MedTech Europe
Code of Ethical Business Practice

BeMedTech InfoDay, 27 March 2017

www.medtecheurope.org

MedTech Europe
from diagnosis to cure

Structure of the presentation

Rational

Why
a new Code?

New MedTech Europe Code

What are
the main
changes?

Additional considerations

What about
BeMedTech?

Discussion

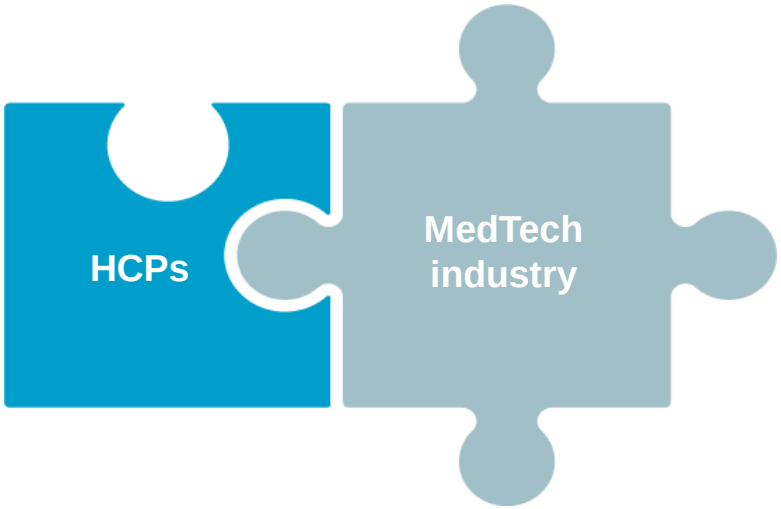
Q&A session
&
Further
information

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.



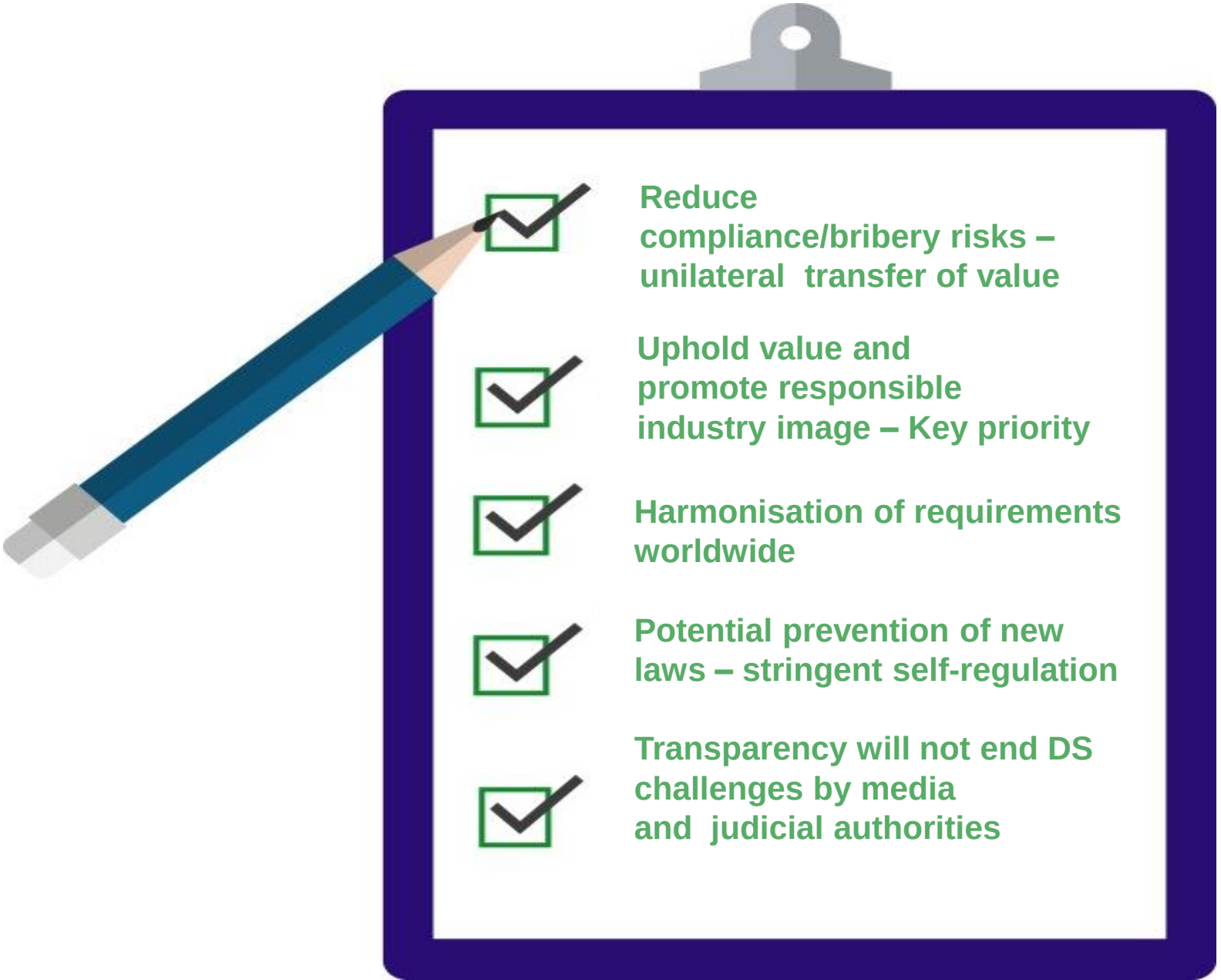
HCPs actively participate in the research to develop new technologies

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

Industry's behaviour must respect high ethical standards & values



- Reduce compliance/bribery risks – unilateral transfer of value
- Uphold value and promote responsible industry image – Key priority
- Harmonisation of requirements worldwide
- Potential prevention of new laws – stringent self-regulation
- Transparency will not end DS challenges by media and judicial authorities

Part 2

WHAT ARE THE MAIN CHANGES?

Six biggest changes

Phasing out direct sponsorship

Transparency of educational grants

Common chapter on general criteria for events

New chapter on demonstration products and samples

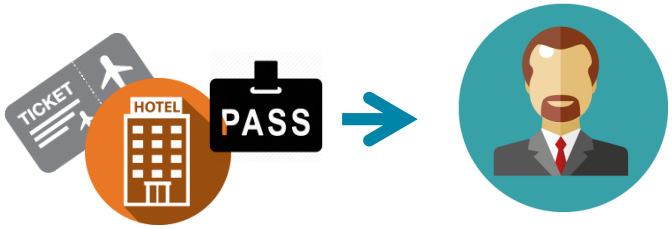
Agreed definitions

Common independent enforcement mechanism

Two types of industry support to Third Party Organised Events

"Direct sponsorship"

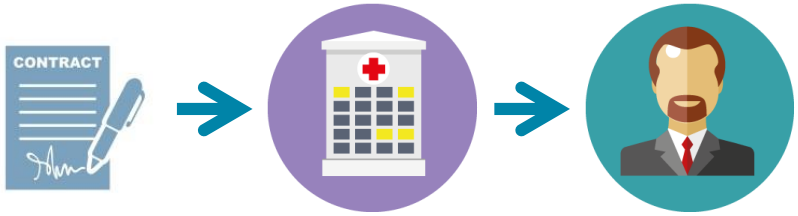
Companies select individual HCPs and **financially support their participation** to Third Party Organised Events.



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.**

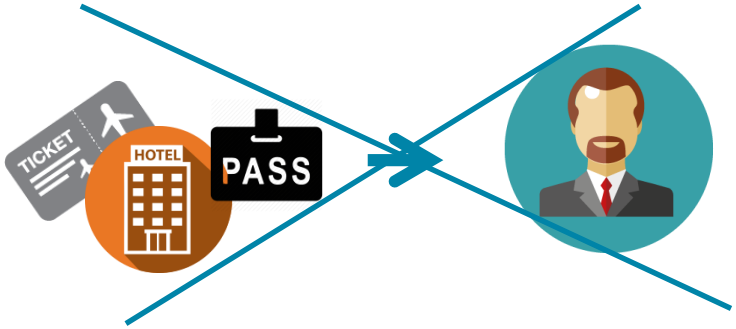


These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**

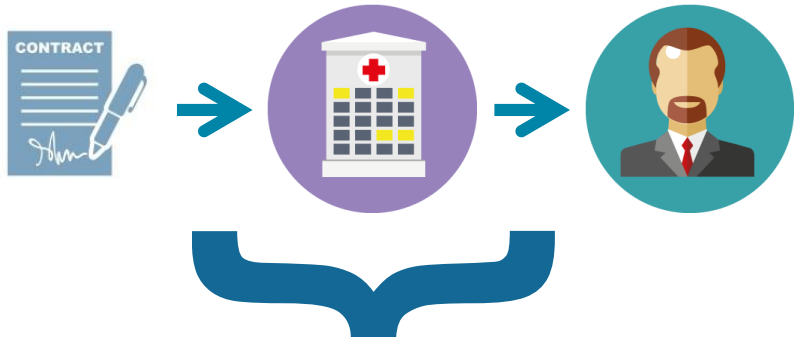
Phasing out of direct sponsorship

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

What are the 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

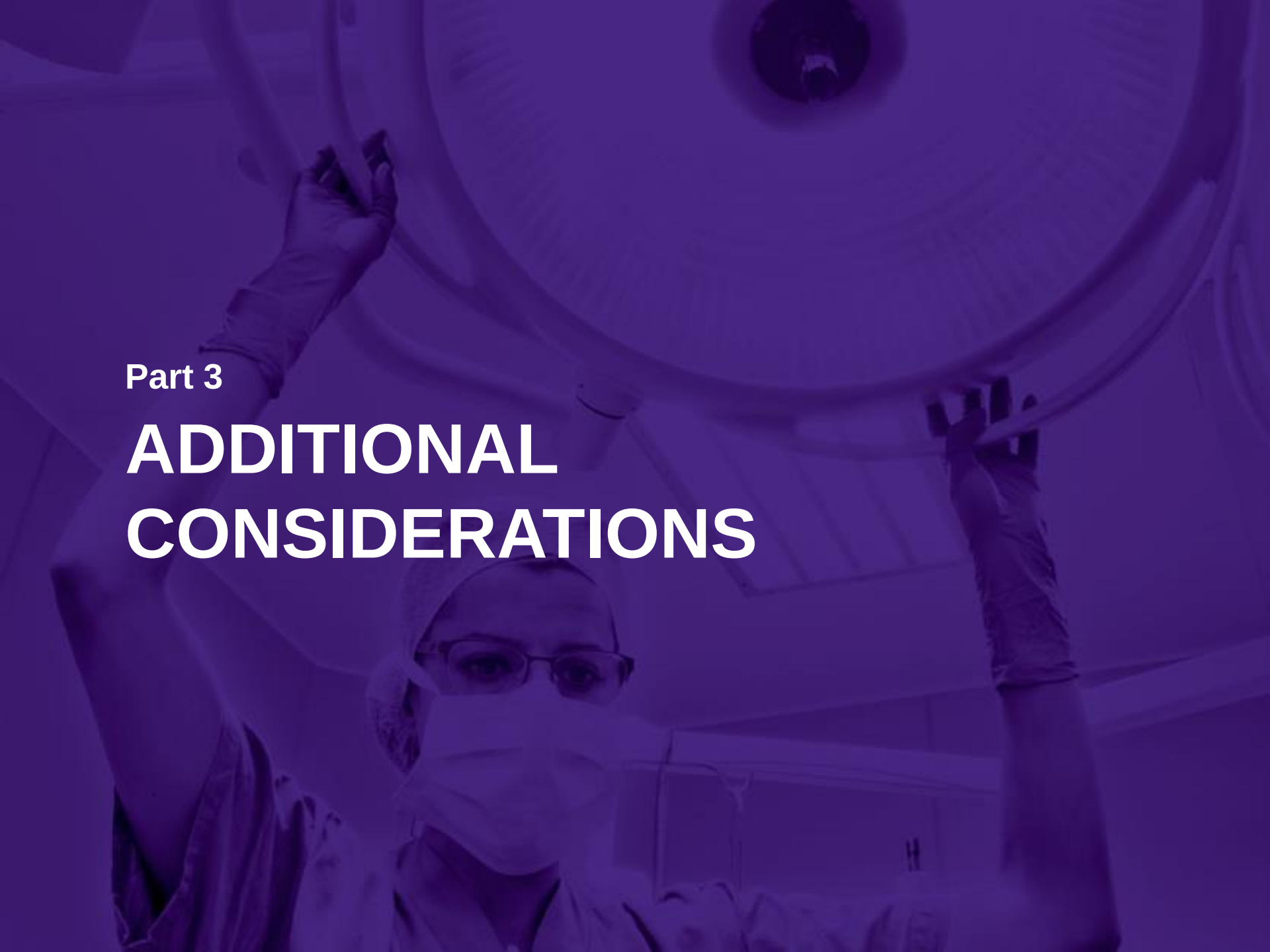
Transparency: What? When? Where?

Educational Grants to support Third Party Organised Events	Other Educational Grants to HCOs
• Support for these Events • Support for HCP Participation	• Scholarships & Fellowships • Grants for Public Awareness Campaigns

2017 data as of 2018

MedTech Europe platform (www.ethicalmedtech.eu)*

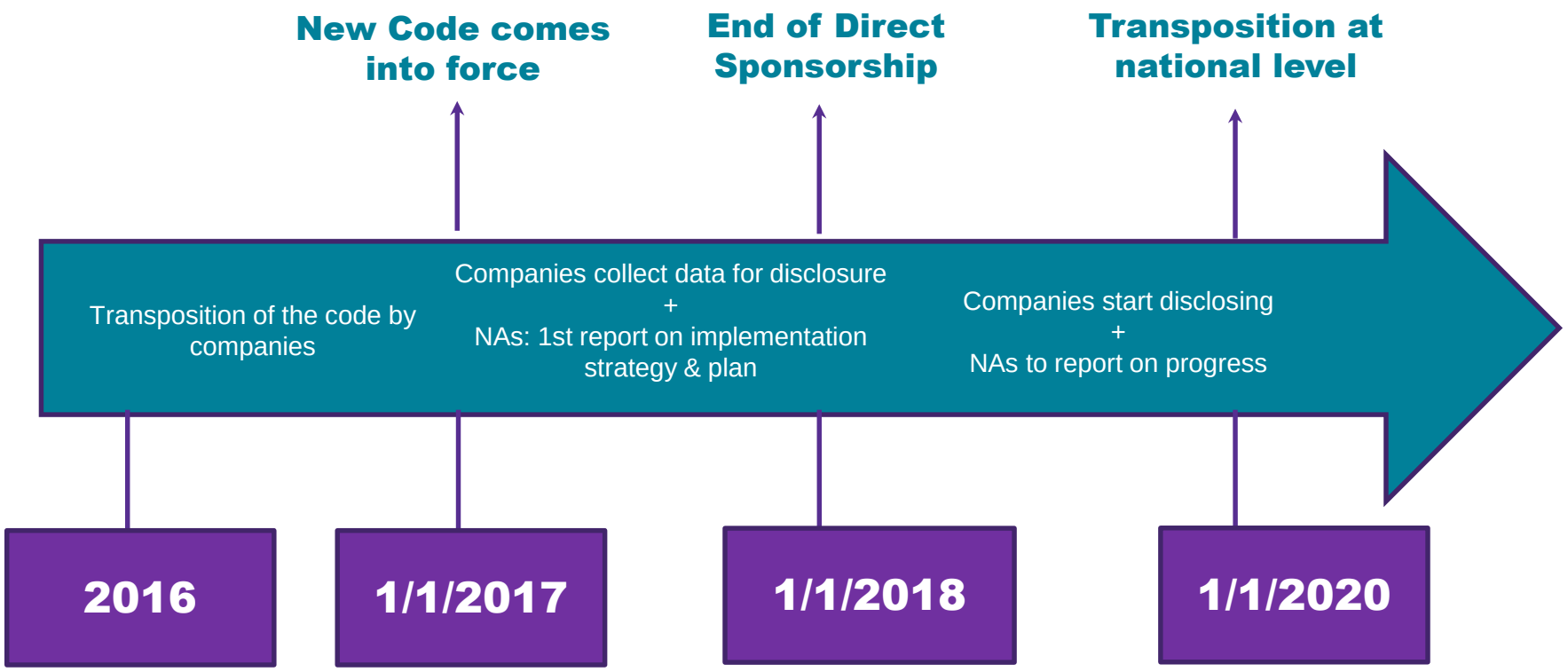
* *No double reporting: Exceptions were granted to countries which have pre-existing & equivalent platforms (e.g. Belgium)*



Part 3

ADDITIONAL CONSIDERATIONS

Timelines for NA & Corporate Members



NA & Corporate Member obligations

National Association

- **Transposing** the MTE Code ('regulation or directive style') by **2020**
- **Recommending** and promoting the MTE Code as best practice
- **Engaging** local stakeholders to change local practice
- Submitting **strategies** and progress reports including public transparency on the MTE website

Member Companies

- **Transpose** the Code by 1/1/2017 & phase out of DS by 1/1/2018
- **Support** National Associations they are member of to support local transposition of the MTE Code

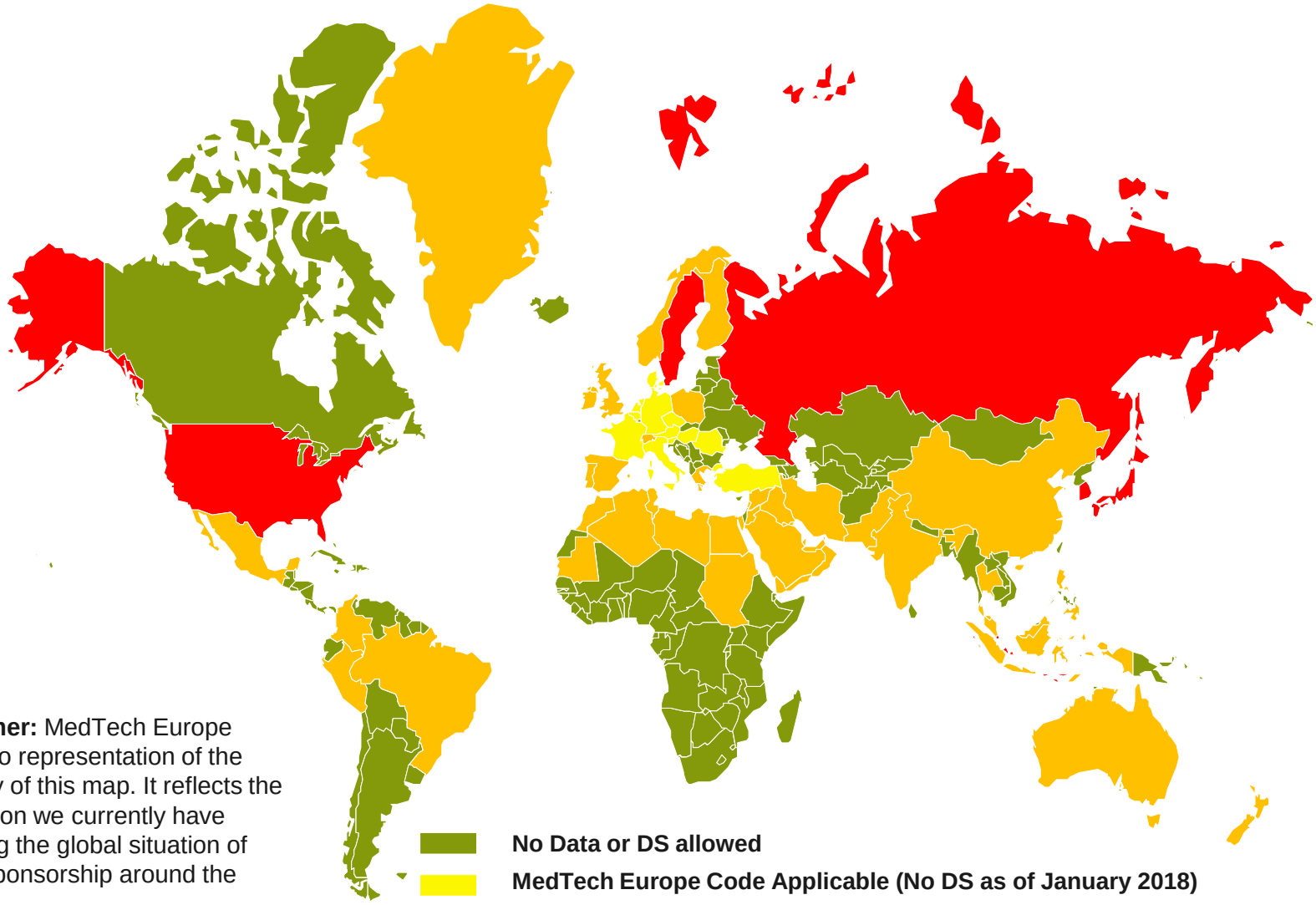
MedTech Europe

- Provide **training** on the MTE Code and the normative framework
- **Support** to National Associations on the transposition of the MTE Code
- **Coordinate** & support communication to external stakeholders

Part 4

DISCUSSION & BACKUP SLIDES

DS prohibition across the world



Disclaimer: MedTech Europe makes no representation of the accuracy of this map. It reflects the information we currently have regarding the global situation of Direct Sponsorship around the globe.

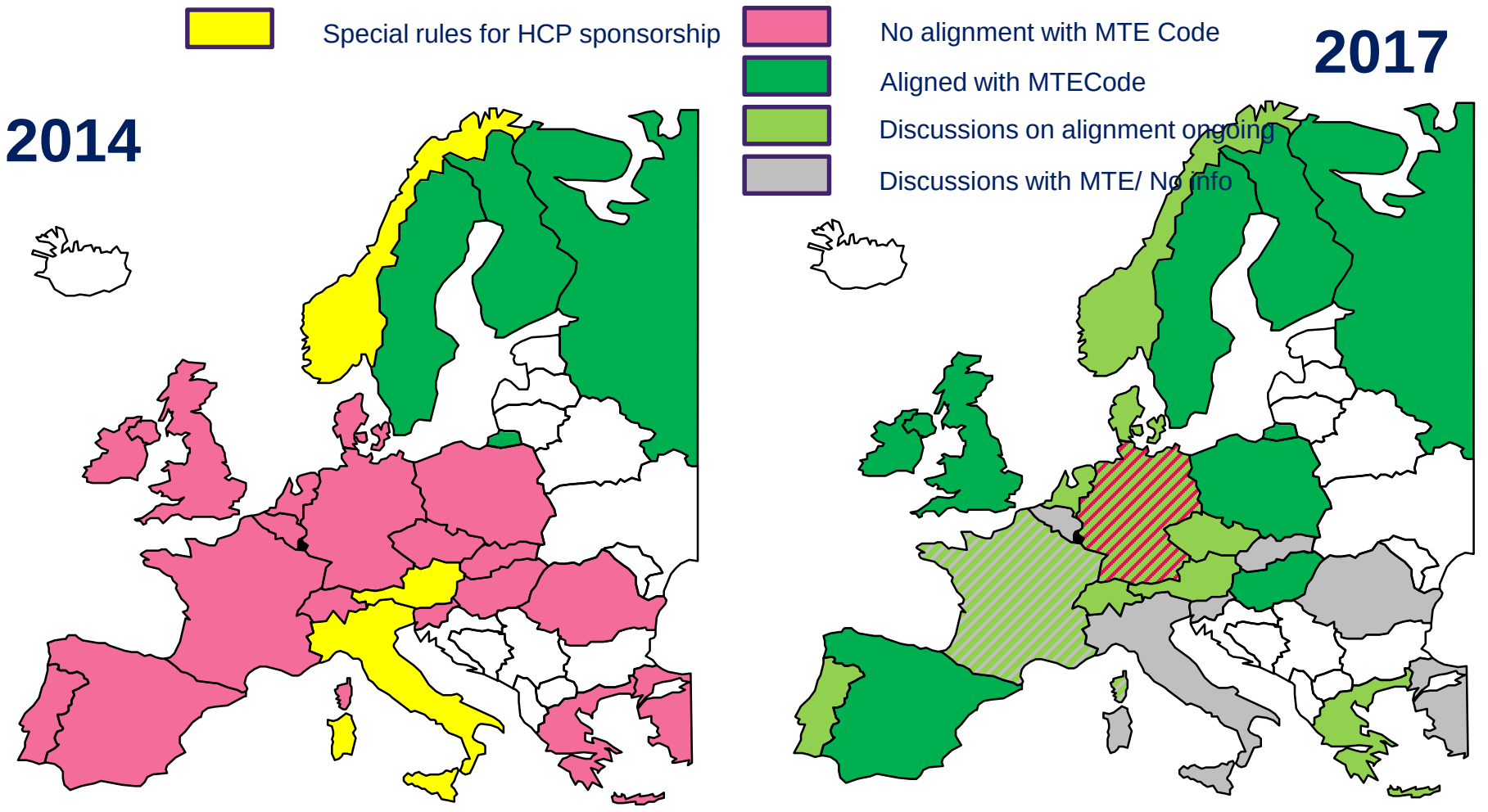
No Data or DS allowed

MedTech Europe Code Applicable (No DS as of January 2018)

National Code banning DS in place or agreed (entry into effect of prohibition may be later)

DS prohibited by law or stakeholder agreement

NA transposition of the MTE Code



How the Code will be enforced?

Independent body

MedTech Europe Compliance Panel

Procedural Framework

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

FOR MORE INFORMATION

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