MedTech Europe
Code of Ethical Business Practice

Version for Member Companies: October 2016

www.medtecheurope.org

MedTech Europe
from diagnosis to cure

Structure of the presentation

Ethics & Compliance

Why is it important?

New MedTech Europe Code

What are the main changes?

New MedTech Europe Code

How could the Code affect Healthcare Organisations (HCOs)?

New MedTech Europe Code

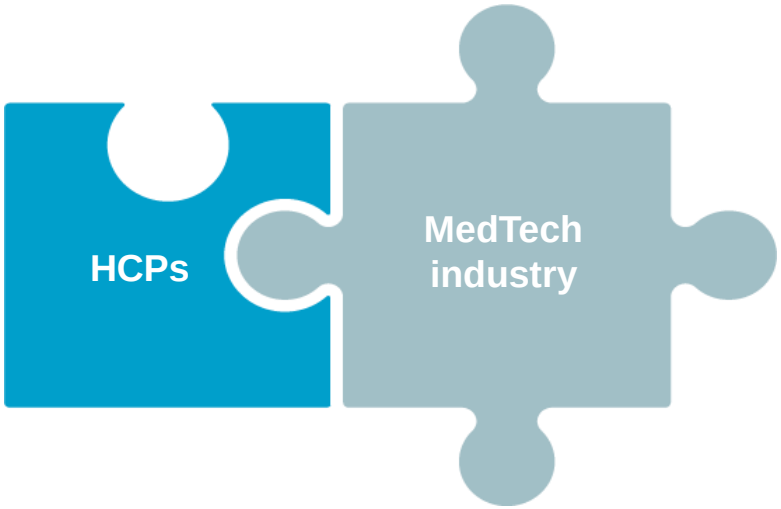
What relationship does MedTech Europe and HCOs have?

Part 1

WHY ETHICS IS IMPORTANT?

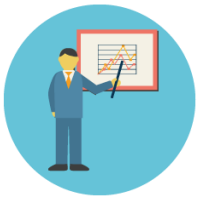
MedTech industry's special relationship with HCPs

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

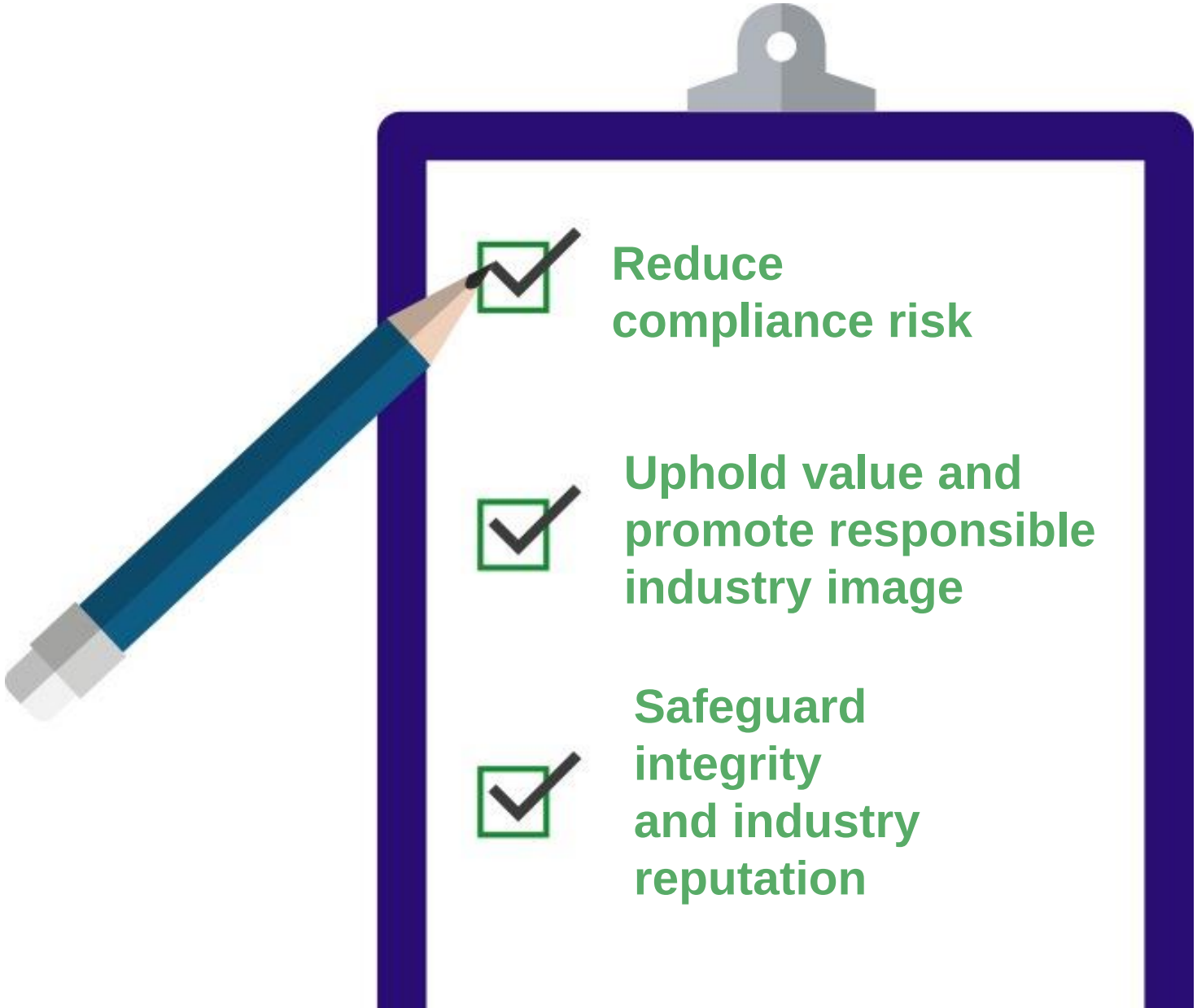
This close collaboration is key to develop innovative technologies to treat patients



HCPs are trained on how to use technologies

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

Industry's behaviour must respect high ethical standards & values



- Reduce compliance risk
- Uphold value and promote responsible industry image
- Safeguard integrity and industry reputation

Part 2

WHAT ARE THE MAIN CHANGES?

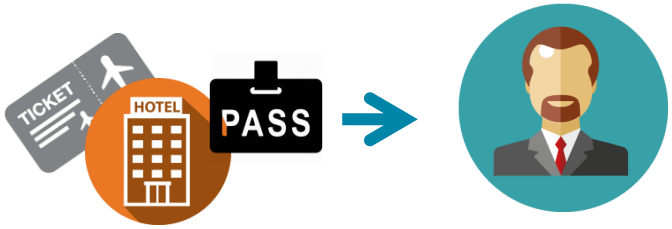
Six biggest changes

1. **Phasing out direct sponsorship**
2. **Transparency of educational grants**
3. **Common chapter on general criteria for events**
4. **New chapter on demonstration products and samples**
5. **Agreed definitions**
6. **Common independent enforcement mechanism**

Two types of industry support to Third Party Organised Events

"Direct sponsorship"

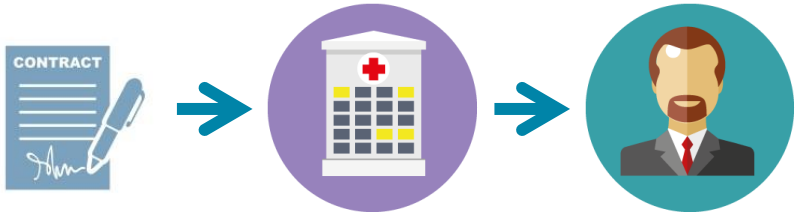
Companies select individual HCPs and **financially support their participation** to Third Party Organised Events.



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.**

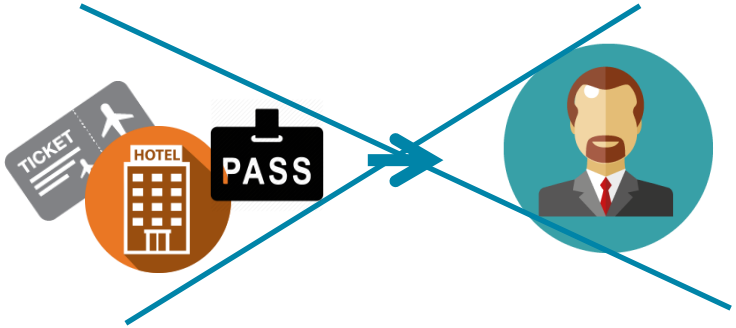


These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**

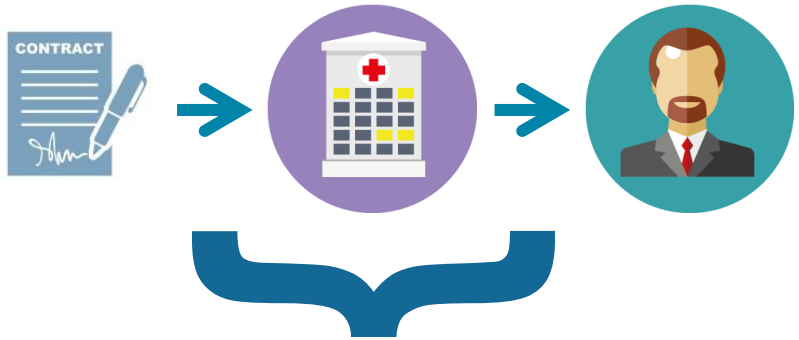
Phasing out of direct sponsorship

2016 2017 2018

“Direct sponsorship”



“Educational grants”



Stronger rules

How the rules for educational grants will change

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

Transparency: What? When?

Educational Grants to support Third Party Organised Events

- Support for these Events
- Support for HCP Participation

Other Educational Grants to HCOs

- Scholarships & Fellowships
- Grants for Public Awareness Campaigns

2017 data as of 2018

Chapter on general criteria for all events

New Chapter


9
Demonstration Products and Samples
CODE
1. General Principles
Member Companies may provide their own products as Demonstration Products and/or Samples (see the Glossary) at no charge in order to enable Healthcare Professionals and/or Healthcare Organisations (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.
Demonstration Products and/or Samples may be either single- or multiple-use products. Member Companies may also provide products from another company in conjunction with the Member Company's own Demonstration Products and/or Samples on an exceptional basis if those
QUESTIONS AND ANSWERS
CODE
other company's products are required in order to properly and effectively demonstrate, evaluate or use the Member Company's products, e.g. computer hardware and software produced by a company other than the Member Company.
Provision of Demonstration Products and/or Samples must not improperly reward, induce and/or encourage Healthcare Professionals and/or Healthcare Organisations to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.
Member Companies shall in all cases maintain appropriate records in relation to the provision of Demonstration Products and/or Samples to Healthcare Professionals and/or Healthcare Organisations, for example recording proof of delivery for any Demonstration Products and/or Samples provided and receipt of return for multiple-use Demonstration Products and/or Samples. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products and/or Samples no later than the time of the supply. The disclosure to Healthcare Professionals and Healthcare Organisations shall be in writing.
This Chapter is limited to the provision of Demonstration Products and/or Samples and related services at no charge and is not intended to apply to provision of products or related services under any other arrangements, for example (but not limited to) provision within the framework for clinical trials and/or other research or commercial supplies by way of rebates or pricing incentives in a public procurement context.
2. Demonstration Products (Demos)
Member Companies may provide examples of their products to Healthcare Professionals and/or Healthcare Organisations in the form of mock-ups (such as unused single use products) that are used for Healthcare Professionals and patient awareness, education and training. For example, a Healthcare Professional may use a Demonstration Product to show a patient the type of technology which will be implanted in the patient or may use the Demo to train other Healthcare Professionals in the use of the product.
QUESTIONS AND ANSWERS

Definitions will be aligned in the new Code

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

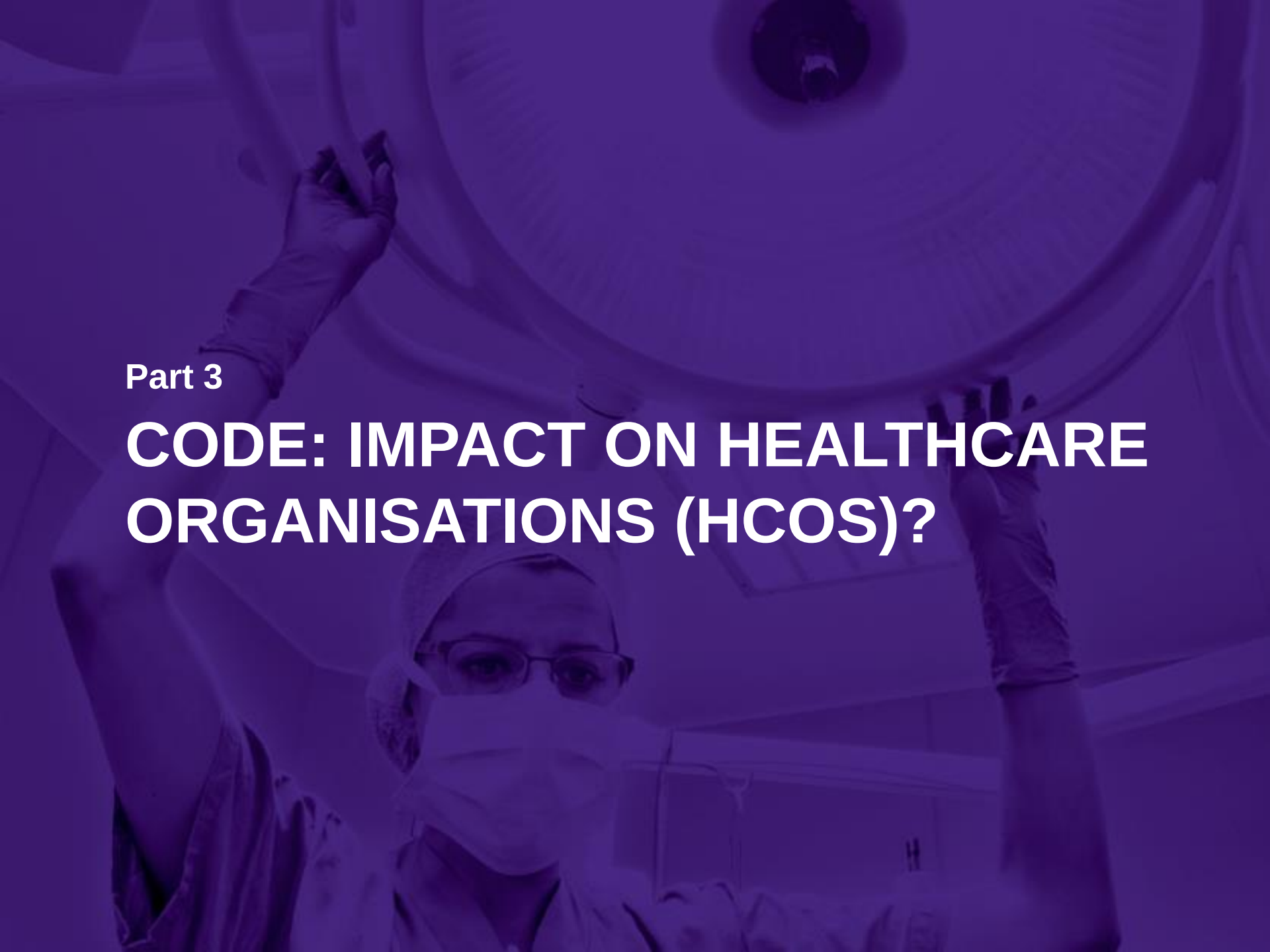
Common enforcement mechanism

- **Independent MedTech Europe Compliance Panel:**

Nancy Russotto
(Chair)

Arthur Muratyan

David Horne



Part 3

CODE: IMPACT ON HEALTHCARE ORGANISATIONS (HCOS)?

Scope – What are HCOs?

- **Healthcare Organisation (HCO):** means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services

Scope – What about PCOs?

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. For example, if a Company provides funding to a PCO to fund HCP delegate places and expenses at a Conference, such Event, where applicable, must have CVS approval and the Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.

How the rules for educational grants will change

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

1. Public disclosure of Educational Grants

Definition of Educational Grants?

- Provision of funding, products or other in kind support to an HCO by or on behalf of a Company on a restricted basis for use solely for the support and the advancement of genuine medical education of HCPs, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Company is interested and/or involved (i. e. sponsorships , Fellowships, Grants for public awareness campaigns)

Publication where?

Unique European website (*N.B.:* if national transparency rules in place, no double reporting).

By whom? Reporting by companies.

When? 2018 (of 2017 data)

2. Compliance with Events requirements, incl. CVS

No/minor changes of the existing criteria – *CVS* needs to approve congresses before any support provision*

- **Image & Reputation**: How would that support be perceived by the public/authorities?
- **Event programme** directly related to the medical practice of HCPs
  - No social, sporting and/or leisure activities or other forms of entertainment
- **Location and venue** should be in or near a city or town which is a recognised scientific or business centre
  - No luxurious, tourist/holiday-oriented, entertainment location & venues
  - No events during touristic season
  - No locations that are hard to access or that are not centrally located
- **No guests:** No facilitation or payment for meals, travel, accommodation or other expenses for guests of HCPs
- **Reasonable hospitality and travel** tied in to the duration of the event
  - No top category or luxury hotels for accommodation
  - No luxurious dinners
  - Only economy or standard class for travel by plane unless the flight time is longer than 5 hours
- **Transparency**: Compliance with all disclosure or approval requirements and at the minimum Employer Notification.

* ***CVS = Conference Vetting System – more on www.EthicalMedTech.eu***

3. Documentation principle

- Grants can only be given to an HCO (never an HCP)
  - The payment (or provision of other support) by always be made out in the name of the HCO
  - Grants cannot be provided in response to requests made by HCPs unless the HCP is an employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the HCO.
- The grant request needs to be done in writing to the Company, and may include:
  - information on the HCO (e.g. legal status)
  - If previous grants: Information how previous funds have been used in accordance to the terms and conditions of the previous Grant agreement.
- Written Grant agreement signed by both parties before provision of any funds.
- Records of everything should be kept.

4. Identification of the final recipients of the Grant

Principle:

- Companies will be able to define in the Grant agreement with the HCO, the type of "final" recipients/beneficiaries (e.g. Romanian ostomy nurses) which should be eligible for the grant but not individual recipients/beneficiaries (e.g. Dr. X).

Practically:

- HCOs, in particular scientific societies, and PCOs will need to consider how to proceed for this selection
- Some HCOs reported that they constituted a database are considering adding objective criteria such as submission of an abstract.

5. Independent process within the companies

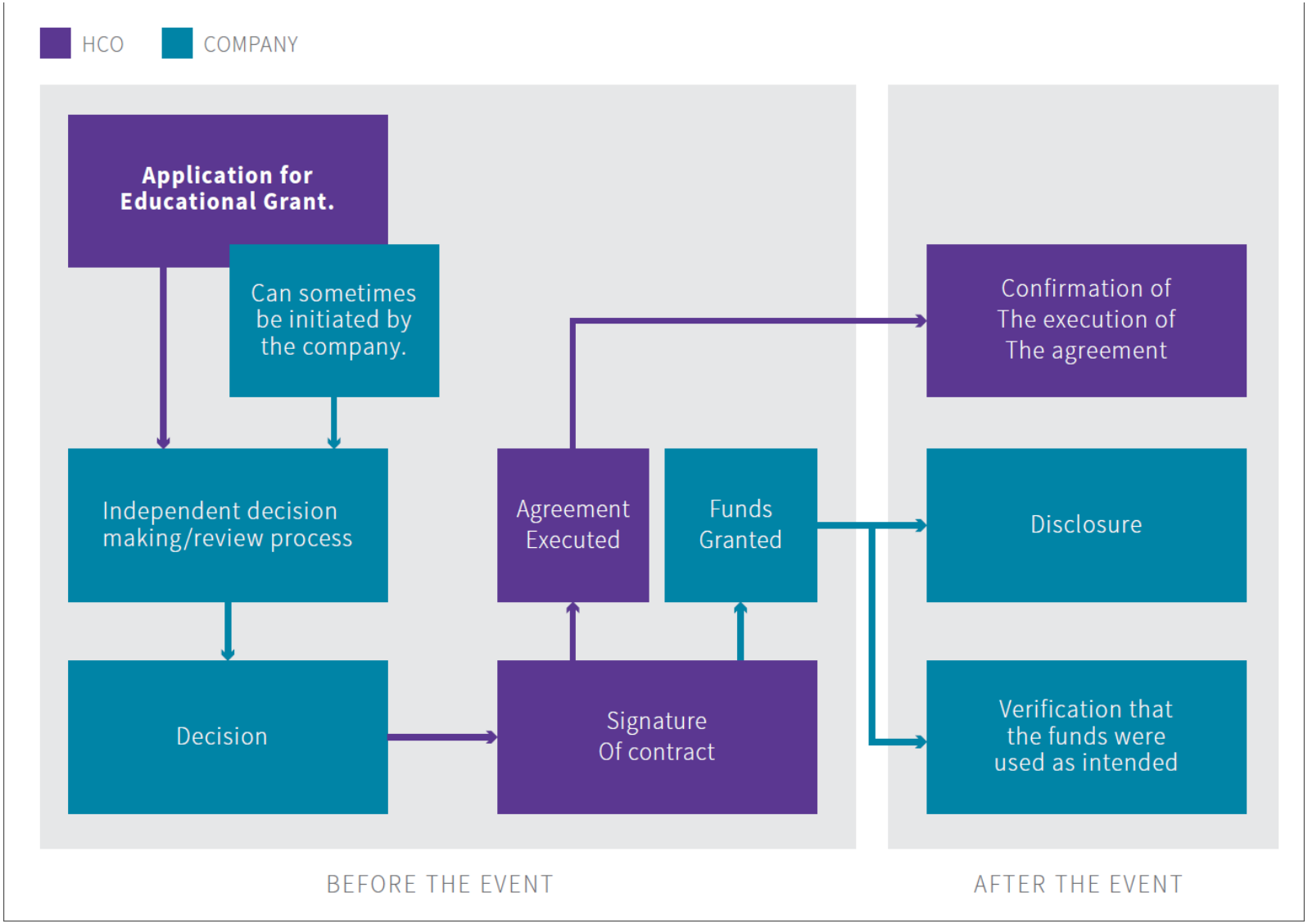
Principle:

- Companies must have an internal & independent (i.e. not primarily sales-driven) process based on objective criteria to assess the grant requests.

Practically:

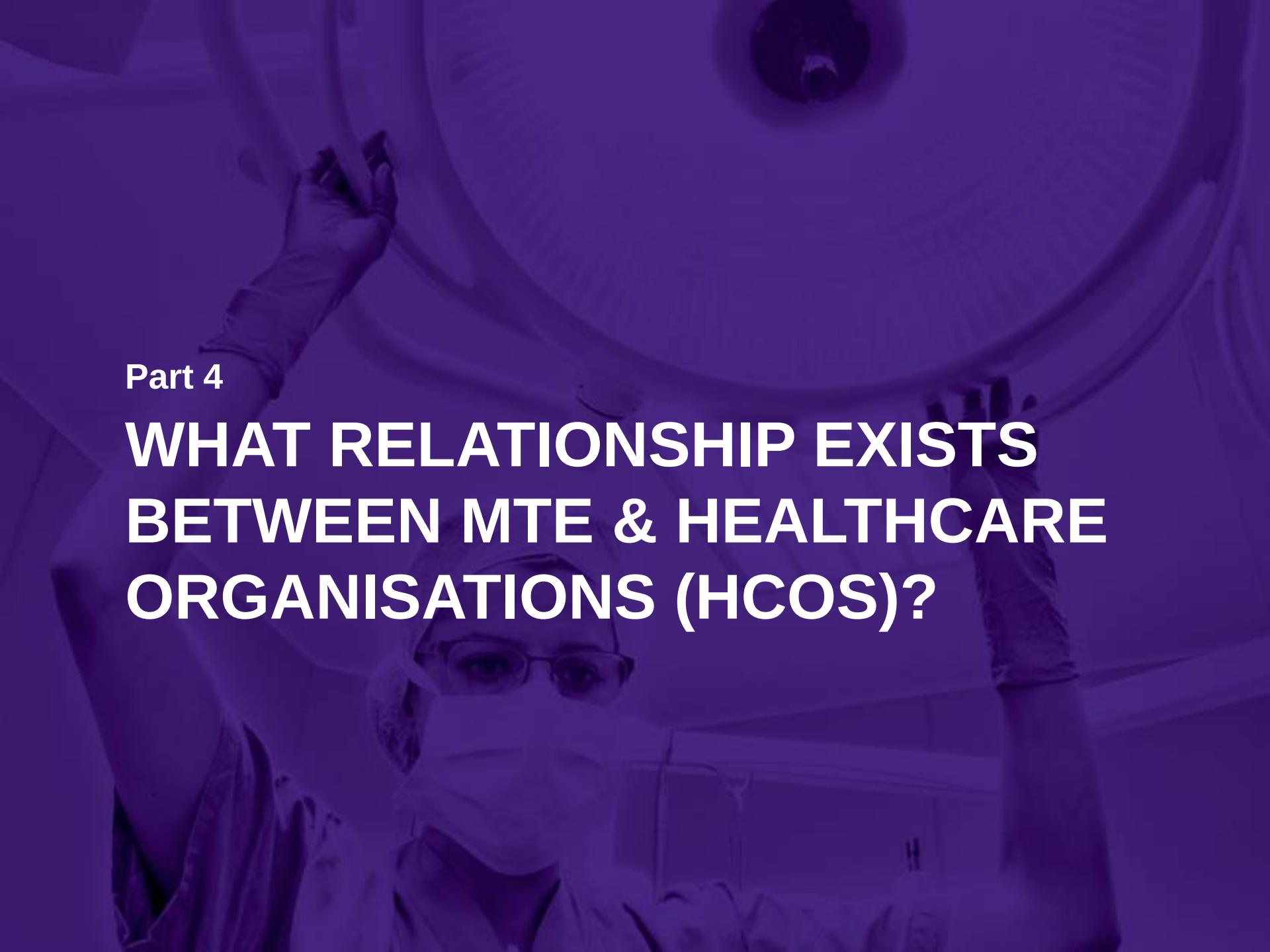
- The HCO can make a written request, containing sufficient information to permit an objective evaluation of the request to be carried out by the Company, to a Company.

Flow chart – Educational Grant process



Miscellaneous – Feedback from the Companies

- Many companies have been providing grants in the past, and will continue to do so, and the process changes are not major.
  - All companies are reviewing and updating if necessary the process to decide on grant allocation
  - All companies run some type of “due diligence” check of the grant recipient
  - Business divisions allocate funds for medical education/grants at the end of each financial year
- Timing of phase out of direct sponsorship varies greatly from company to company, up to 1/01/2018
- Promotion
  - Sales teams still are able to promote fund availability to customers and possibly may make suggestions to potential beneficiaries on how to apply
  - Some companies display educational grant submission forms on their website



Part 4

WHAT RELATIONSHIP EXISTS BETWEEN MTE & HEALTHCARE ORGANISATIONS (HCOS)?

Some history…

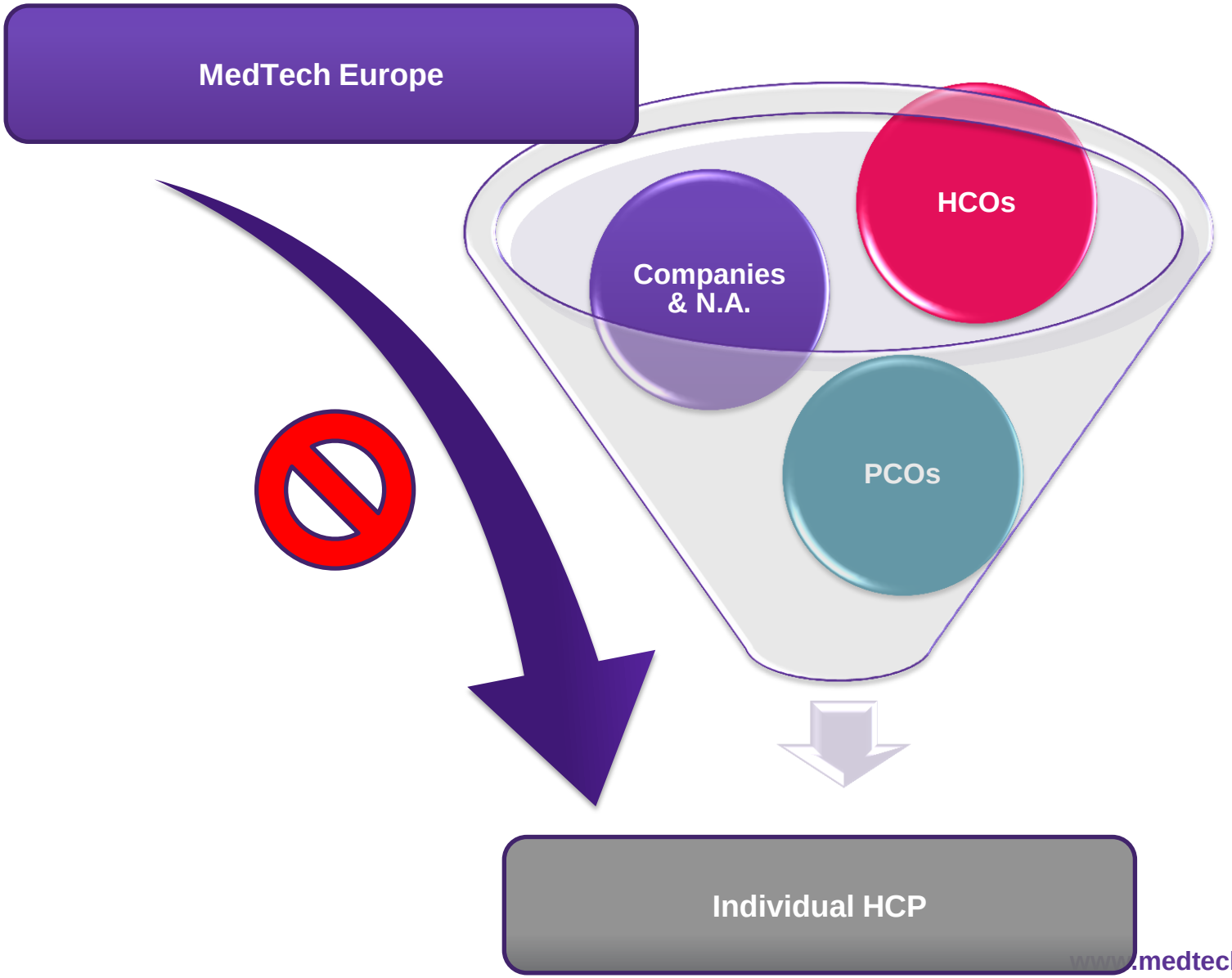
- **Until 2014** – Broader discussions driven by Sector Groups (e.g. Ortho, CV, Ophthalmology, Diabetes)

- **2014** – systematic outreach on potential changes of industry code of ethics. Focus on **bilateral discussions** to collect concerns and feedback.

- **2015** *(until vote Dec. 2015)* – MTE multi-stakeholder dialogue platform: **Advisory Group on the Future of Medical Education**

- **2016**
  - Upon request of societies, MTE re-engaged in **bilateral discussions** to provide technical details
  - InfoDay with **Advisory Group** (incl. new members) on 21/09/2016.

MedTech Europe's limitations



Summary of some of the key concerns of HCOs

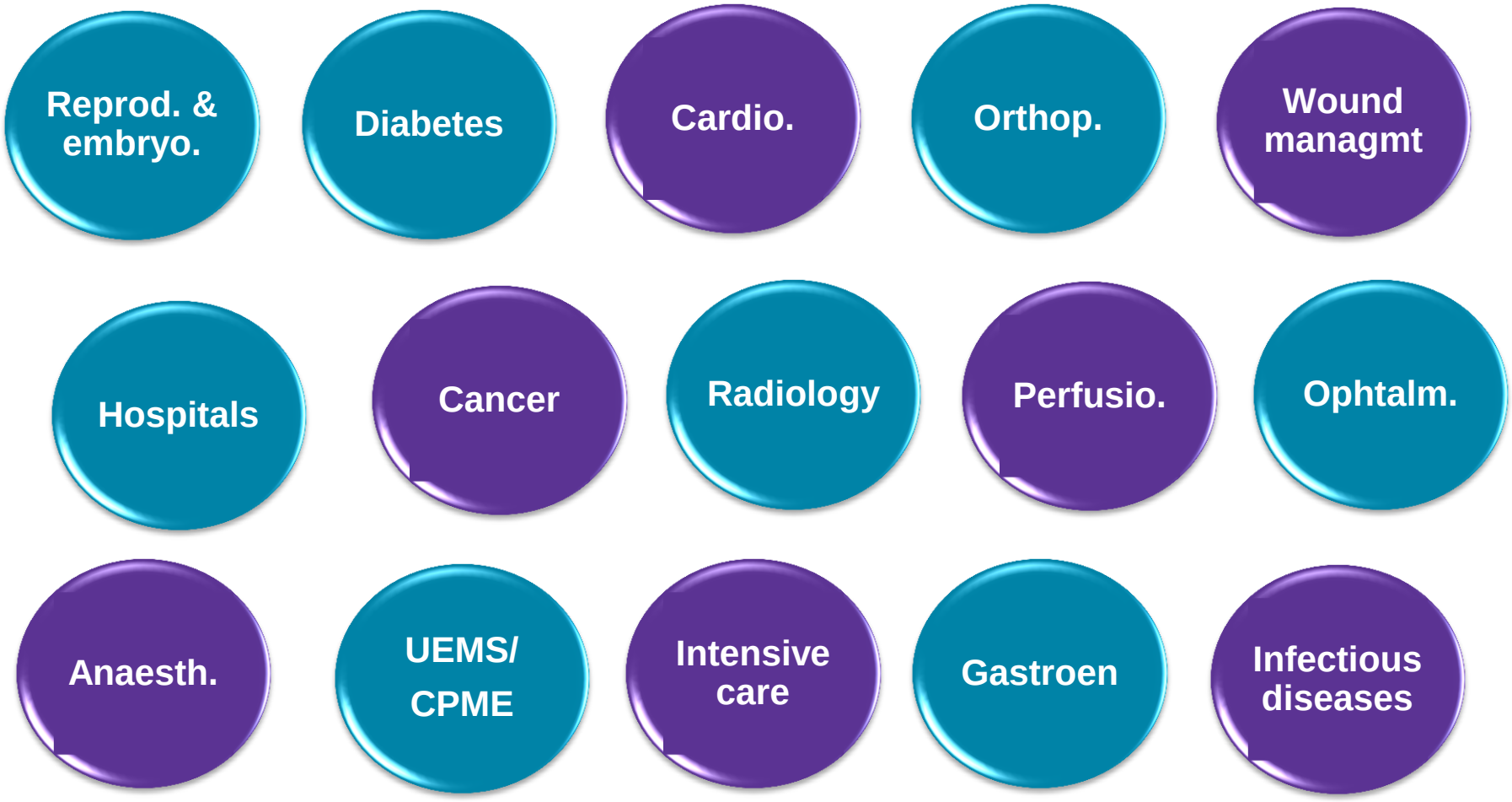
General concerns

- Medical education of HCPs at stake – vulnerable HCPs/countries
- Concern that industry funding to societies may decrease
- Involvement & funding of other actors in medical education (e.g. hospitals, PCOs, companies)

Technical concerns

- Which HCPs to invite? Which database? What selection process?
- How to reach the HCPs?
- Travel & accommodation management – infrastructure/HR
- Timing alignment (planning vs. funding)
- Differentiation company-event vs third-party organised event not well understand

HCOs present at the last Advisory Group meeting (21/9)



FOR MORE INFORMATION

Aline Lautenberg

General Counsel – Director
Legal & Compliance

a.lautenberg@medtecheurope.org

+32 2 761 22 82

Pablo Rojas Abad

Legal & Compliance Assistant

p.rojas@medtecheurope.org

+32 2 300 96 41

Clarisse Aillet

Medical Education consultant

C.Aillet@medtecheurope.org

+32 487 53 92 65