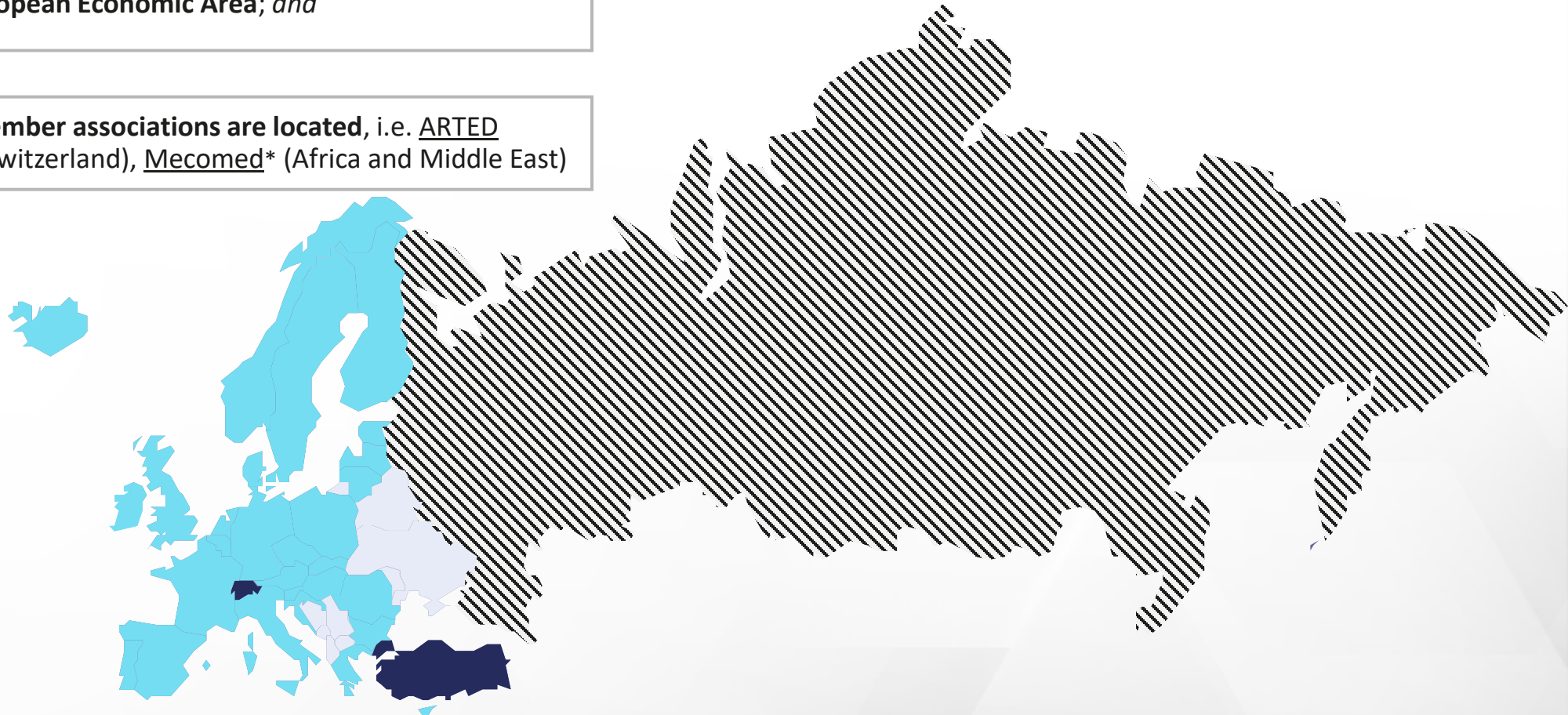
Definitions: HCPs & HCOs



Definitions: MedTech Europe Geographic Area

Countries in the **European Economic Area**; and

Countries **where member associations are located**, i.e. ARTED (Turkey), FASMED (Switzerland), Mecomed* (Africa and Middle East)



Definitions: MedTech Europe Geographic Area



***Mecomed**
Geographic Area

The Code's core principles



Image & Perception

No luxury hotels, luxurious dinners, etc.

Transparency

Disclose any interaction



Equivalence

Fair Market Value of any fee for service



Separation

Decision-making is not primarily sales-driven



Documentation

Contract & documentation expenses



Key elements

General Criteria for Events

⇒ All apply to **both** Third Party Organised and Company Organised Events



Promoting an ethical industry



Banning direct sponsorship (2015)

“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.



Transparency of Educational Grants (2015)

“Educational grants” (Indirect sponsorship)

Companies provide educational grants to **hospitals, medical societies** and other third parties to support **genuine medical education**.



These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**

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

			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

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
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

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
Direct sponsorship of HCPs allowed	YES	NO (unless demonstrations of non-portable equipment are necessary)

Requirements for Company Events

Event	Setting		Direct Support for HCP attendance	
			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

General 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
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*

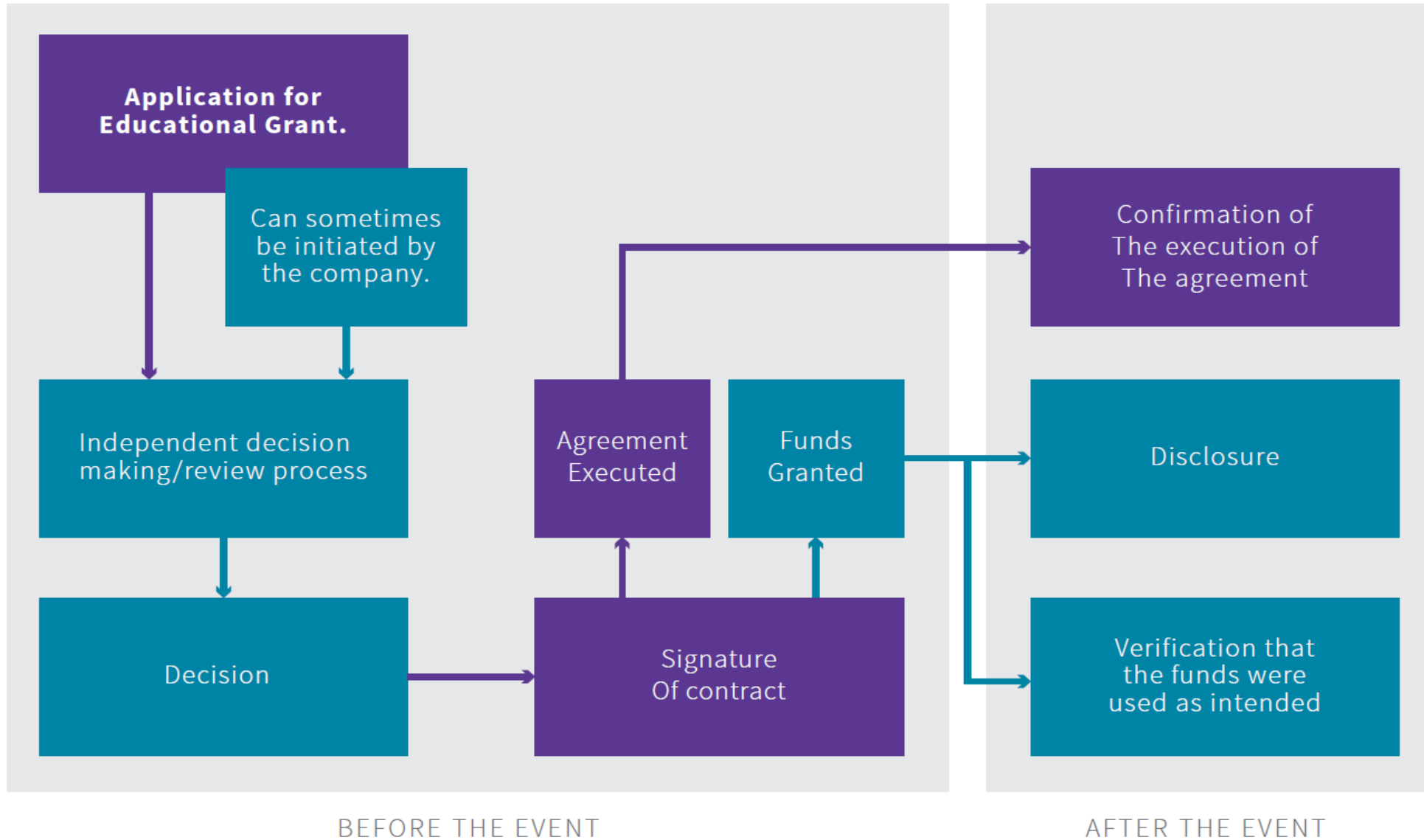
Scholarship and fellowships

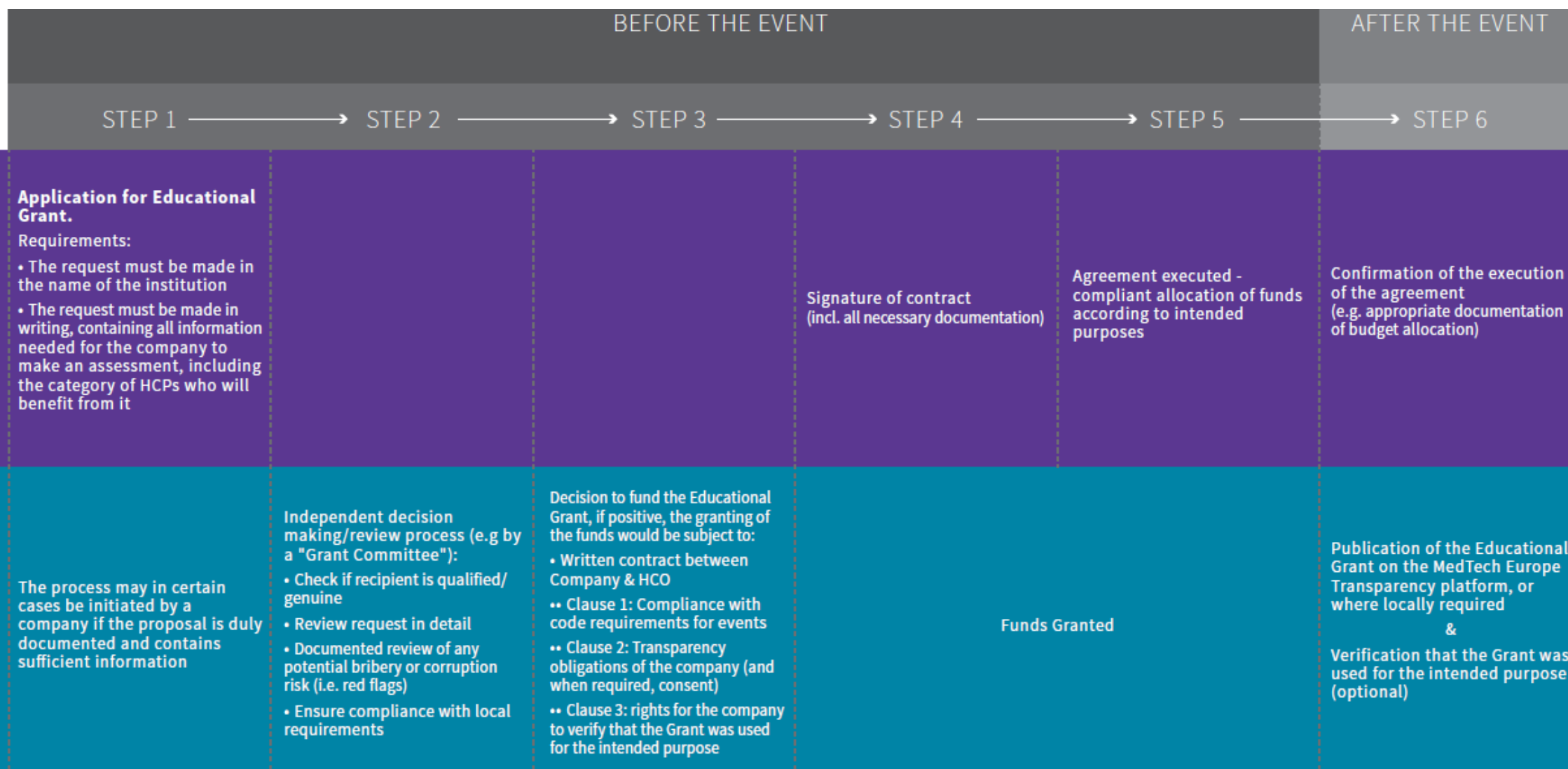
Grants for public awareness campaigns

Educational Grants for general medical educational topics

Can only be provided to HCOs

List not exhaustive



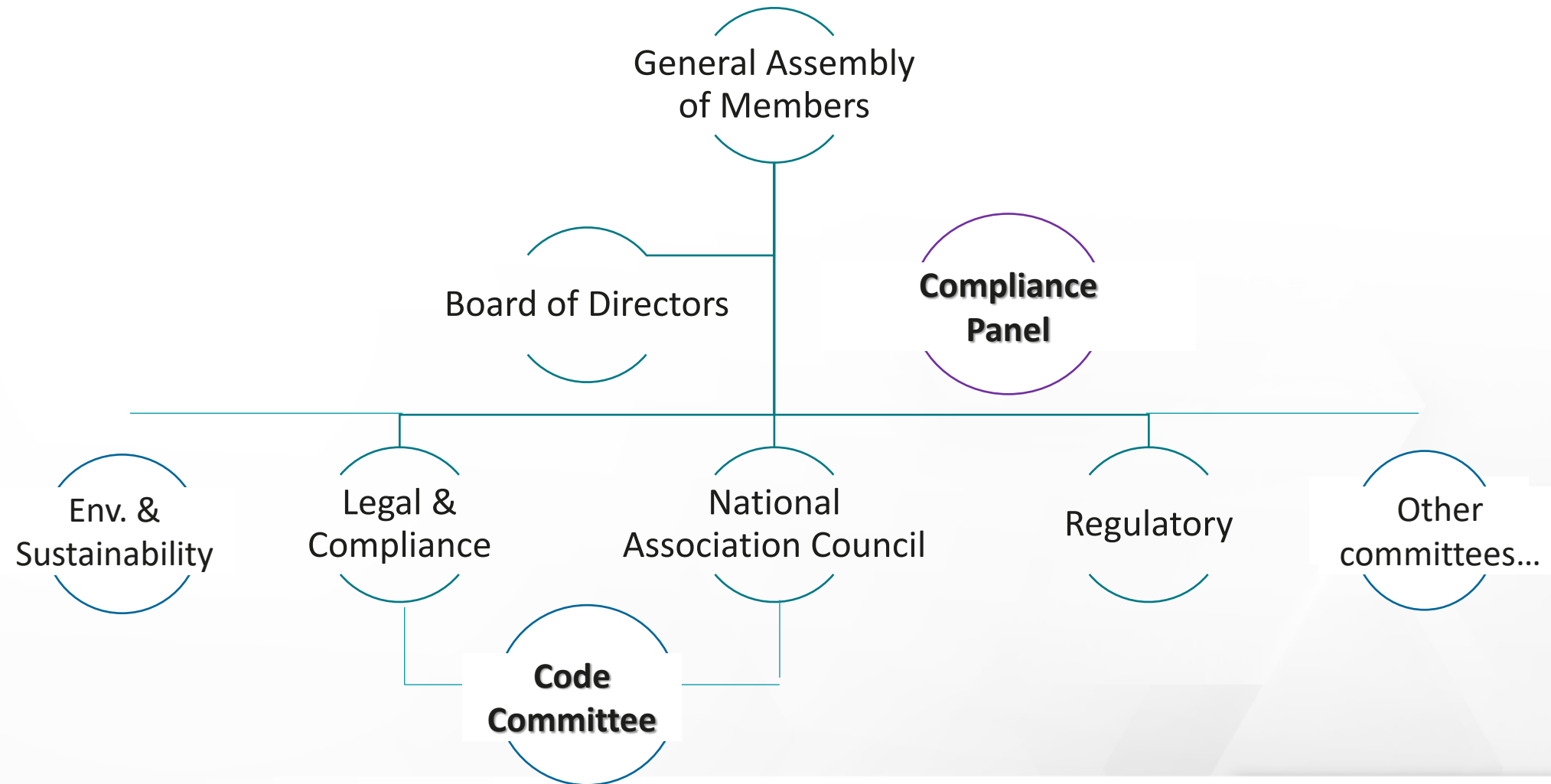


Specific requirements for Educational Grants

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

Roles & responsibilities

MedTech Europe roles & responsibilities



Roles & responsibilities within MTE membership



Additional resources & references

For more information



Conference Vetting System e4ethics Transparent MedTech Ethical Charter **Resources**

Search



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

GUIDANCE AND PRESENTATIONS

VIDEO TRAININGS

NATIONAL ASSOCIATIONS' CODES

Available Material

MedTech Europe Code

- MedTech Europe - Code of Ethical Business Practice
- Summary of the MedTech Europe Code
- French translation of the MedTech Europe Code
- Summary of the MedTech Europe Business Practice
- MedTech Europe - Code of Ethics
- MedTech Europe Code

Training material

- Ethical MedTech Webinar: CVS & e4ethics requirements and deadlines (November 2021)
- Presentation at IPCAA (March 2019)
- Presentation - European Healthcare
- Presentation at IPCAA (March 2019)
- e4ethics requirements and deadlines
- Ethical MedTech Webinar: CVS & e4ethics requirements and deadlines

Training material (in French)

- Présentation e4ethics - Séminaire LEEM / CODEEM (October 2021)
- Webinar sur l'organisation de congrès médicaux en France - Nouvelles règles européennes et leur nouvelles règles européennes et leur congrès médicaux en France - Séminaire sur l'organisation de LEEM / CODEEM (October 2021)
- Présentation e4ethics - Séminaire

Q&A session

Conclusions

For more information [con't]

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Thank you!

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