MedTech Europe Code of Ethics
Paris 5th November

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MedTech Europe
from diagnosis to cure

Structure of the presentation

MedTech Europe Code of Ethical Business Practice

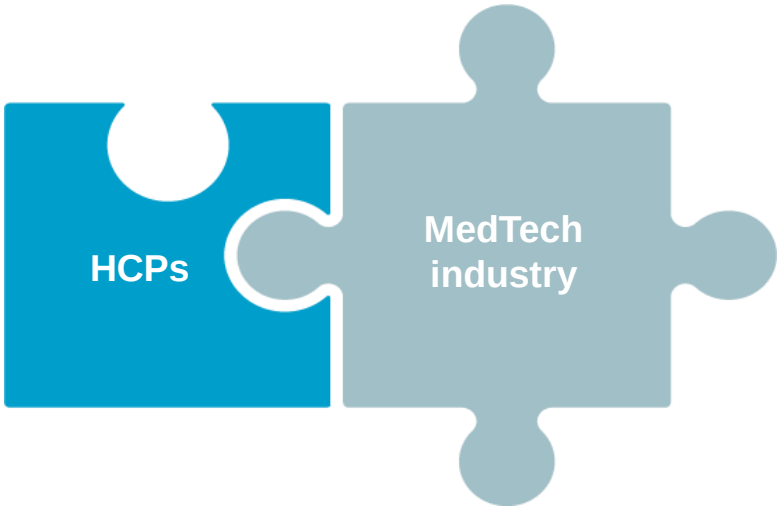
- Why phasing out of Direct Sponsorship
- Main changes
- Impact so far

Why phasing out of Direct Sponsorship

MedTech Europe
from diagnosis to cure

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.



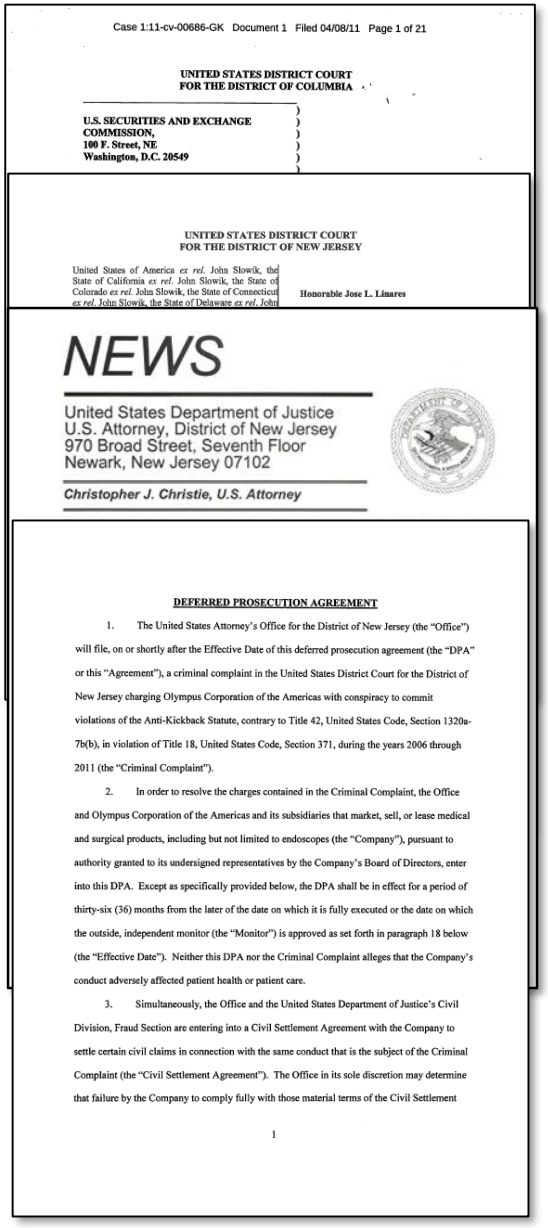
HCPs actively participate in the research to develop new technologies

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

MedTech industry's special relationship with HCPs



Case 1:11-cv-00686-GK Document 1 Filed 04/08/11 Page 1 of 21

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

U.S. SECURITIES AND EXCHANGE COMMISSION,
100 F. Street, NE
Washington, D.C. 20549

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

United States of America *ex rel.* John Slowik, the State of California *ex rel.* John Slowik, the State of Colorado *ex rel.* John Slowik, the State of Connecticut *ex rel.* John Slowik, the State of Delaware *ex rel.* John

Honorable Jose L. Linares

NEWS

United States Department of Justice
U.S. Attorney, District of New Jersey
970 Broad Street, Seventh Floor
Newark, New Jersey 07102

Christopher J. Christie, U.S. Attorney

DEFERRED PROSECUTION AGREEMENT

1. The United States Attorney's Office for the District of New Jersey (the "Office") will file, on or shortly after the Effective Date of this deferred prosecution agreement (the "DPA" or this "Agreement"), a criminal complaint in the United States District Court for the District of New Jersey charging Olympus Corporation of the Americas with conspiracy to commit violations of the Anti-Kickback Statute, contrary to Title 42, United States Code, Section 1320a-7b(b), in violation of Title 18, United States Code, Section 371, during the years 2006 through 2011 (the "Criminal Complaint").

2. In order to resolve the charges contained in the Criminal Complaint, the Office and Olympus Corporation of the Americas and its subsidiaries that market, sell, or lease medical and surgical products, including but not limited to endoscopes (the "Company"), pursuant to authority granted to its undersigned representatives by the Company's Board of Directors, enter into this DPA. Except as specifically provided below, the DPA shall be in effect for a period of thirty-six (36) months from the later of the date on which it is fully executed or the date on which the outside, independent monitor (the "Monitor") is approved as set forth in paragraph 18 below (the "Effective Date"). Neither this DPA nor the Criminal Complaint alleges that the Company's conduct adversely affected patient health or patient care.

3. Simultaneously, the Office and the United States Department of Justice's Civil Division, Fraud Section are entering into a Civil Settlement Agreement with the Company to settle certain civil claims in connection with the same conduct that is the subject of the Criminal Complaint (the "Civil Settlement Agreement"). The Office in its sole discretion may determine that failure by the Company to comply fully with those material terms of the Civil Settlement

1

"Surgeons. . . were often lavished with trips and other expensive perquisites. . . Prior to our investigation, many orthopedic surgeons. . .made decisions predicated on how much money they could make – choosing which device to implant by going to the highest bidder. With these agreements in place, we expect doctors to make decisions based on what is in the best interests of their patients – not their bank accounts."

-SEC 2007 Press Release

"[Polish Company] also paid for public doctors and hospital administrators to travel to medical conventions in Poland and abroad in order to influence tender committee decisions in their favor. Sponsored doctors were taken on trips in exchange for influencing the doctors' decicions to purchase [Parent Company's] medical products or to award hospital tenders to [Parent Company]. Some of the trips were to the United States for conferences. Some of the trips were to tourist areas in Europe, and some included spouses and family members to what amounted to vacations."

-Government Complaint, U.S. Securities and Exchange Commission v. [Company]

"[Company] also sponsored physician vacations disguised as physician education. For example, [Company] sponsored an annual event called the Masters MIS forum. In 2009, the forum was held at the prestigious Colony Hotel in Kennebunkport, Maine on July 7-11."

-Complaint, United States of America v. [Company]

"It was a further part of the conspiracy that [Company] paid doctors' expenses for travel, leisure, and recreation during programs requiring doctor travel, including week-long trips to Japan, to reward past purchases and induce future purchases of [Company] products. For example:

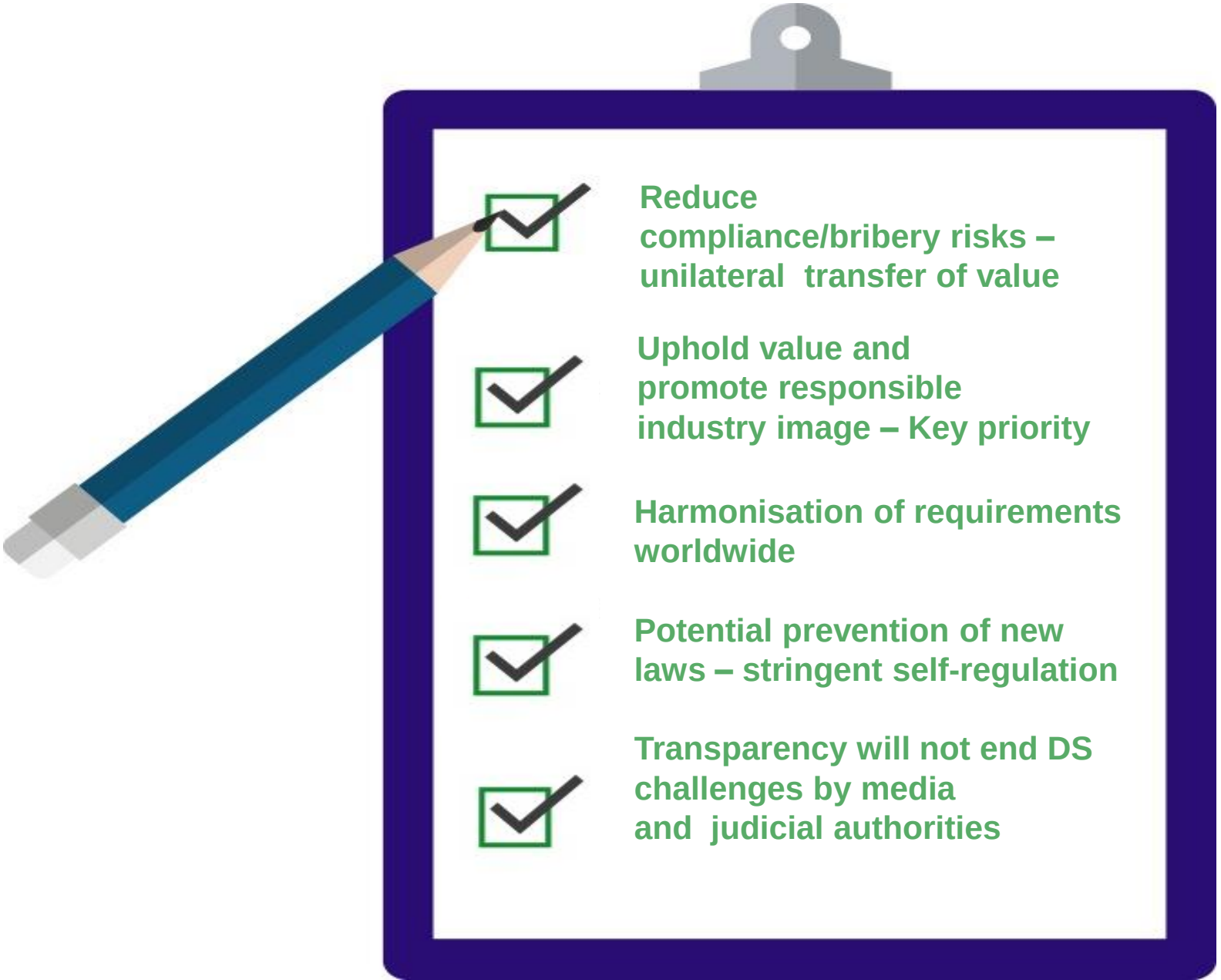
b. Every year from 2006 through 2009, [Company] treated the physican president of a prominent professional organization and (except for 2009) his or her spouse to a week-long trip to Japan and paid the physician a $10,000 honorarium to give one lecture during the trip.

[Company] paid for doctors' lavish meals, ballooning, winery tours, golf, and spa treatment at [a

c. Company]-sponsored forum because it was 'a great way to network, talk business, socialize without our competitors.'"

-Deferred Prosecution Agreement between U.S. Attorneys Office and [Company]

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

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

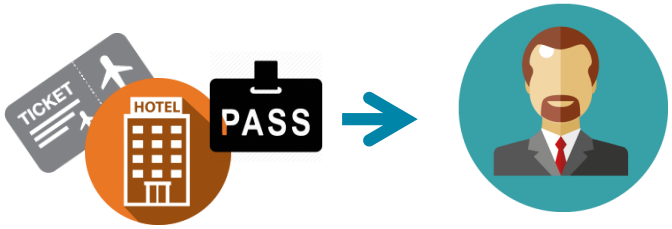
Agreed definitions

Common independent enforcement mechanism

Two types of industry support to Third Party Organised Events

"Direct sponsorship"

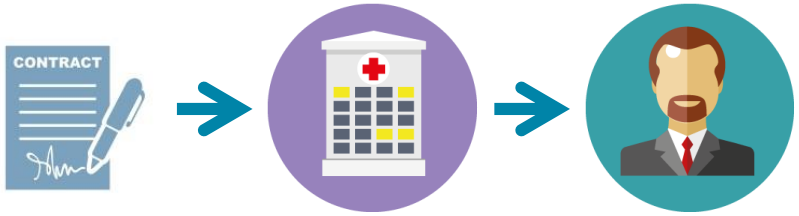
Companies select individual HCPs and **financially support their participation** to Third Party Organised Events.



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.**

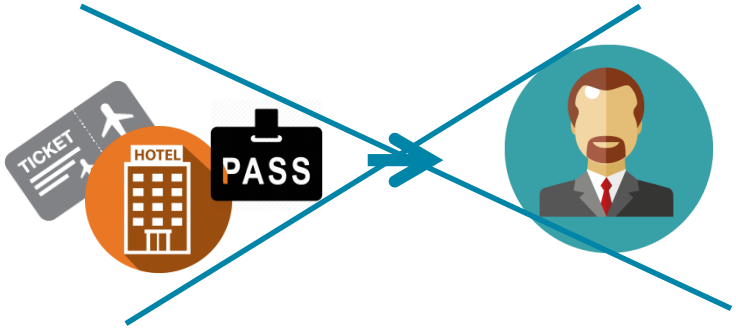


These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**

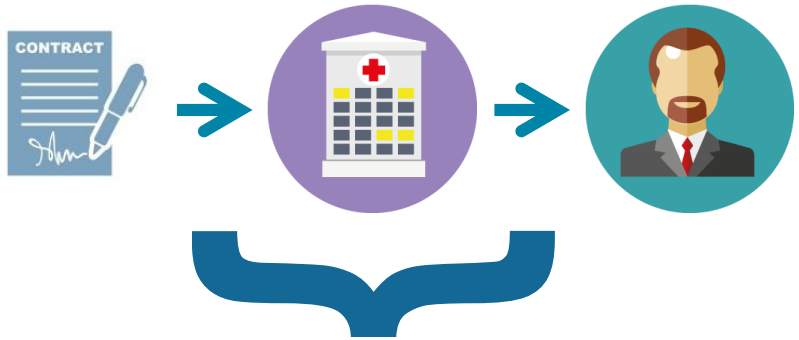
Phasing out of direct sponsorship

2016 2017 2018

“Direct sponsorship”

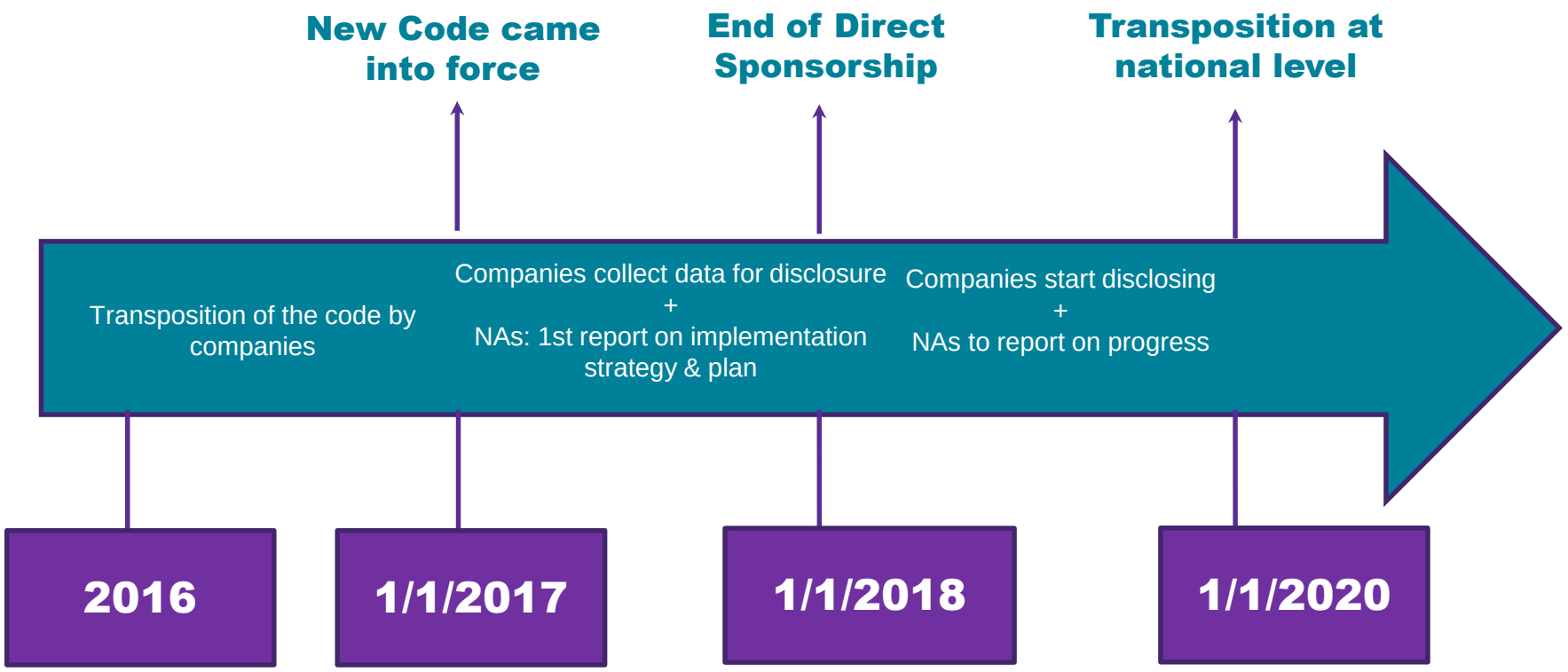


“Educational grants”



Stronger rules

Timelines for NA & Corporate Members



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? 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, France)*

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 unutilised 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:**

Arthur Muratyan
(Chair)

Jean-Claude Najar

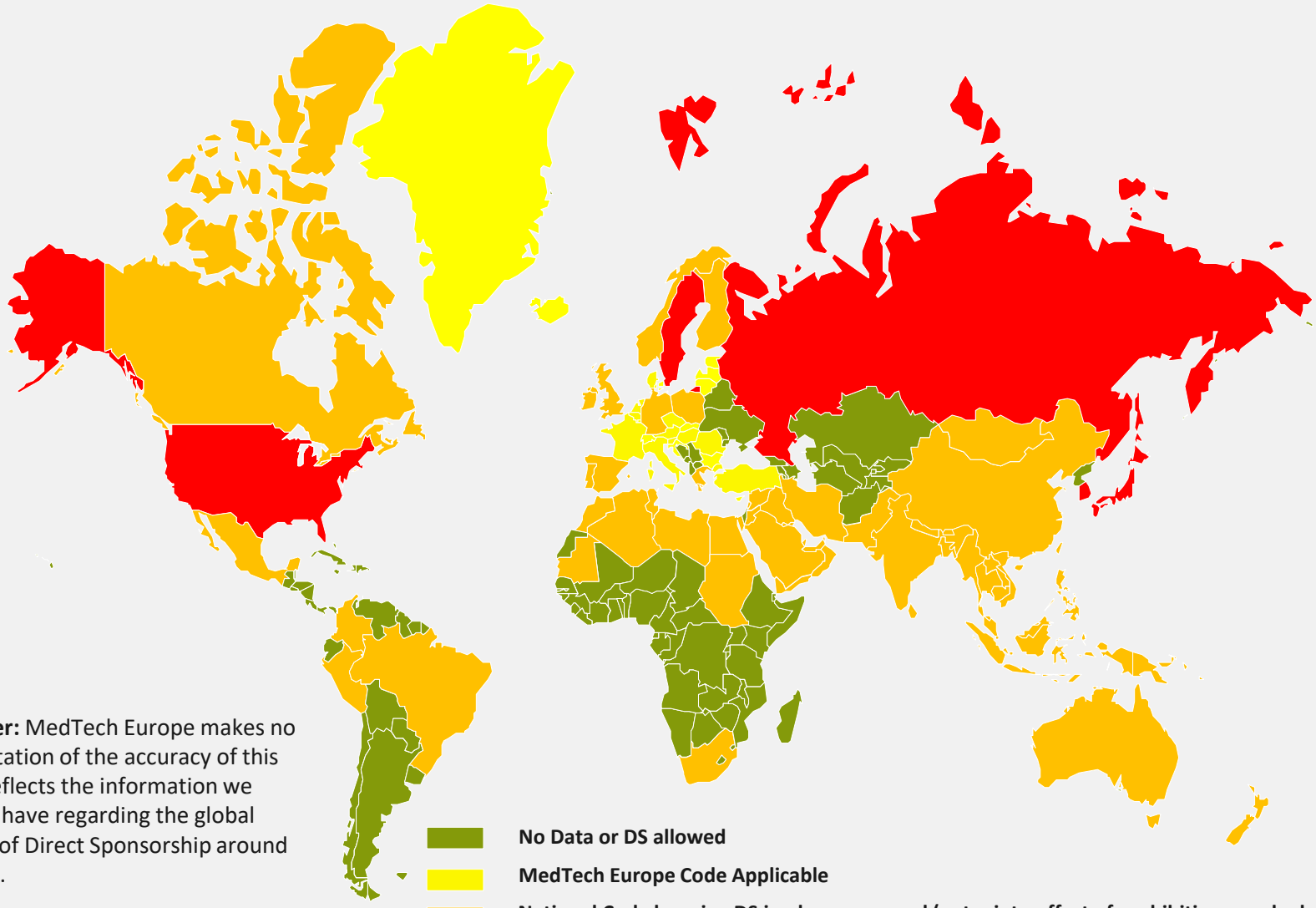
David Horne

Impact so far

Impact so far…

1. Impact of CVS in increasing conference compliance
2. Transposition efforts by corporate & NA members
3. Copy/Paste of our Code in other parts of the world
4. Extensive discussions with HCOs & PCOs
5. More disputes considering formal resolution
6. New challenges

DS prohibition: A global discussion



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

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

DS prohibited by law or stakeholder agreement

Main lessons

1. A long process to phase out direct sponsorship

2. The complexity of local realities and laws

3. Necessary investment in stakeholder outreach

Questions

Questions

- Sales and marketing activities,
- Expansion into emerging markets,
- Speaker programs and medical conferences
- Sponsoring of HCPs at international congresses and associated rules
- Visibility of reportable transfers of value for transparency reporting purposes
- Any other?