

# MedTech Europe Code of Ethical Business Practice

Training for Healthcare Organisations & Professional Conference Organisers





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MedTech  
Europe

Introduction

2

New MedTech  
Europe Code

Why a Code?

3

Main changes  
& CVS

Focus on  
HCOs & PCOs

4

Other aspects of  
the Code

This presentation should be complemented by reading the Code and its supporting documentation, e.g. Q&As, Annexes, presentation



Part 1

# ABOUT MEDTECH EUROPE



MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. They represent Diagnostics and Medical Devices manufacturers operating in Europe.

MedTech Europe started as an alliance in October 2012 formed by two organisations:

- EDMA
- Eucomed

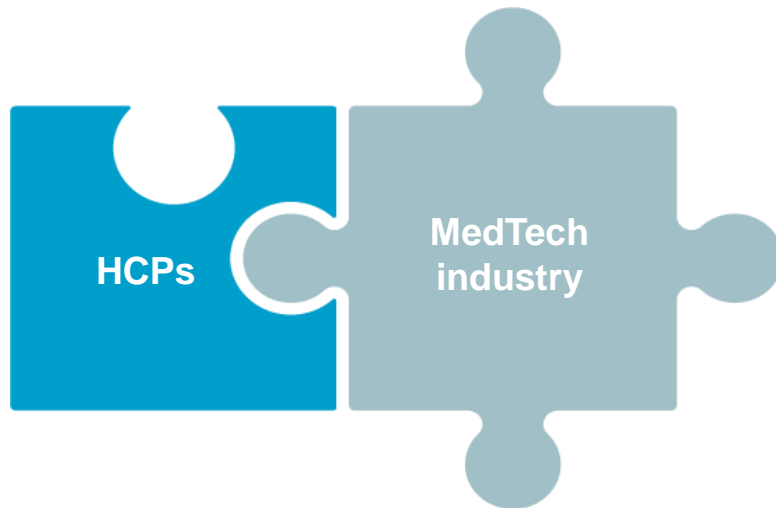


# MedTech Europe

from diagnosis to cure



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



HCPs actively participate in the research to develop new technologies



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



HCPs are trained on how to use technologies



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

A healthcare worker, likely a nurse or technician, is shown from the chest up, wearing a white surgical mask, glasses, and a hairnet. They are wearing white gloves and are reaching up with both hands to adjust a large, circular, overhead surgical light fixture. The background shows the interior of an operating room with other light fixtures and equipment. The entire image has a purple color overlay.

Part 2

# WHY A CODE?





## CODE

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.



Part 3

# THE MEDTECH EUROPE CODE OF ETHICAL BUSINESS PRACTICE



1

The principles of the Code

2

Support to Third party organised educational events, modalities, exceptions.

3

The general criteria that all events need to comply with in order to receive support from a company, regardless of who organises it.

4

The role of CVS

5

Rules for Educational Grants

6

Gifts



1

## Image & Perception

- No luxury hotels, luxurious dinners etc.

2

## Transparency

- Informing institution/superior of any interaction

3

## Equivalence

- Setting the fee for service on strict FMV methodology

4

## Separation

- Decision-making is not primarily sales-driven

5

## Documentation

- Signing the contract & documenting expenses



**Charitable Donations:** means provision of cash, equipment, 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 on an unrestricted basis and to *bona fide* charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.

**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>.

**Code:** means this MedTech Europe Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines, the Procedural Framework and the Dispute Resolution Principles. For the avoidance of doubt the Dispute Resolution Principles shall be replaced by the Procedural Framework and shall cease to have effect once the MedTech Europe Board approves the Procedural Framework.

**Disclosure Guidelines:** means the Code provisions setting out the public disclosure requirements under the Code.

**Demonstration Products (Demos):** means either single-use or multiple-use products provided free of charge by or on behalf of a Member Company to HCOs or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples;
- Evaluation Products;
- Products provided at no charge as part of a Charitable Donation or as part of a Business Event;
- Products provided as part of a Business Event.

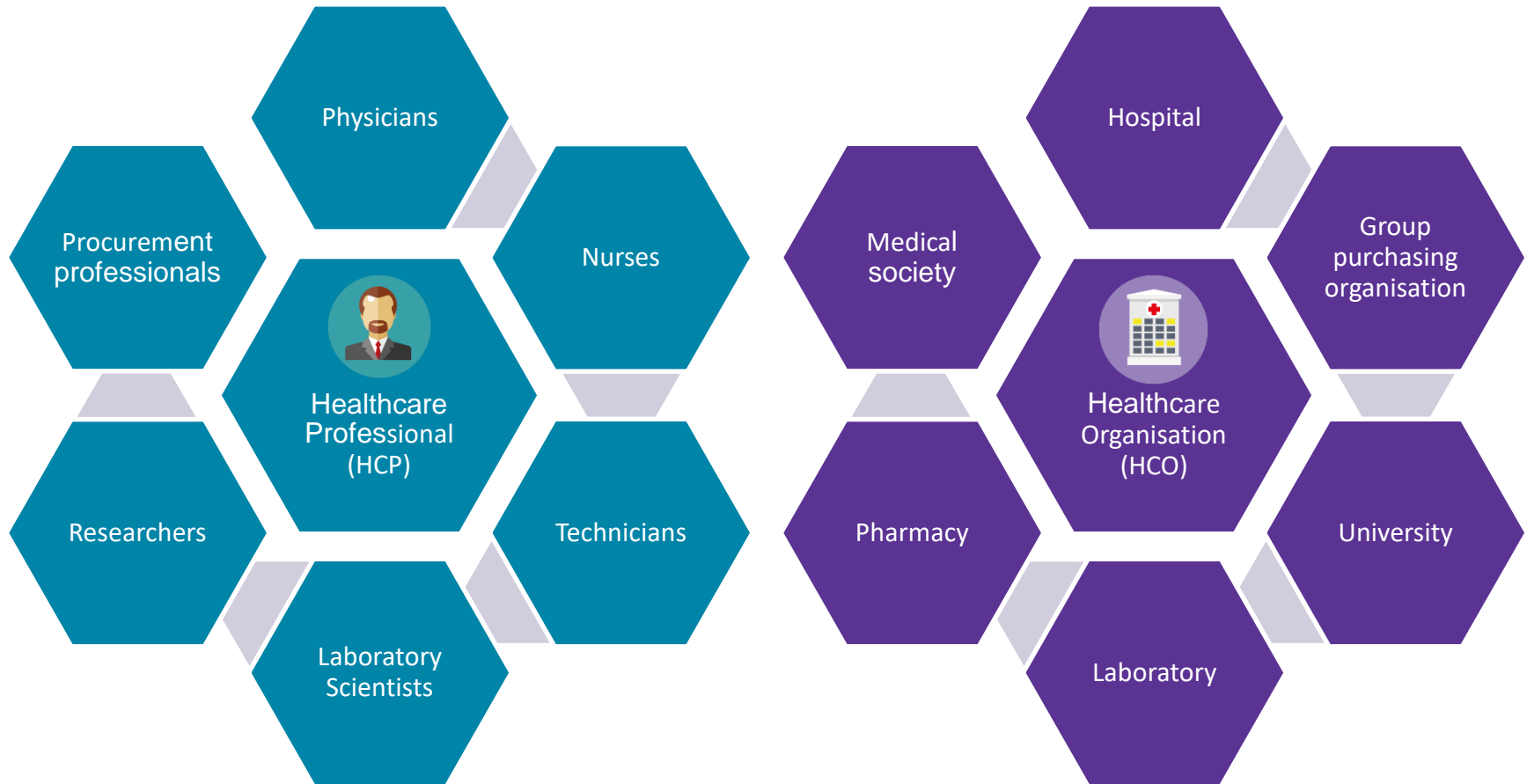
Healthcare  
defined  
supply

as part

Business Event.

coming from  
the patient  
the Organisa-  
tion documented

# Who is covered?





**Member Companies may enter into a commercial sponsorship arrangement with a PCO organising a Third Party Organised Educational Event independently of any HCO.**

However, such arrangements do not fall within the definition of Educational Grant as PCOs are for-profit organisations.

These sponsorship arrangements are therefore commercial in nature and Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code.

**In addition, where a Company provides funds earmarked for the advancement of genuine educational purposes to a PCO, acting independently of any HCO, all the Code provisions governing Educational Grants shall also apply.**

# Third Party Organised Educational Events



- Third Party Organised Educational Conferences

- Third Party Organised Procedure Training



- **Third Party Organised Educational Conference:**

- A genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare
- Consistent with relevant guidelines established by professional societies or organisations for such educational meetings

## Examples:

- Conferences organised by national, regional, or specialty medical associations/societies
- Hospitals
- Professional Conference Organisers (PCOs)
- Patients organisations or accredited continuing medical education providers

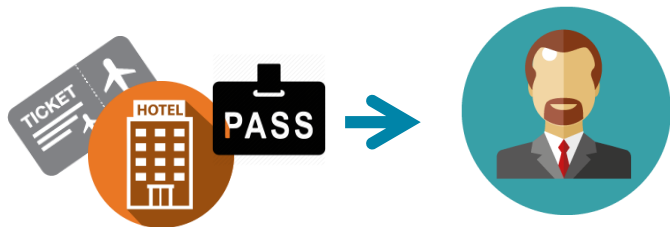


- Third Party Organised Procedure Training:
  - **Primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:**
    - Specific therapeutic, diagnostic or rehabilitative 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.



## “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”

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



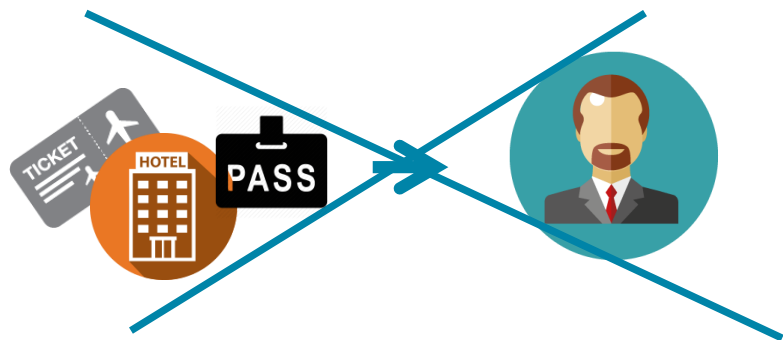
These include educational grants provided to support HCP participation to Third Party Organised Event. HCPs are selected by the receiver of the grant.

2016

2017

2018

“Direct sponsorship”



“Educational grants”



Stronger rules

# What are the requirements for support under the Code?



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
Until 31/12/2017: Is direct sponsorship of HCPs allowed?	YES	YES
As of 01/01/2018: Is direct sponsorship of HCPs allowed?	NO	YES

\*CVS approval will be required for the following types of funding starting in January 2018: Educational Grants, promotional activity (e.g. booths) and satellite symposia.

# General Criteria for Events

A common chapter on criteria for all events:



Event  
programme



Event location  
and venue



Guests



Reasonable hospitality



Travel



Transparency  
(Employer Notification)

# What does the Code require when it comes to travel?



- Any reimbursed/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?

Appropriate



Economy or standard class



Business class for flights longer than 5 hours

Not appropriate



Business class for flights shorter than 5 hours



First class

# How to determine what needs to be done under transparency principle?



Are there any applicable laws with regard to the disclosure or approval requirements associated with financial support of HCPs?

YES

National disclosure/approval requirements apply:

A Member Company to proceed in accordance with the requirements of the law

NO

Code transparency requirements apply:

A Member Company to require Employer Notification is made prior to the event

# Who is competent to assess the General Criteria for Events?



The Conference Vetting System (CVS) reviews the compliance of Third-Party Organised Educational Events (educational conferences and procedure trainings) with the MedTech Europe Code of Ethical Business Practice.

It issues a binding decision on the appropriateness for Member Companies to financially support eligible events through educational grants, promotional activity (e.g. booths) or satellite symposia.

# What is the Conference Vetting System?



## ELIGIBLE EVENTS

The nature of participation: meaning that delegates are coming from at least two or more of the

Countries covered by Medtech Europe

The geographic location: meaning all International and/or pan-European events organized within the geographic scope of Medtech Europe.

## WHO CAN SUBMIT?

MedTech Europe and Mecomed members

Conference Organisers (COs)

Medical Societies (MS)



# THE CONFERENCE VETTING SYSTEM REVIEWED CRITERIA





Support for Third Party Organised Educational Events:

- Support for HCPs participation
- Support for event

Scholarships and fellowships

Grants for public awareness campaigns

Can only be provided to HCOs



1

Grants will be publicly disclosed, ensuring increased transparency of the funds allocated to medical education

2

Conferences will still need to comply with specific requirements and with the Conference Vetting System

3

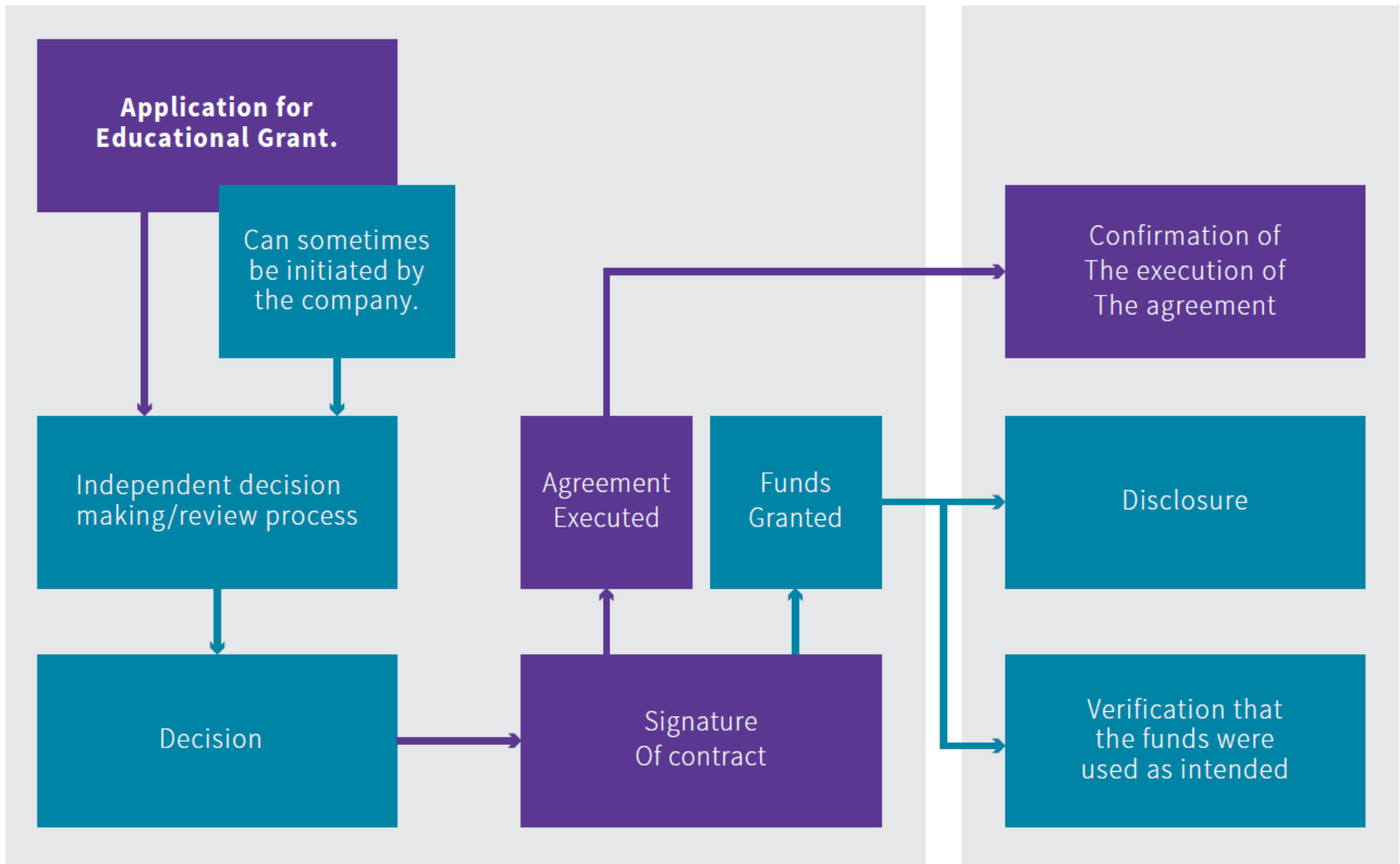
Grants can only be provided to legal entities but never individuals and will require a written contract & other related documentation

4

Companies will be able to define the type of recipients which should be eligible for the grant but not individual recipients

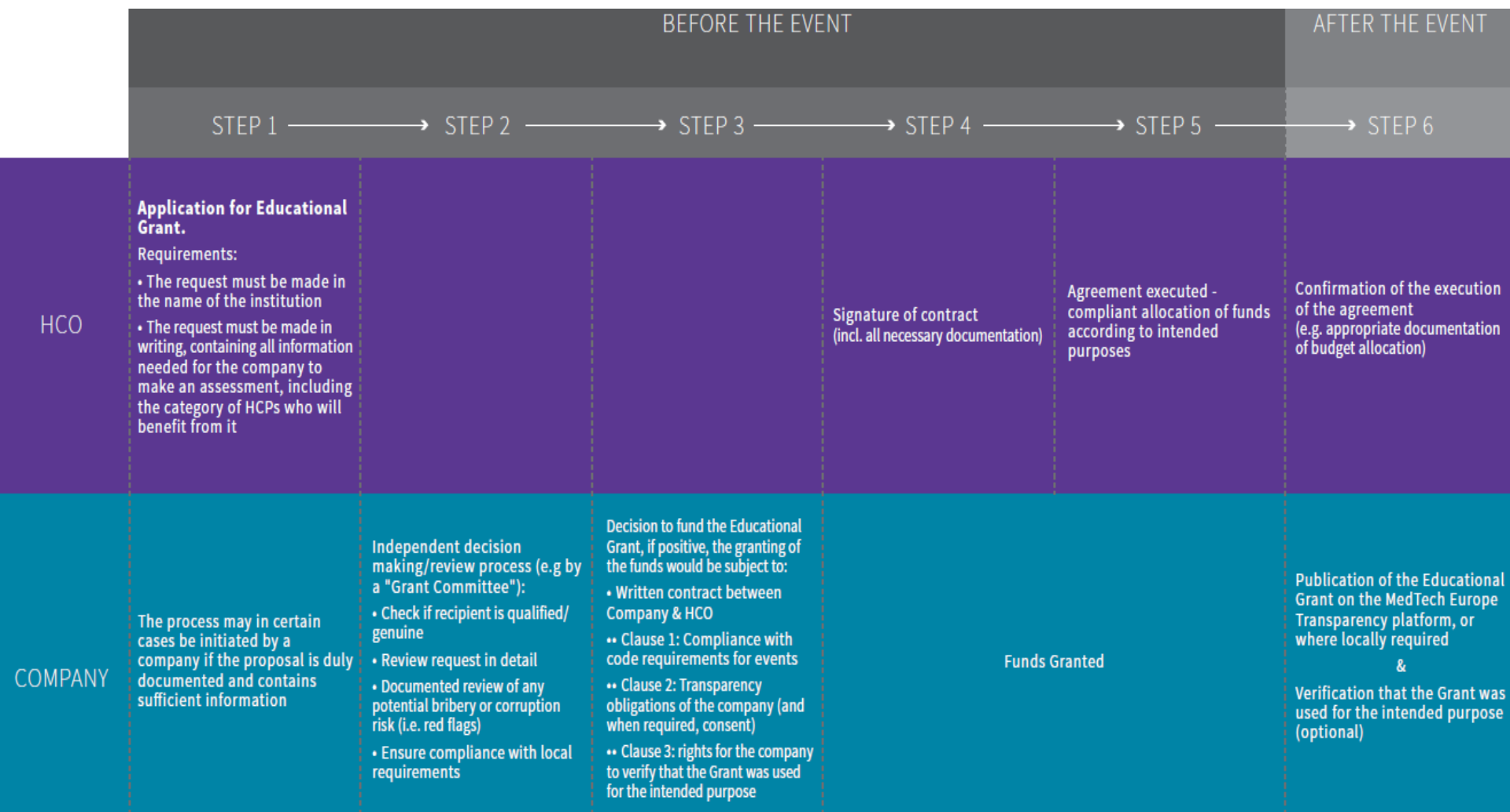
5

Companies must have an internal & independent process based on objective criteria to assess the grant requests



BEFORE THE EVENT

AFTER THE EVENT



# What are main 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

# Gifts and Educational Items

Member Companies may only provide educational items and/or gifts, if these are:

Compliant with applicable local requirements

Provided on exceptional basis

Related to the HCP's practice, or benefit patients, or serve a genuine educational function

Not provided in response to requests made by HCP

Inexpensive

Exception: if greater value, then can only be provided to an HCO

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



Never allowed



Food, 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



Cash or cash equivalence



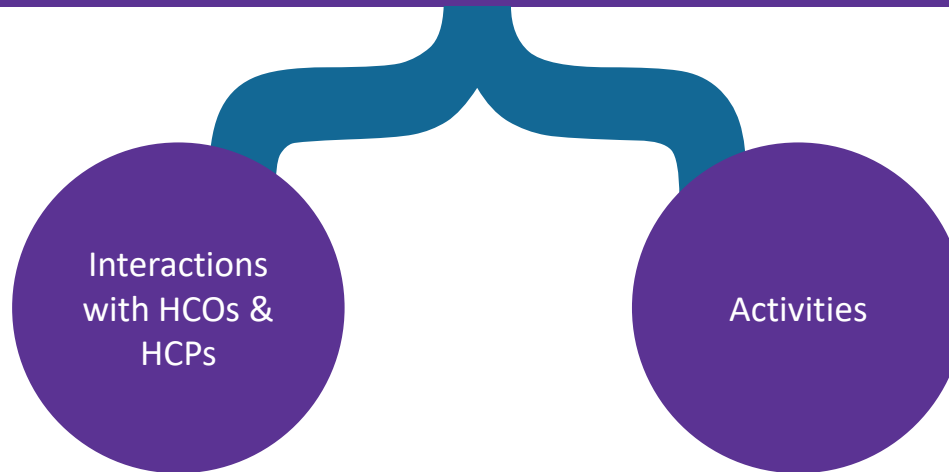
Part 4

# OTHER ASPECTS OF THE CODE



## MedTech Europe Geographic Area

- 1 Countries in the European Economic Area; and
- 2 Countries where Member Associations are located (e.g. Russia, Turkey, the Mecomed countries)



### IMPORTANT:

The Code sets out the minimum standards to Member across MedTech Europe Geographic Area.  
The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members.



EEA countries + those where Eucomed/EDMA have Full or Associate National Associations Members (MENA-Mecommed, Switzerland-FASMED, Turkey-ARTED and Russia-IMEDA)



Small countries also included in the MTE Geographical Area:

Liechtenstein  
Palestinian Authority  
Bahrain  
Malta  
Luxemburg



## Independent body

MedTech Europe  
Compliance Panel



## Procedural Framework

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



- Independent MedTech Europe Compliance Panel:



Nancy Russotto  
(Chair)



Arthur Muratyan



David Horne

## FOR MORE INFORMATION

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