MedTech Europe
Code of Ethical Business Practice

Version for Member Companies: December 2015

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

What companies need to do?

New MedTech Europe Code

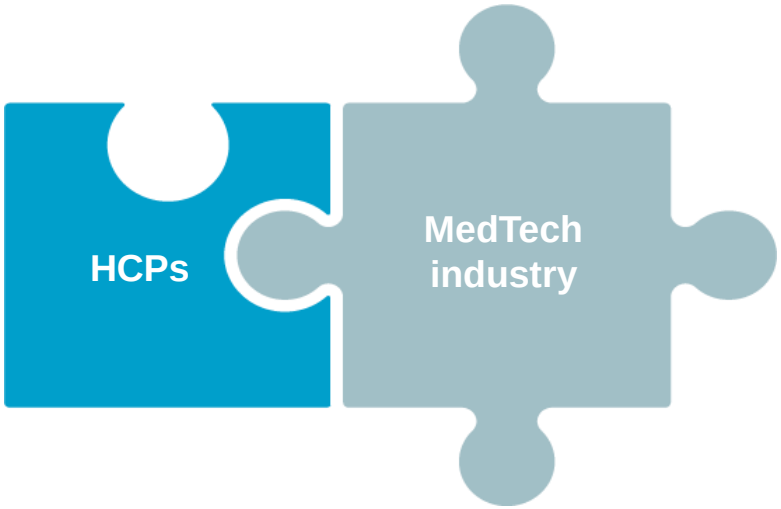
What does it cover?

Part 1

WHY ETHICS IS IMPORTANT?

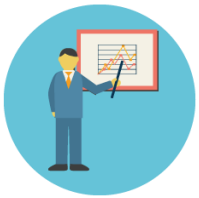
MedTech industry's special relationship with HCPs

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

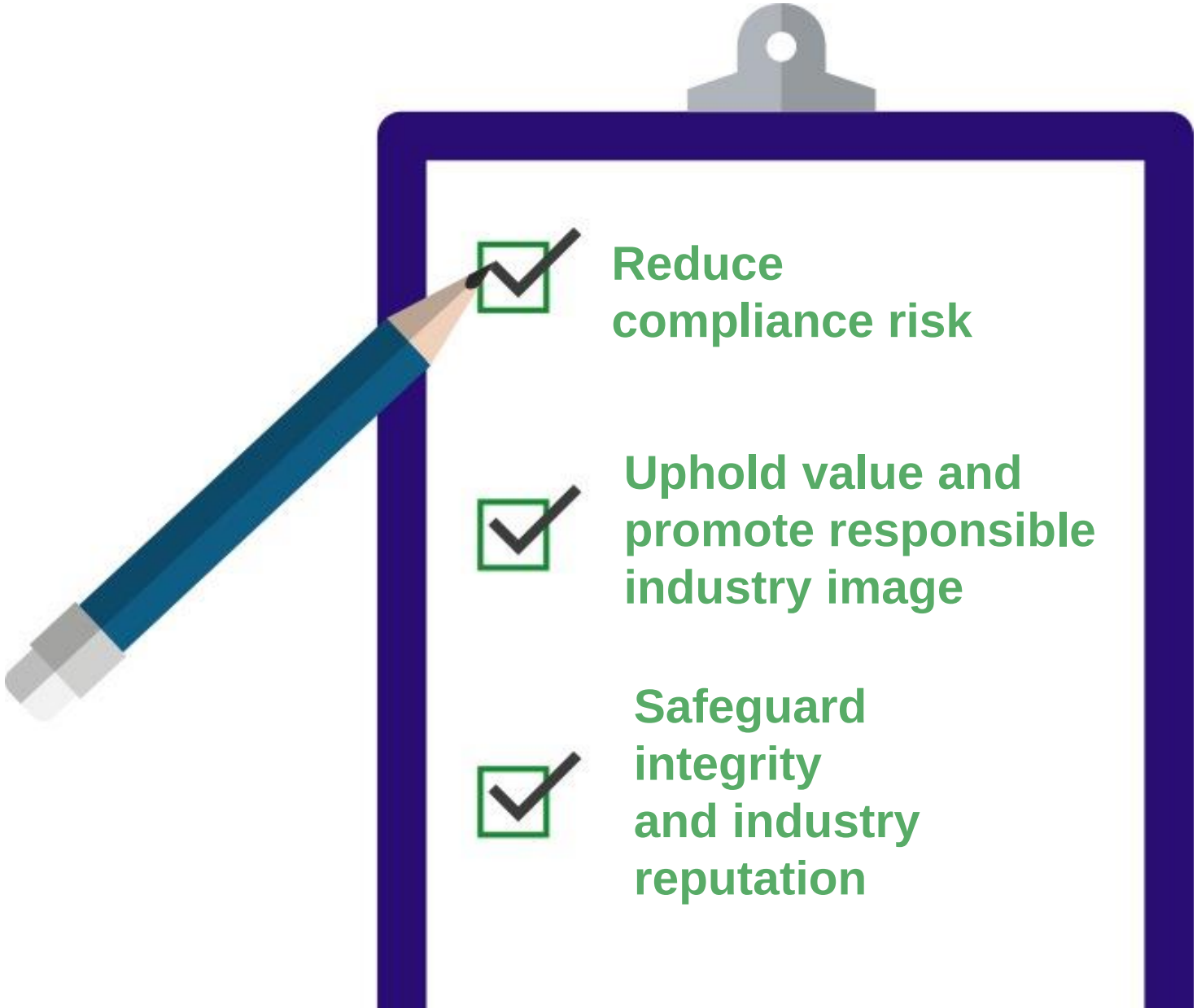
This close collaboration is key to develop innovative technologies to treat patients



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



MedTech Europe Code of Ethical Business Practice

CODE

Party Organised Educational Events, Entertainment must be outside of the educational programme schedule and paid for separately by the Healthcare Professionals. Entertainment should not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session. The Entertainment should not be the main attraction of the Third Party Organised Educational Event.

2. Event Location and Venue

The Event location and venue should not become the main attraction of the Event. For the location and the venue Member Companies must take into account at all times the following considerations:

- Potential adverse public perceptions of the location and venue for the Event. The perceived image of the location and venue must not be luxury, or tourist/holiday-oriented or that of an Entertainment venue.
- The Event location and venue should be centrally located when regard is given to the place of residence of the majority of invited participants.
- The need for ease of access for attendees.
- The Event location and venue should be in or near a city or town which is a recognised scientific or business centre suitable for hosting an Event which is conducive to the exchange of ideas and the transmission of knowledge.
- Member Companies must take into account the season during which the Event is held. The selected time of year must not be associated with a touristic season for the selected geographic location.

Part 2

WHAT ARE THE MAIN CHANGES?

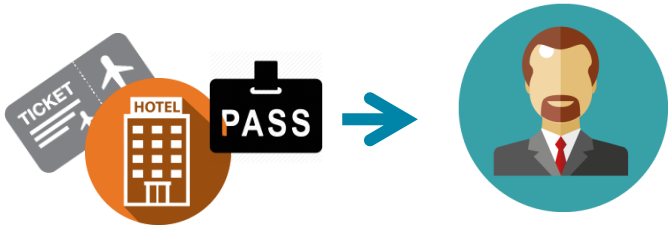
Six biggest changes

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”

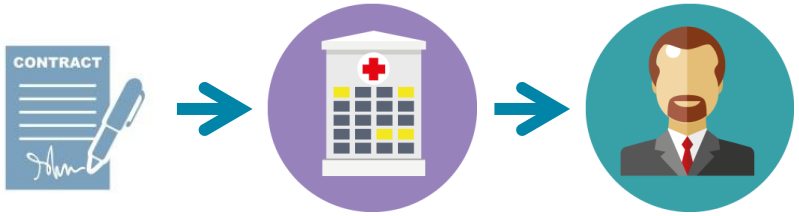
Companies select individual HCPs and **financially support their participation** to Third Party Organised Events.



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.**

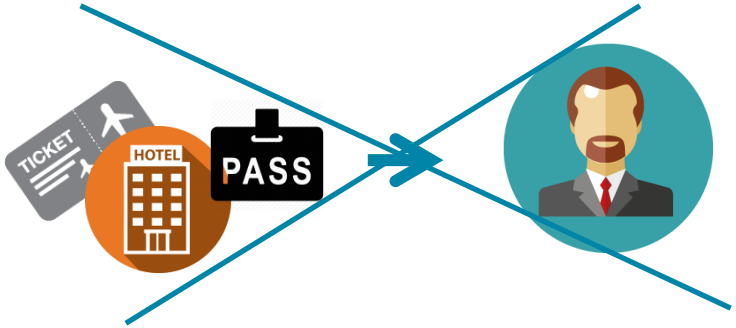


These include educational grants provided to support HCP participation to Third Party Organised Event. **HCPs are selected by the receiver of the grant.**

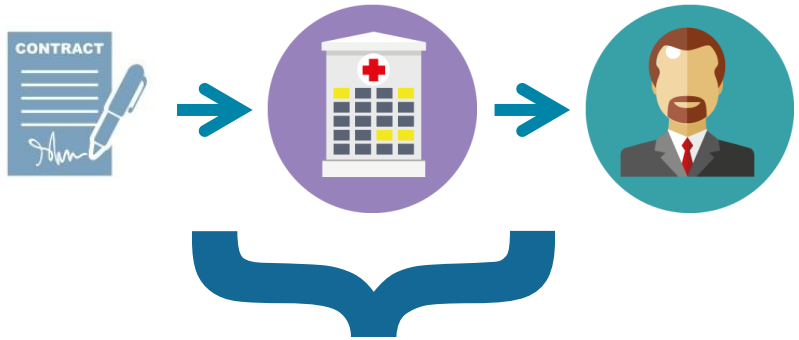
Phasing out of direct sponsorship

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

Transparency: Where?

www.ethicalmedtech.com

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:**

Nancy Russotto
(Chair)

Arthur Muratyan

David Horne

Part 3

WHAT COMPANIES NEED TO DO?

Timelines

2016

2017

New code comes into force

2018

Direct Sponsorship banned

Part 4

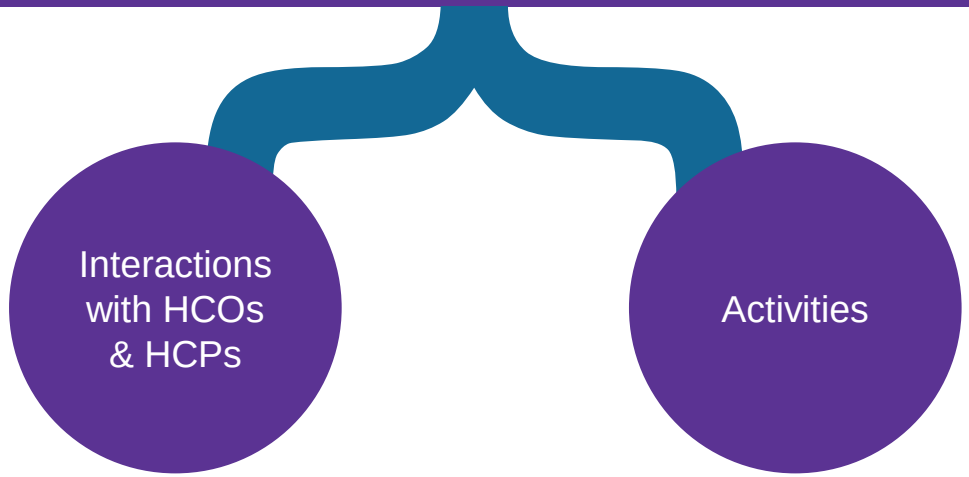
NEW CODE OF ETHICS: CONTENT

Who is covered?

What is the scope?

MedTech Europe Geographic Area

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

Five principles

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

Chapter 1

General Criteria for Events

A common chapter on criteria for all events:

1. **Event programme**
2. **Event location and venue**
3. **Guests**
4. **Reasonable hospitality**
5. **Travel**
6. **Transparency (Employer Notification)**

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**

What is Entertainment?

Does not constitute entertainment

- ✔ Incidental, background music
- ✔ Reasonable hospitality

Entertainment

- ✗ Examples: dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) etc.

Entertainment in Third Party Organised Educational Events

- **Entertainment in Third Party Organised Educational Events should:**
  - be outside of the educational programme schedule and paid for separately by the Healthcare Professionals
  - not dominate or interfere with the overall scientific content of the programme and must be held during times that do not overlap with a scientific session.
  - not be the main attraction of the Third Party Organised Educational Event.

What are the criteria for appropriate Event location & venue?

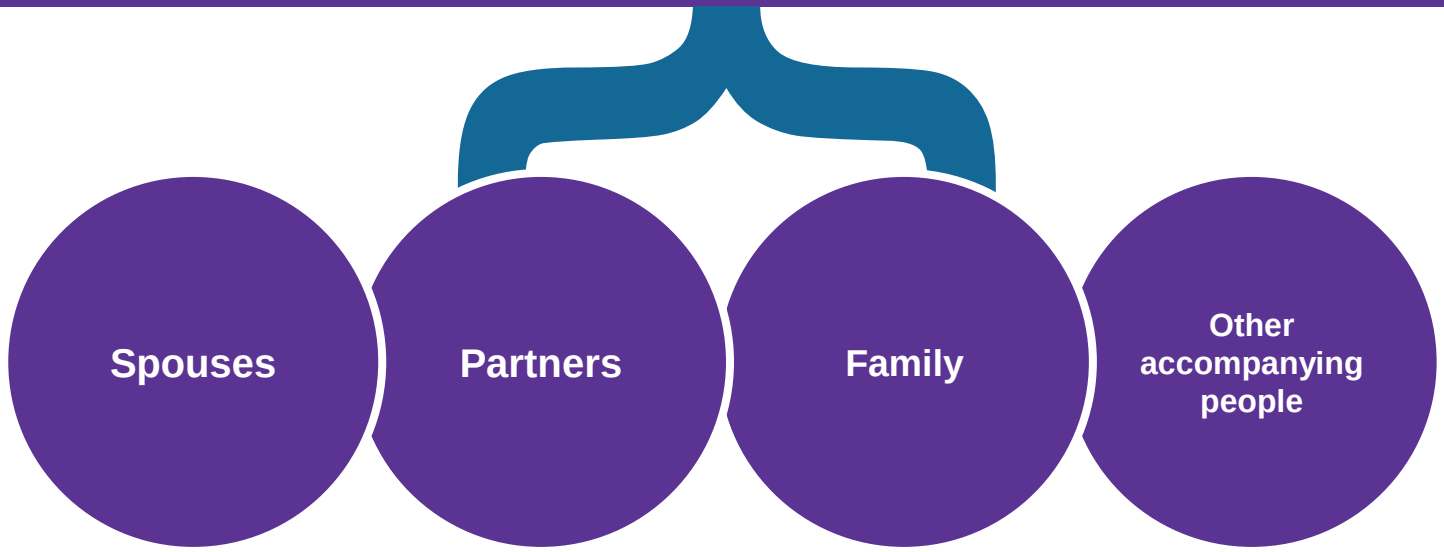
1. **Perceived image**
   - Must not be perceived as luxury, or tourist/holiday-oriented, or that of an Entertainment venue
2. **Centrality**
   - Centrally located when regard is given to the place of residence of the majority of invited participants
3. **Ease of access**
   - In close proximity to an airport and / or train station / ground transportation infrastructure
4. **Recognised scientific or business centre**
   - Near a city or town which is a recognised scientific or business centre, suitable for hosting an Event
5. **Selected time of year**
   - Selected time of the year outside a touristic season for the selected geographic location

What about Guests?

- **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



Quiz: Guest of HCPs

Q: A physician asks whether he can bring his wife to a company event organised to train cardiac surgeons. He sends proof that his wife is running a private dermatology practice and has been a practicing HCP for 25 years. Can the company allow him to bring his wife along and participate in the training as well as cover her costs for accommodation and travel?

NO ✗

a. Yes, the company can allow him to bring his wife as he has provided the necessary documentation that she is an HCP as well.

NO ✗

b. Yes, the company can allow him to bring his wife to participate in the trainings, if she only participates passively and the cost of her meals is paid by the HCP.

YES ✔

c. No, under the MedTech Europe Code it is not permissible to bring a spouse who does not have *bona fide* professional interest in the information being shared at the 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**

How to determine what needs to be done under transparency principle?

Are there any applicable laws with regard to the disclosure or approval requirements associated with financial support of HCPs?

YES

National disclosure/approval requirements apply:

A Member Company to proceed in accordance with the requirements of the law

NO

Code transparency requirements apply:

A Member Company to require Employer Notification is made prior to the event

Chapter 2

Third Party Organised Educational Event

- Third Party Organised Educational Conferences

- Third Party Organised Procedure Training

What are Third Party Organised Educational Conferences?

- **Third Party Organised Educational Conference:**
  - A genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare
  - Consistent with relevant guidelines established by professional societies or organisations for such educational meetings

Examples:

- Conferences organised by national, regional, or specialty medical associations/societies
- Hospitals
- Professional Conference Organisers (PCOs)
- Patients organisations or accredited continuing medical education providers

What are Third Party Organised Procedure Trainings?

- **Third Party Organised Procedure Training:**
  - Primarily intended to provide HCPs with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
    - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
    - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.
  - For the avoidance of doubt, proctorship and preceptorship are not considered to constitute 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 is required for the following types of funding: Educational Grants, promotional activity (e.g. booths) and satellite symposia.

Chapter 3

Company Events

- Product and Procedure Training and Education Events

- Sales, Promotional and Other Business Meeting

What is Product and Procedure Training and Education Event?

- **Product and Procedure Training and Education Event:**
  - Primarily intended to provide HCPs with genuine education, including information and/or training on:
    - Safe and effective use of medical technologies, therapies and/or related services, and/or
    - Safe and effective performance of clinical procedures, and/or
    - Related disease areas
  - In all cases the information and/or training directly concern a Member Company's medical technologies, therapies and/or related services.

What is Sales, Promotional and Other Business Meeting?

- **Sales, Promotional and Other Business Meeting:**
  - Has the objective to effect the sale and/or promotion of a Members Company's medical technologies and/or related services, including meetings to discuss product features, benefits and use and/or commercial terms of supply.

What does the Code require when it comes to Company Events?

Requirements	Product and Procedure Training and Education Events	Sales, Promotional and Other Business Meetings
Compliance with general criteria for Events (Chapter 1)?	YES	YES
CVS approval?	NO	NO
Is direct sponsorship of HCPs allowed ?	YES	NO for travel & accommodation (unless demonstrations of non-portable equipment are necessary)

Chapter 4

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

What are types of Educational Grants?

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

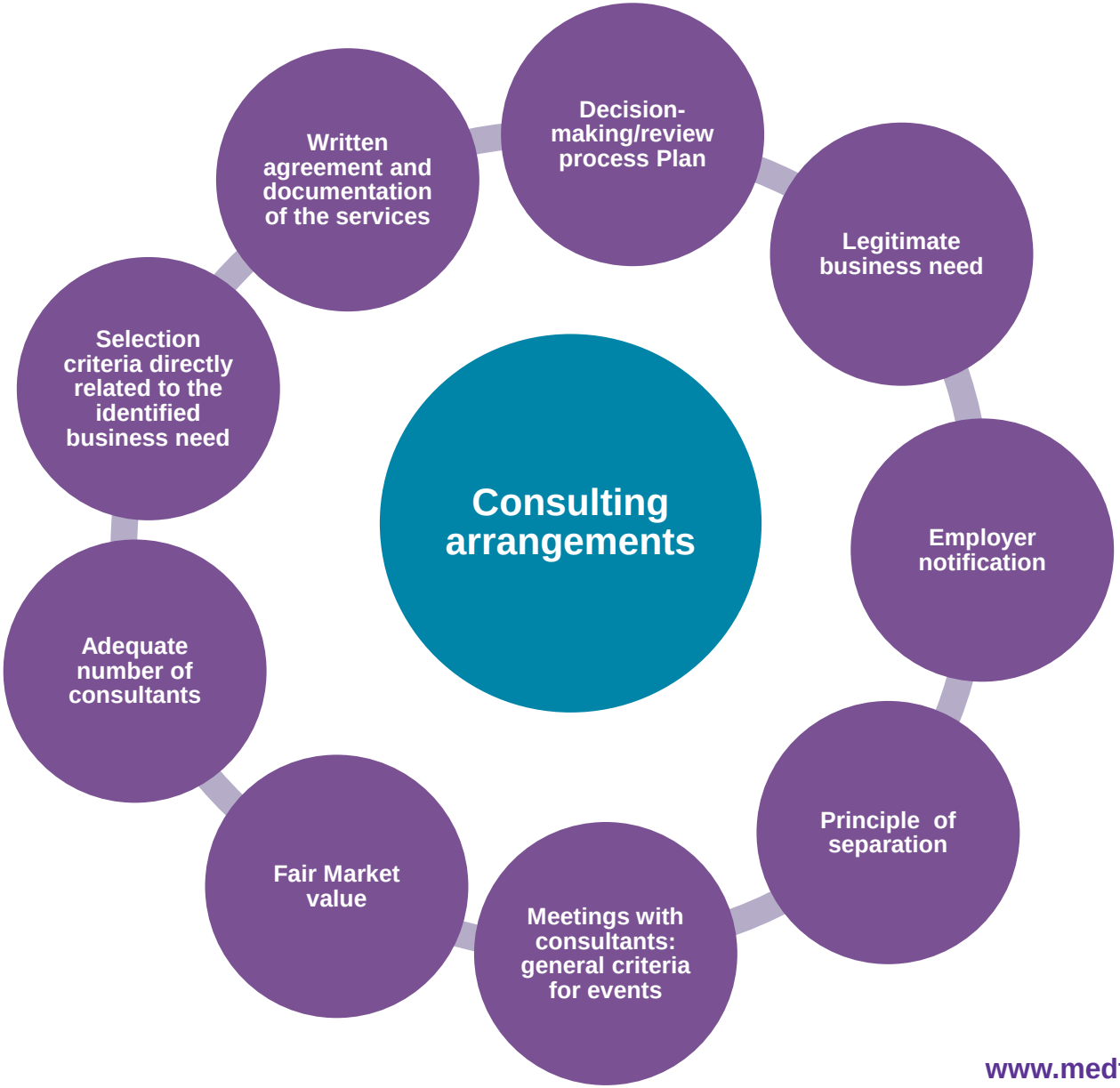
Chapter 5

Arrangements with Consultants

- **Member Companies may engage HCPs to provide *bona fide* consulting and other services, e.g.:**
  - Research
  - Participation on advisory boards
  - Presentations at Company Events and product development

- **Member Companies may pay HCPs reasonable remuneration for performing these services**
  - The Code is applicable also to those cases where a consultant HCP declines a fee for provision of their services

What are the requirements for consulting arrangements?



Quiz: Written agreement

Q: An employee of a in vitro diagnostics company wants to engage an HCP to provide specific consulting services. The employee's superior told him that a written contract is required for such services. Which rules apply as far as contracts for consulting services are concerned?

NO ✗

a. Consulting services may only be provided on the basis of a written contract that precisely describes the services (nature, time, benefit for the company, etc.), whereas the remuneration may be agreed upon orally.

YES ✔

b. A written agreement must be in place before the services are rendered. Such agreement should describe, in detail, the nature of the services to be provided and the basis for payment of these services.

NO ✗

c. A written contract is needed only for multiple consulting services, whereas an agreement by telephone or e-mail is fully sufficient for a single service, in particular when the services is for free.

Chapter 6

Research

- **Member Company-Initiated Research**
- **Member Company-Post Market Product Evaluation**
- **Third Party-Initiated Research**

Falls under *Chapter 4: Grants & Charitable Donations*

What does the Code require for Member Company-Initiated Research?

Legitimate business need for data, e.g.

- Medical needs, e.g. patient safety
- Research and development
- Scientific purposes, e.g. performance indicators
- Regulatory, e.g. post-market surveillance, vigilance, safety
- Reimbursement and health economic, e.g. clinical and cost-effectiveness data

Documentation of any arrangements to procure research-related services:

- Written agreement referencing written research protocol
- Written Schedule of work
- Required consents, approvals and authorisations

Compliance with applicable Good Clinical Practice guidelines, if relevant

Appropriate clinical trial transparency:

- Appropriate disclosure of information about company's clinical trials, e.g. in external public registries

What does the Code require for Member Company-Post Market Product Evaluation?

Legitimate business need to obtain evaluation/feedback from HCPs and HCOs in relation to the evaluation products

Evaluation products may be provided on a no charge basis in return for the requested user feedback

Documented in a written protocol or questionnaire forming part of the contract

Provision of evaluation products must not improperly induce and/or encourage HCPs/HCOs to purchase, lease, recommend etc. companies' products or services

Chapter 7

Royalties

A Member Company and an HCP may enter into royalty arrangement where the HCP is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method, such that the HCP would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations

Appropriate royalty arrangements

✔ **A written agreement on royalty arrangements providing appropriate and reasonable remuneration in accordance with applicable laws and regulations**

Not appropriate royalty arrangements

✗ **Royalties paid are conditioned on a requirement that the HCP recommends products or services of the company**

Chapter 8

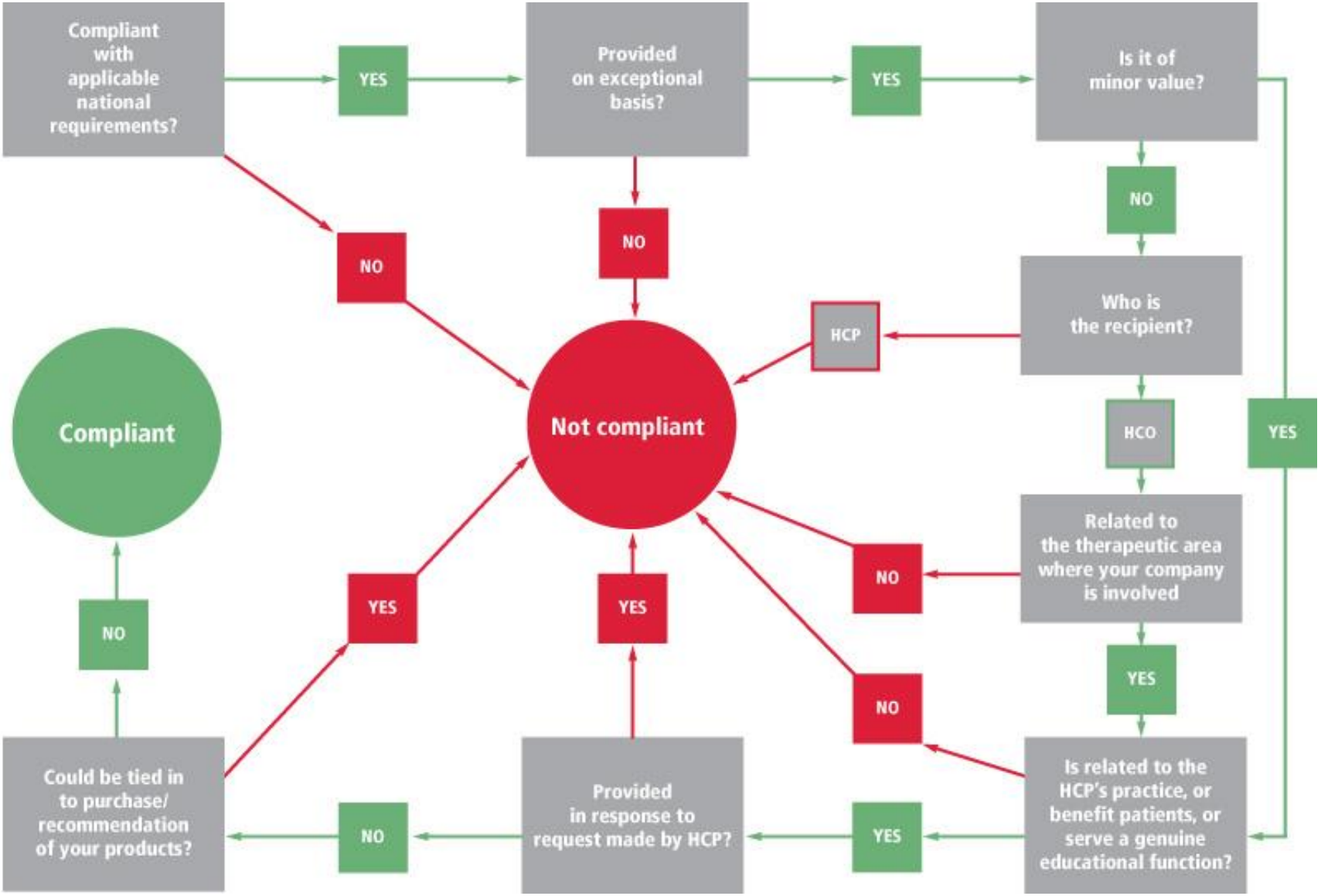
Educational Items and Gifts

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?



Are there any gifts that are never appropriate?

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**

Quiz: Gifts

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.

Chapter 9

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/funcionality 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

What are other requirements?

Demonstration Products	Samples
Provided solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use	Provided in order to enable HCPs to familiarise themselves with the products in clinical use
	Single-use Samples: - Quantity not exceeding the amount reasonably necessary to acquire adequate experience
	Multiple-use Samples: - Specific length of time (depending on the frequency of anticipated use, duration of the training, the number of HCPs etc.) - Company to retain title to Samples - Process in place to remove Samples at the conclusion of the period

How the Code will be enforced?

Independent body:

MedTech Europe Compliance Panel

Procedural rules:

Procedural Framework to be drafted before 1 January 2017

FOR MORE INFORMATION

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