

MedTech Europe Distributor Training on Code of Ethical Business Practice

Warsaw, Poland - November 2017





1

Anti-Bribery/Anti-Corruption & Compliance

Why is it important to distributors?

2

New MedTech Europe Code

What are the main changes?

3

New MedTech Europe Code

What distributors need to do?

4

New MedTech Europe Code

Case Studies

A person wearing a white lab coat, a surgical mask, and gloves is working on a large, circular medical device. The person is looking up at the device, which has a central circular opening. The background is a light blue wall with a grid pattern. The entire image is overlaid with a semi-transparent purple filter.

Part 1

WHY COMPLIANCE WITH GLOBAL ANTI-BRIBERY LAWS IS IMPORTANT?



1

Bribery and corruption are prohibited by local criminal, civil , and administrative laws across countries where distributors do business

- U.K. Bribery Act
- U.S. Foreign Corrupt Practices Act (FCPA)

2

Violation of these laws risk a host of negative consequences:

- Termination of contracts with manufacturers or local governments
- Civil money penalties (both distributor company and individuals)
- Criminal prosecution of distributors

3

Enforcement actions involving a handful of distributors has put spotlight on all distributors

4


Effectiveness of manufacturer's compliance programs includes their management of 3rd parties



Bribes: What are they & when can they occur??

- Offer, payment, promise or agr. to pay, authorization of or receipt of payment
- Directly or indirectly, anything of “value”
- To or by gov. official or private party
- For purpose of obtaining or retaining business

- Mere offer of a bribe is sufficient for liability, no actual payment needed
- Bribe paid via 3rd party still a bribe
- Distributors **MAY** be prosecuted for bribes made directly or indirectly through sub-distributor, agent or 3rd party

 May commit a crime if you have **reason to know** that bribe will be paid by another and you take no action to prevent it

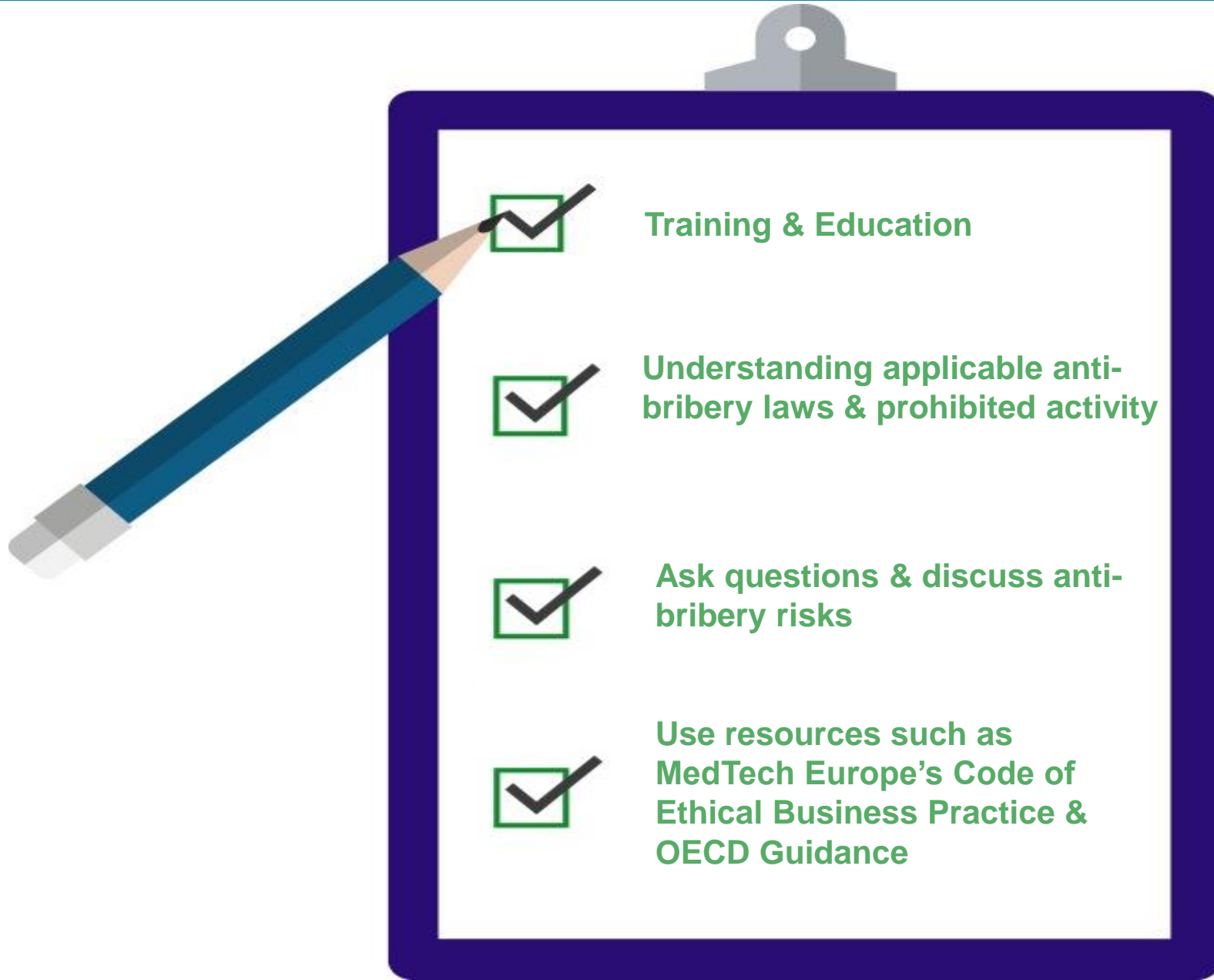


January 2017

- Brazilian subsidiary of U.S. parent company
- Sold products via 3rd party distributors, who resold to HCPs, private & gov. owned hospitals
- Large discounts to distributors, used profits from discount to pay doctors
- Nearly \$3 million SEC fine

June 2016

- Danish subsidiary of U.S. parent company
- Overpayment to subsidiary by distributor and subsequent payments by subsidiary from excessive funds to unknown 3rd parties
- SEC & DOJ investigations; individual liability of CFO
- Nearly \$3.5 million criminal fine by DOJ

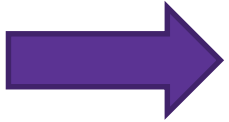


A person wearing a white lab coat, a white surgical mask, and white gloves is working on a circular ceiling fixture. The person is looking up at the fixture. The background is a purple-tinted image of the same person working on the ceiling fixture.

Part 2

HOW DOES CODE IMPACT DISTRIBUTORS & WHAT ARE THE MAIN CHANGES?

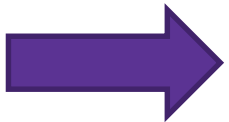
The MedTech Europe Code and Distributors Role



Member Companies' commitment to the MTE Code extends to Distributors because liable for activities of 3rd parties



Expectation that Distributors with regular HCP and HCO interaction comply with provisions of the Code



Due to possible consequences, companies likely to prefer to do business with Distributors they know conduct business in line with the Code



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**



“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.**



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



Educational Grants to support Third Party Organised Events

- Support for these Events
- Support for HCP Participation

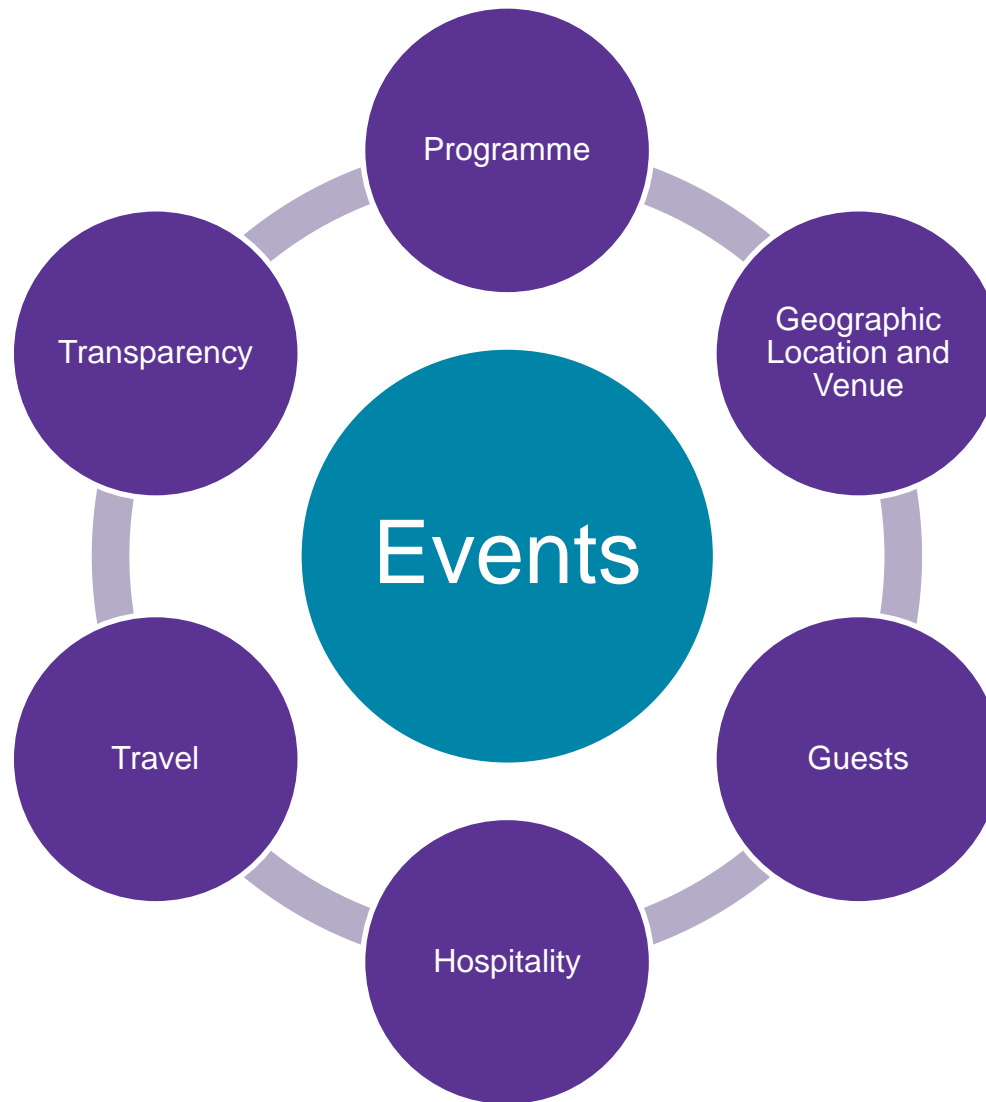
Other Educational Grants to HCOs

- Scholarships & Fellowships
- Grants for Public Awareness Campaigns

2017 data as of 2018

MedTech Europe platform (www.ethicalmedtech.eu)*

** No double reporting: Exceptions were granted to countries which have pre-existing & equivalent platforms (Belgium, France, & Portugal)*





Part 4

NEW CODE OF ETHICS: CONTENT

MedTech Europe Geographic Area

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



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

What are the criteria for Event programme?



- The Event programme should be:
 - directly related to the specialty and/or medical practice of the HCPs who will attend the Event, or
 - sufficiently relevant to justify the attendance of the HCPs
 - for Third Party Organised Educational Events: under the sole control and responsibility of the third party organiser

Not appropriate



Organising Events which include Entertainment



Supporting Entertainment elements where part of Third Party Organised Educational Events

Who is competent to assess the General Criteria for Events?



The **CVS** (Conference Vetting System) 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 these events through educational grants, promotional activity (e.g. booths) or satellite symposia when they are in scope of the system.

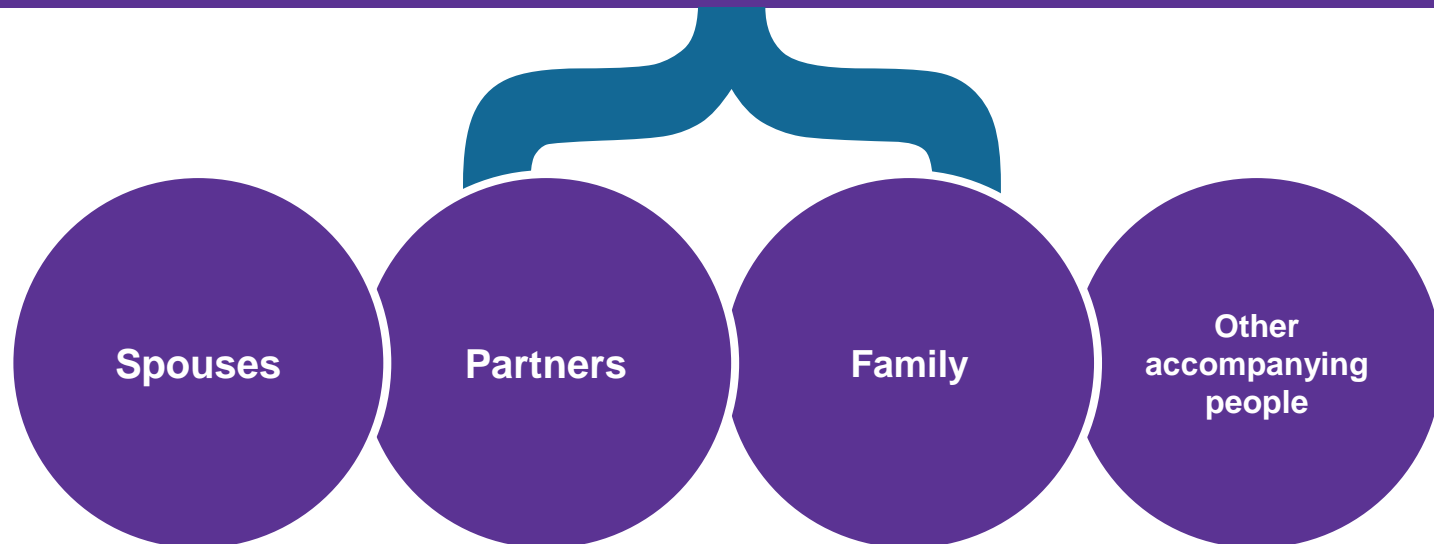
Find out more about the Conference Vetting system at www.ethicalmedtech.eu.



- Member Companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for Guests of HCPs

Guests of HCPs

Any person who does not have a *bona fide* professional interest in the information being shared at an Event



What is required when it comes to hospitality?



- **Meals + accommodations = hospitality**
- **Any hospitality offered must be:**
 - Subordinate in time
 - Focus to the Event purpose
 - Reasonable

Reasonable hospitality



Appropriate standard for the given location



Complying with the national laws, regulations and professional codes of conduct

Not considered as reasonable



Lodging at top category or luxury hotels

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

Third Party Organised Educational Event



- Third Party Organised Educational Conferences

- Third Party Organised Procedure Training

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.

Grants and Charitable Donations

- Charitable Donations

- Educational Grants

- Research Grants

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



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

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

Educational Items and Gifts

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 HCPs

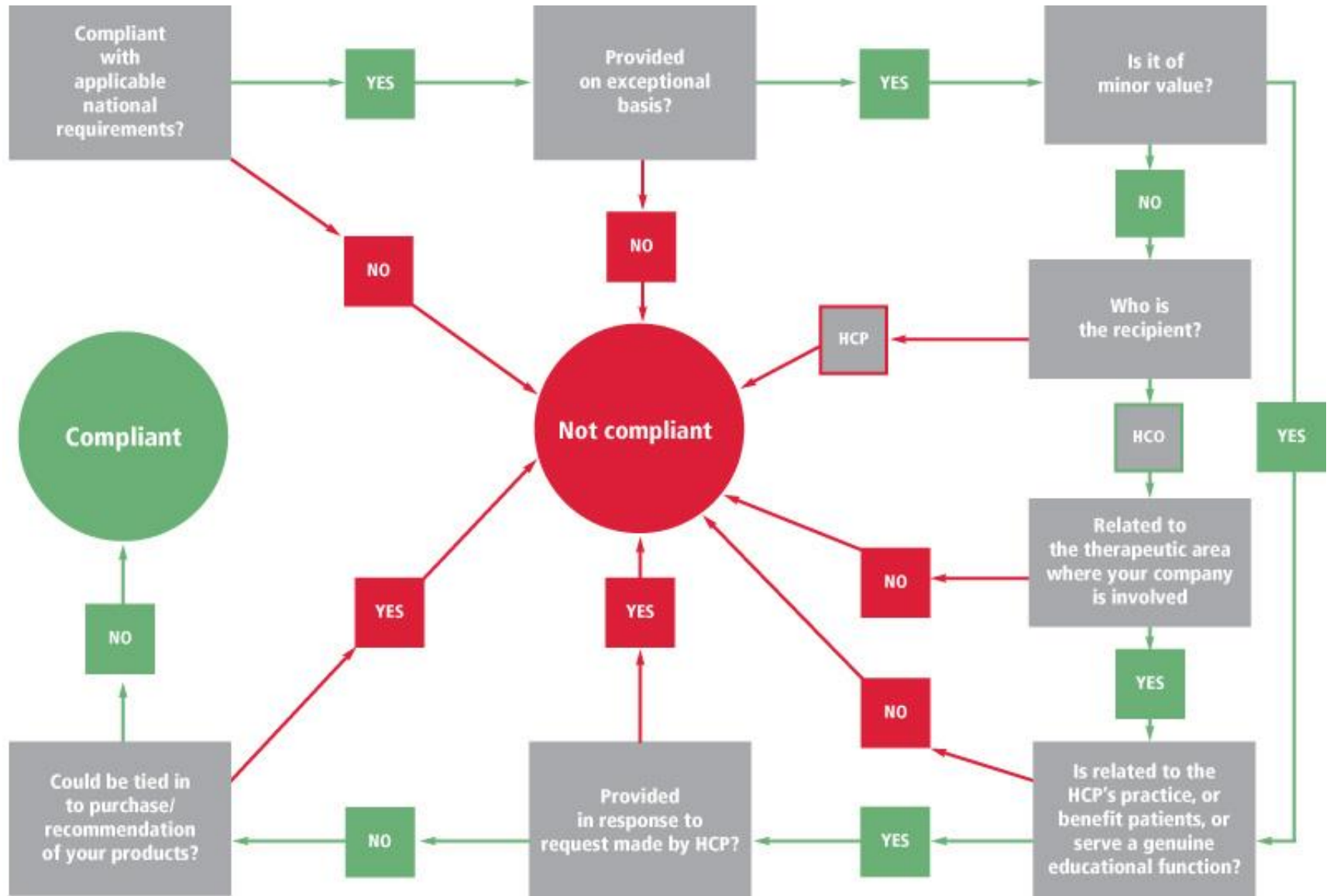
Inexpensive

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

How to determine if the gift is appropriate under the new code?








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



Q: An employee of a medical device company has been working with an HCP for several years. It is early December and Christmas is coming. Furthermore, the HCP celebrates the 25th anniversary of her practice in January. The company employee wonders what kind of gift he can give the HCP and for what occasion.

- NO**  **a.** The employee can give a bottle of wine to the HCP for the 25th anniversary of her practice, but not for the occasion of Christmas, as this is a general holiday.
- NO**  **b.** The employee can give a calendar or diary for the 25th anniversary of her practice and clinical items such as wipes, nail brushes or surgical gloves for Christmas.
- YES**  **c.** The employee cannot offer a gift of modest value that relates either to the 25th anniversary of the HCP's practice or for the occasion of Christmas.

Demonstration and Evaluation Products

- **Member companies may provide Demonstration Products and/or Samples at no charge in order to:**

Enable HCPs/HCOs to evaluate/familiarise themselves with safe and appropriate use/functionality of the product/related service

Determine if to use order, purchase etc. the product and/or service in the future

Provision of such products must not improperly reward, induce and/or encourage HCPs/HCOs to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services

What does the Code require for Demonstration Products and Samples?



- **Maintaining appropriate records, e.g.:**
 - Proof of delivery for any Demonstration Products/Samples provided
 - Receipt of return for multiple-use products

- **Documenting the no-charge basis and other applicable conditions no later than the time of the supply:**
 - Clear record in the Member Company's records
 - Clear disclosure in writing to HCPs/HCOs

Case Study #1

ABC Distributors is the primary distribution company in Country X for Smiley Company, a Member of MedTech Europe, and sales of Smiley's medical devices comprises the majority of ABC's sales.

As part of the distribution agreement with Smiley, ABC receives a certain percentage of its sales to assist with marketing-related events linked to Smiley's products. ABC typically develops a marketing plan (with Smiley's approval), interacts with event coordinators and other third parties to implement the marketing plan, and is reimbursed for said costs up to the marketing allowance.

This year, Smiley Company has proposed a new program. The program involves providing funds and equipment for educational events hosted by select medical associations . According to Smiley, certain medical associations, to be selected by ABC, will offer educational events, varying from one day to one week, in major cities. Physicians and administrators from key hospitals will be invited to the events . In addition, Smiley is offering limited educational grants to certain hospitals through the new program .

Case Study #2

Another part of Smiley Company's newly proposed program, includes the option for its distributors to offer product trainings during the educational events hosted by the medical associations.

ABC, excited about this new opportunity, quickly agreed to offer product trainings on behalf of Smiley Company at the upcoming Doctors-R-Us Conference hosted by the Cardiology Society of Ambrosia. The conference will be held at the scientifically world renowned Pathos Resort & Convention Center. This center is state of the art and includes a research institute. Thus the accompanying hotel and resort provide unrivaled accommodations. Additionally, given its prime location on the coast of Ambrosia, it is also a popular destination for travelers from all over the world.

ABC plans to organize the product training to coincide with the Doctors-R-Us conference and to offer travel and accommodation for some of the physicians and administrators from the key hospitals that will be invited to the events.

Moreover, as ABC has historically managed the marketing activities and interacted with the service providers to carry out the marketing plan, Smiley has asked ABC to serve a similar role related to the new educational events program. To fund this new initiative, Smiley is offering a significant additional allowance and asked that ABC oversee payments for the training events and grants, as well as distribution of product samples to the medical associations.



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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