

MedTech Europe Code of Ethical Business Practice

HOPE meeting , 6th April 2016

Structure of the presentation



The revision of the codes

Why is it
necessary?



The changing environnement

Why the medical
education
sponsorship
system should
be revised ?



The way forward

A transparent
commitment to
fund medical
education



Medical societies and industry funding

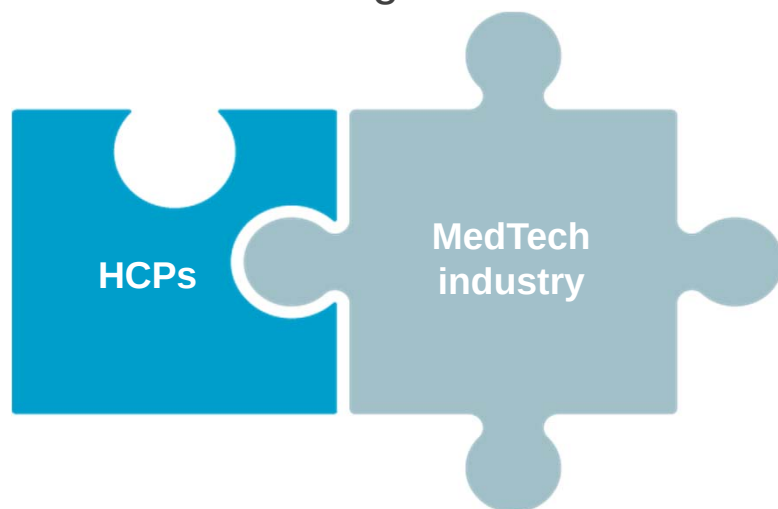
How the status
quo is
changing?

Part 1

WHY A NEW CODE?

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

Rationale for the revision of the EDMA & Eucomed Codes of Ethics



Current codes - drafted in **2007/2008** - are **dated** and include **inconsistencies** and **contradictions**



An updated, joint code needs to **reflect how society has evolved**



The existence of **two codes** creates **confusion**; there is a need to introduce **clarity to the rules** applicable to the industry

The adoption of the Code: an important move forward

- Finalisation of a 3 years process of consultation and involvement of key stakeholders in a continuous effort to reinforce high business ethical standards.
- Adoption of a common and updated framework for EDMA and Eucomed.
- Adoption of common business ethical standards across Europe for the Medical Technology industry to protect our needed interaction with HCPs and HCOs but also to:



Reduce compliance risk



Safeguard integrity and industry reputation



Uphold value and promote responsible industry image

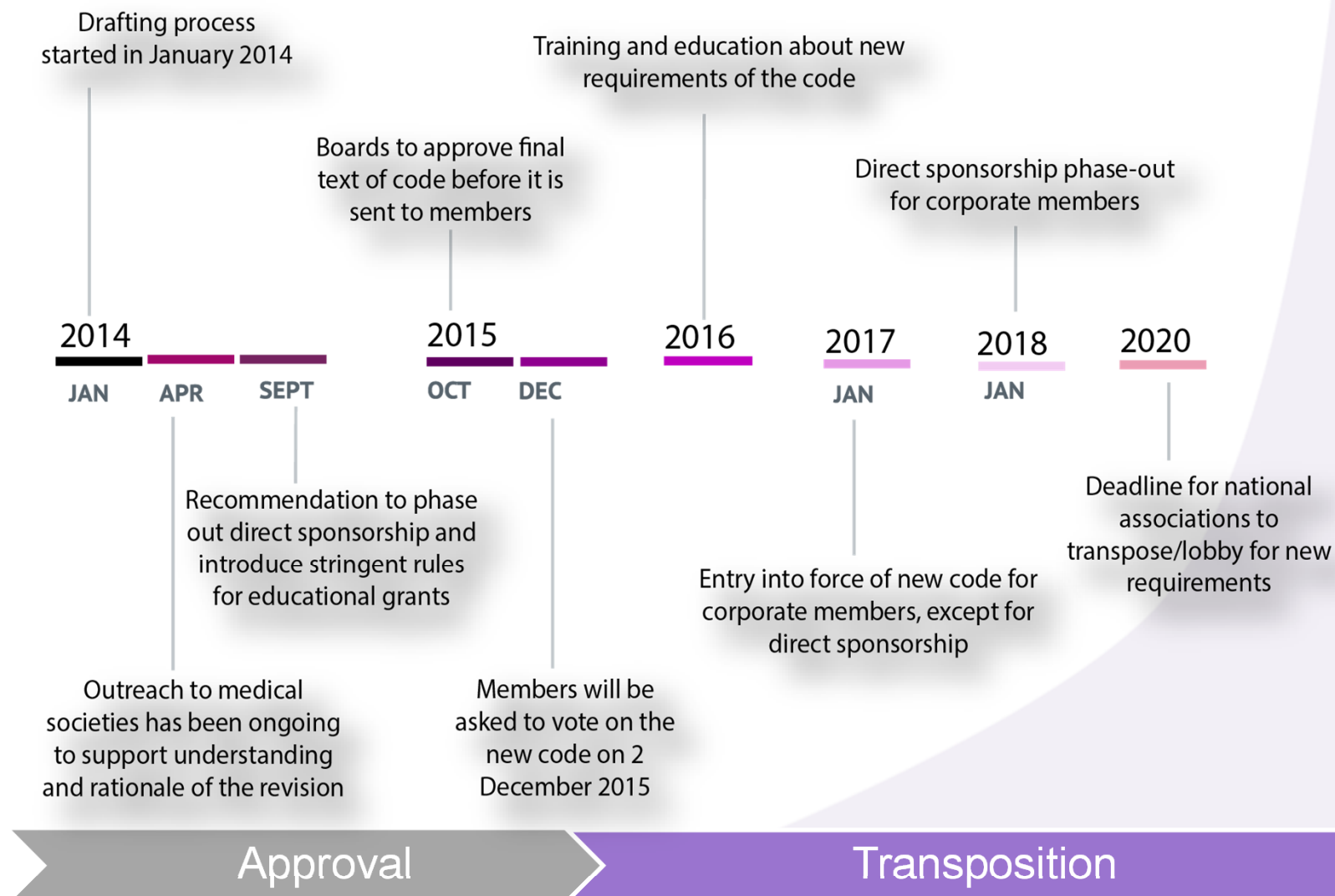
MedTech Europe Code of Ethical Business Practice

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www.medtecheurope.org

Approval and transposition process



Part 2

THE CHANGING ENVIRONMENT:

***WHY THE MEDICAL EDUCATION
SPONSORSHIP SYSTEM SHOULD
BE REVISED ?***

Emerging trends require industry to re-asses its approach to direct sponsorship and educational grants



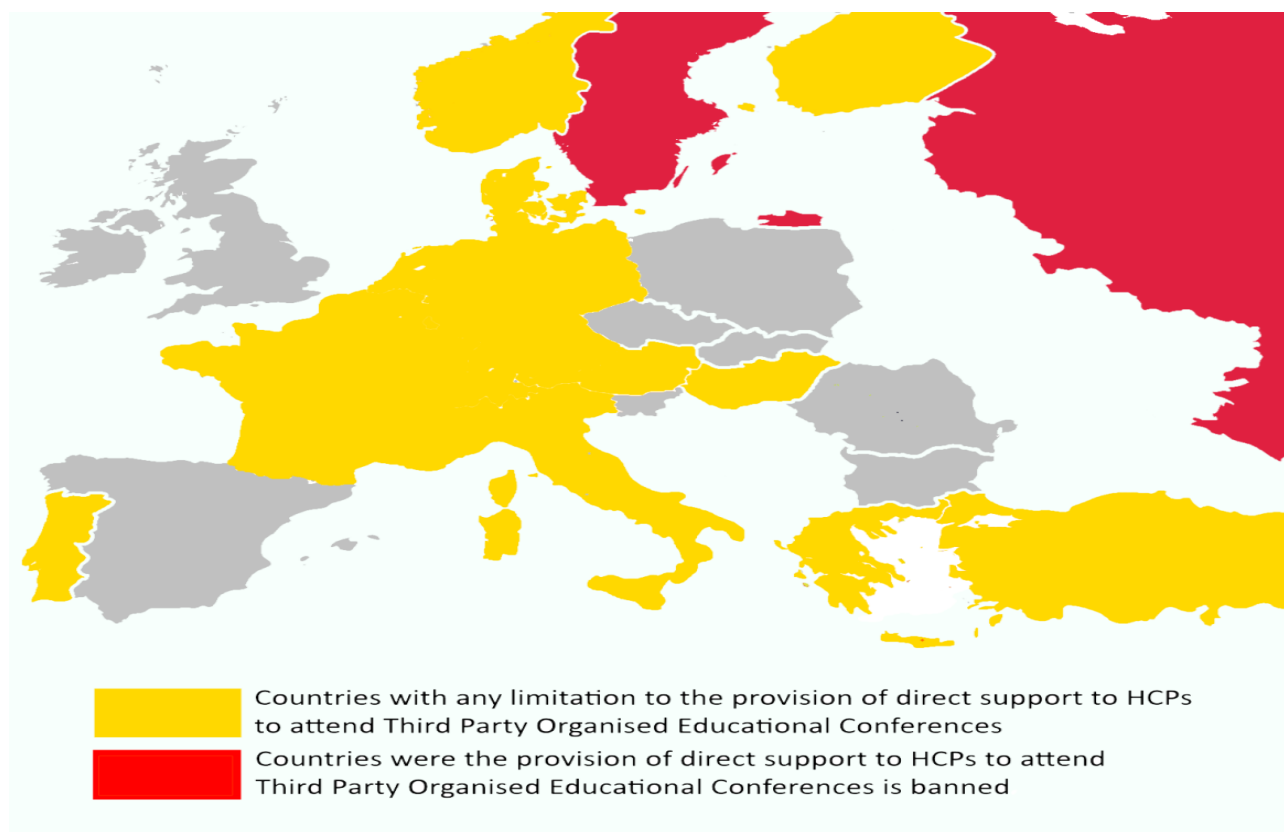
Relationship between industry-HCPs **under increasing scrutiny** by regulators, press and the general public

Public opinion questions whether **medical judgement** is **unbiased**

Increasing amount of court cases **cost industry** hundreds of millions of Euros

Many countries have either **restricted or banned** direct sponsorship altogether

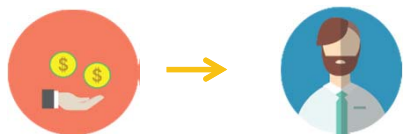
More and more countries are regulating the relationship with HCPs



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.**

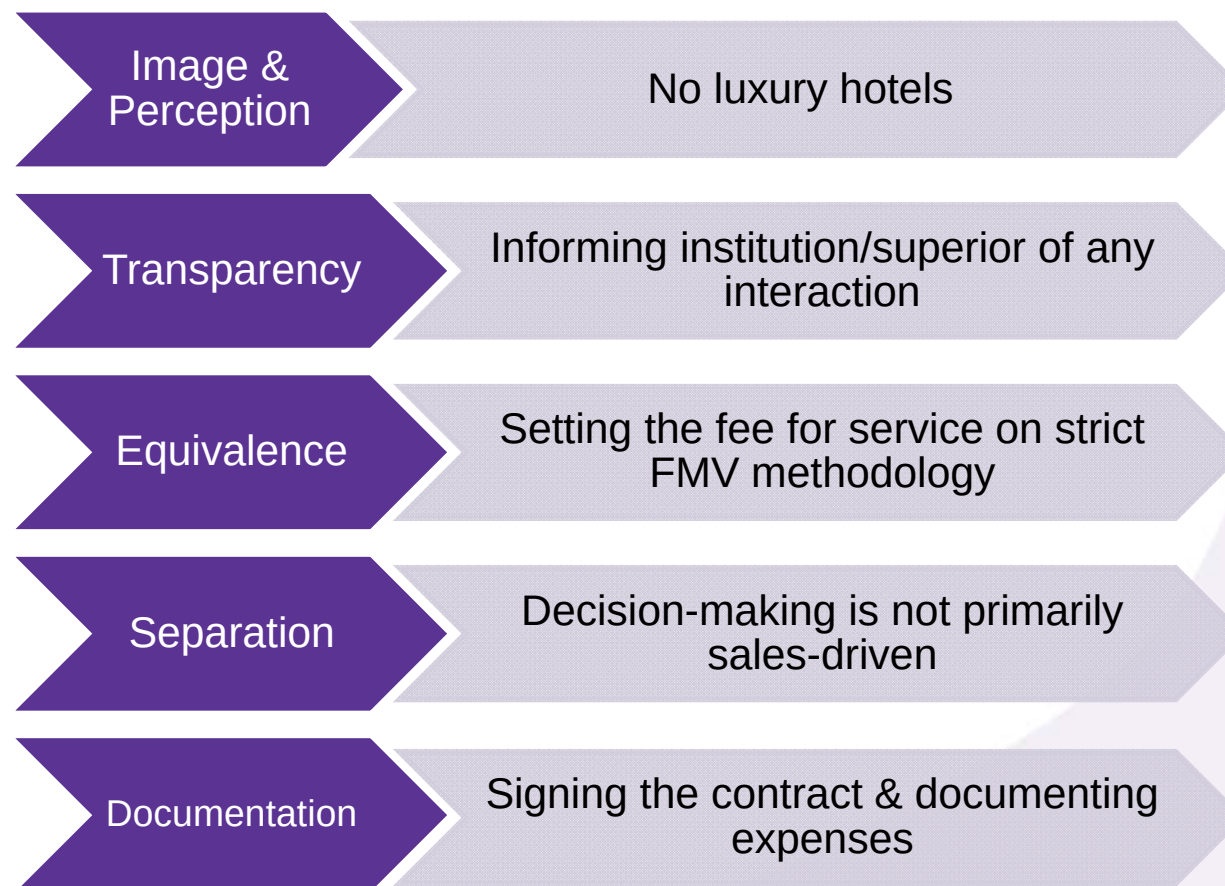


These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**

Part 3

THE WAY FORWARD: *A TRANSPARENT COMMITMENT TO FUND MEDICAL EDUCATION*

Main principles



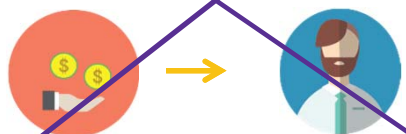
Main changes

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**

Phasing out of direct sponsorship

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

Transparency: Where?

- www.ethicalmedtech.com



WELCOME TO EUROPE'S MEDTECH CONFERENCE VETTING SYSTEM

AboutUs

EthicalMedTech is a platform, supported by [Eucomed](#), dedicated to ethics and compliance projects in the European MedTech industry.

The Ethical MedTech platform hosts the [Conference Vetting System](#) (CVS), a unique initiative in the healthcare industry. This independently managed system reviews the compliance of third-party educational conferences with the Eucomed Code of Ethical Business Practice (the "Code") to determine the appropriateness for companies which are members of Eucomed and members of the national associations affiliated with Eucomed to sponsor Healthcare Professionals to participate in such conferences.

CVS aims to simplify and centralise decision-making for Eucomed members by establishing a single assessment procedure based on a set of criteria provisioned in the [Eucomed Code of Ethical Business Practice](#). It also aims to harmonise the interpretation of the Code across the European medical technology industry with the goals of greater consistency and transparency in industry behaviour.

 CODE OF ETHICAL BUSINESS PRACTICE	 SUBMIT CONFERENCE	 UNDER ASSESSMENT
 ASSESSMENT CRITERIA	 SUBSCRIBE TO THE NEWSLETTER	 LOOK UP CONFERENCE

Chapter on general criteria for all events



New Chapter

Chapter 9: Demonstration Products and Samples

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 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.

Definitions will be aligned in the new Code

PART 3: Glossary and Definitions

- **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.

Common Enforcement mechanism

- **Independent MedTech Europe Compliance Panel:**

- Nancy Russotto (Chair)
- Arthur Muratyan
- David Horne

