

MedTech Europe Code of Ethical Business Practice

Version for Sales & Business professionals: March 2017





1

Ethics & Compliance

Why
is it
important?

2

New MedTech Europe Code

What are
the main
changes?

3

New MedTech Europe Code

What
companies
need to do?

4

New MedTech Europe Code

What does
it cover?

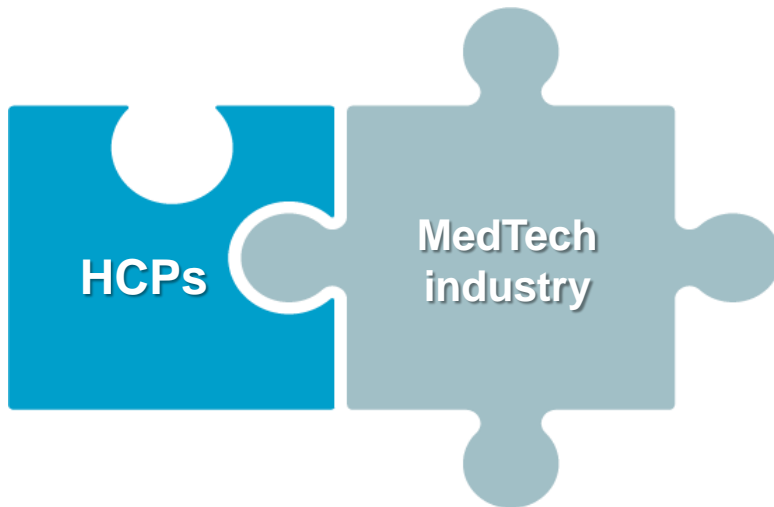


Part 1

WHY ETHICS IS IMPORTANT?



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

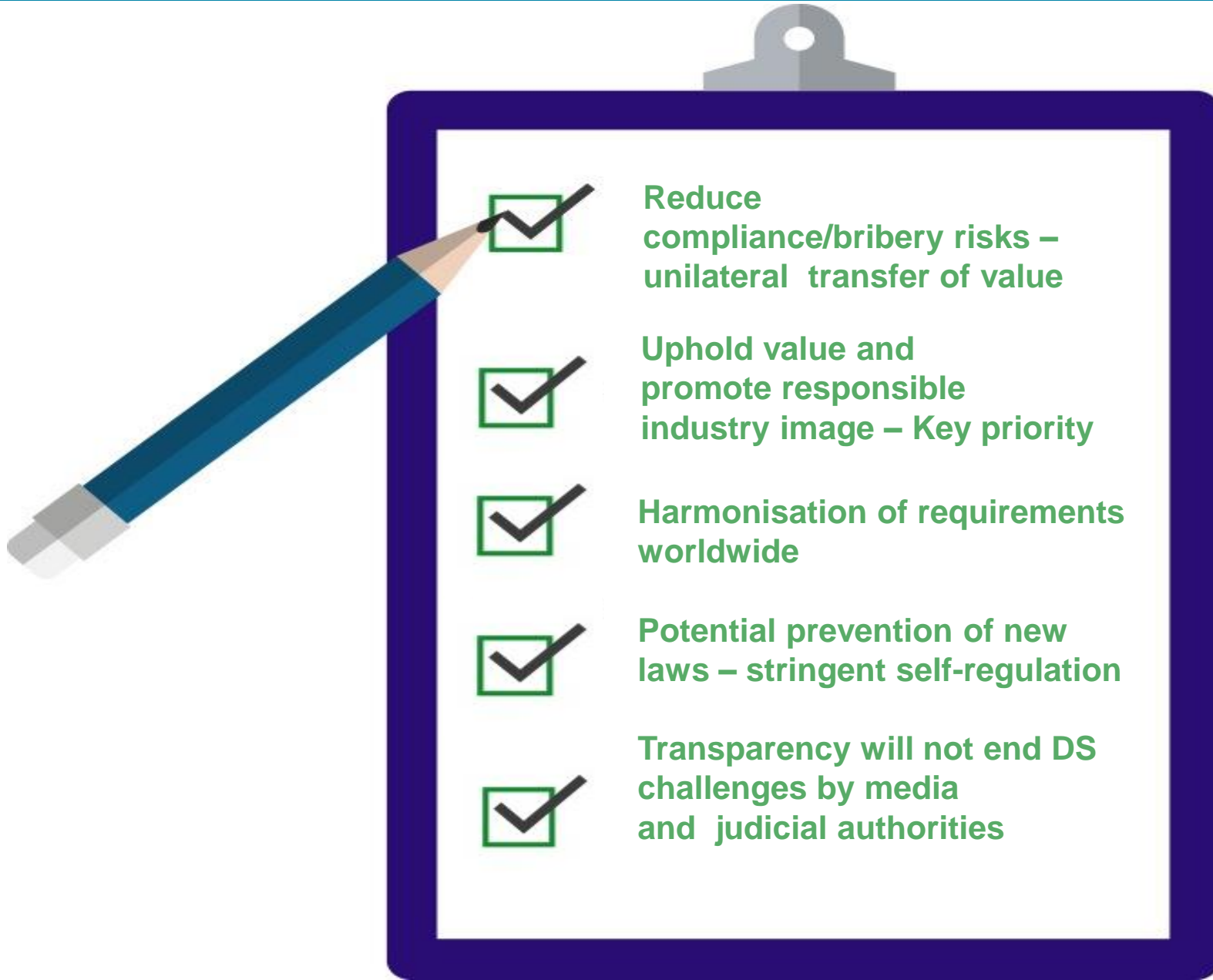


HCPs are trained on how to use technologies



The industry liaises regularly with HCPs to ensure that the technologies are updated and maintained

Industry's behaviour must respect high ethical standards & values





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.

- Training slide decks
- Leaflets for HCOs (in different languages);
- Leaflets for HCPs (in different languages);
- Information slide deck for HCOs;
- Educational Grant Agreement Template;
- Summary of the Code;
- Key messages;
- Letter template for Doctors.

These tools are available at www.medtecheurope.org & Member's Area

For questions: Hotline: ethics@medtecheurope.org

Leaflet for HCPs

Leaflet for HCOs



A person wearing a surgical mask, glasses, and gloves is working on a large, circular ceiling light fixture in an operating room. The person is looking up at the fixture, and their hands are raised to touch it. The background shows the interior of the operating room with other light fixtures and equipment.

Part 2

WHAT ARE THE 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

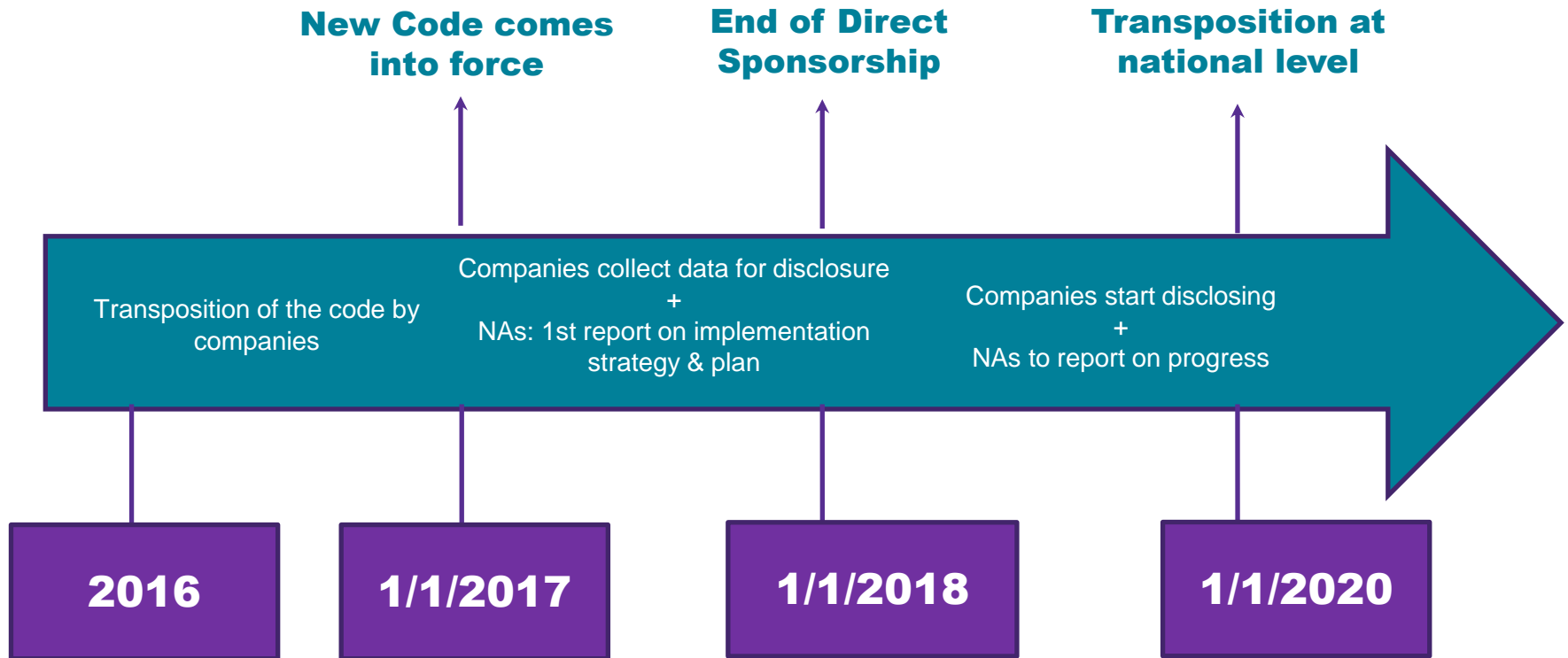
**Common independent
enforcement mechanism**

A person wearing a surgical mask, glasses, and gloves is working on a large, circular, white ceiling fixture. The person is looking up at the fixture with both hands raised. The background is a plain white wall. The entire image is overlaid with a semi-transparent purple filter.

Part 3

WHAT COMPANIES NEED TO DO?

Timelines for NA & Corporate Members

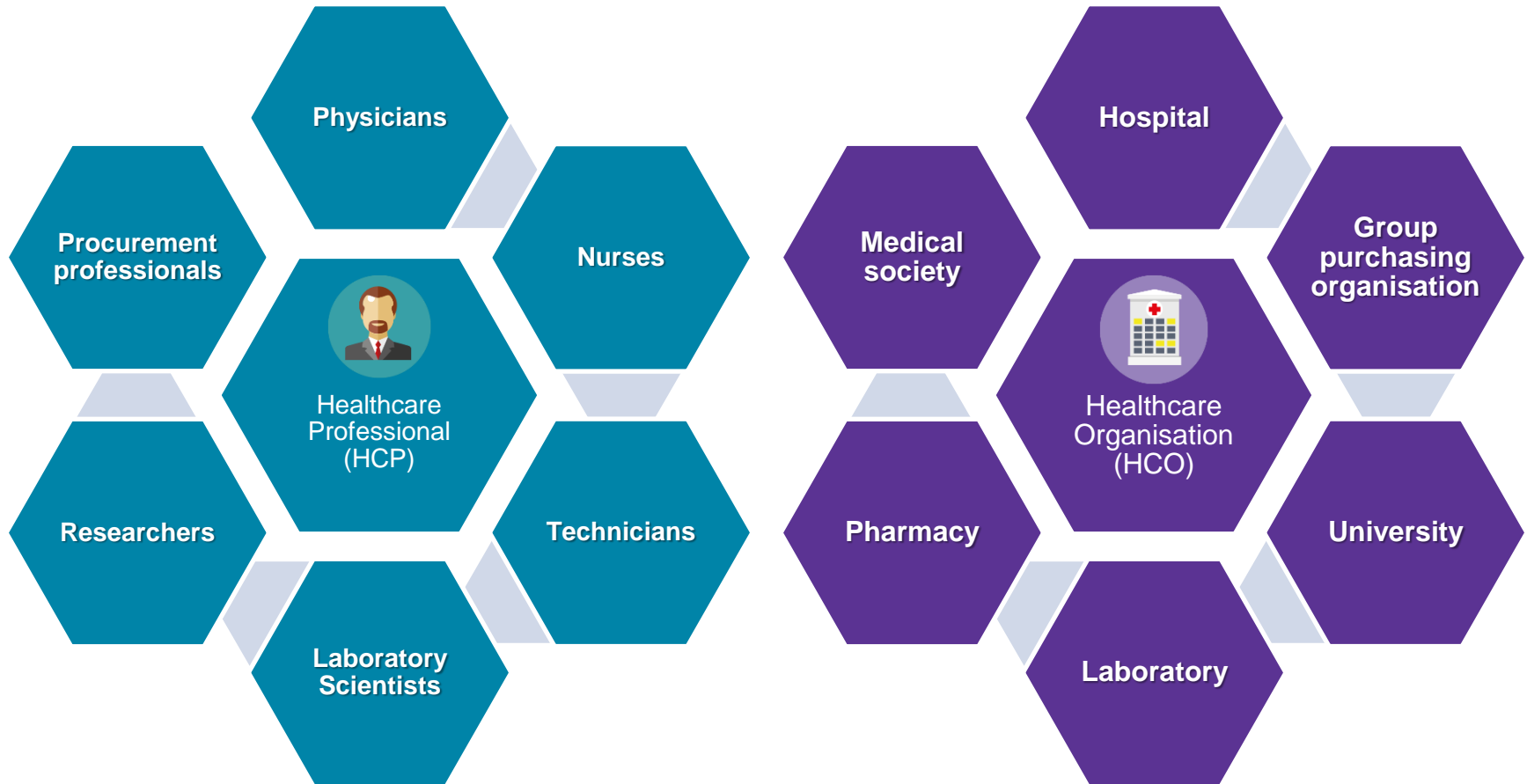




Part 4

NEW CODE OF ETHICS: CONTENT

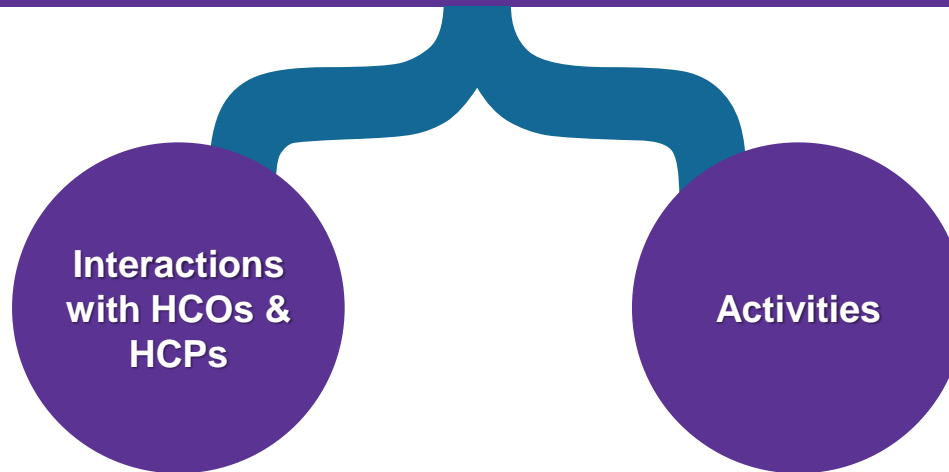
Who is covered?





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.



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

General Criteria for Events

A common chapter on criteria for all events:



Event
programme



Event location
and venue



Guests



Reasonable
hospitality



Travel



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



**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 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.



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

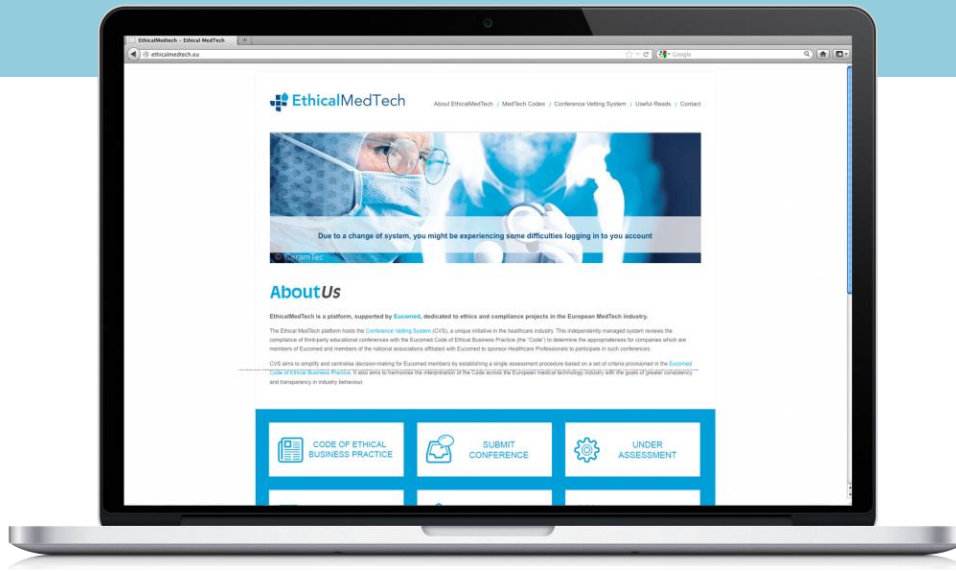
Selected time of year

- Selected time of the year outside a touristic season for the selected geographic location

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

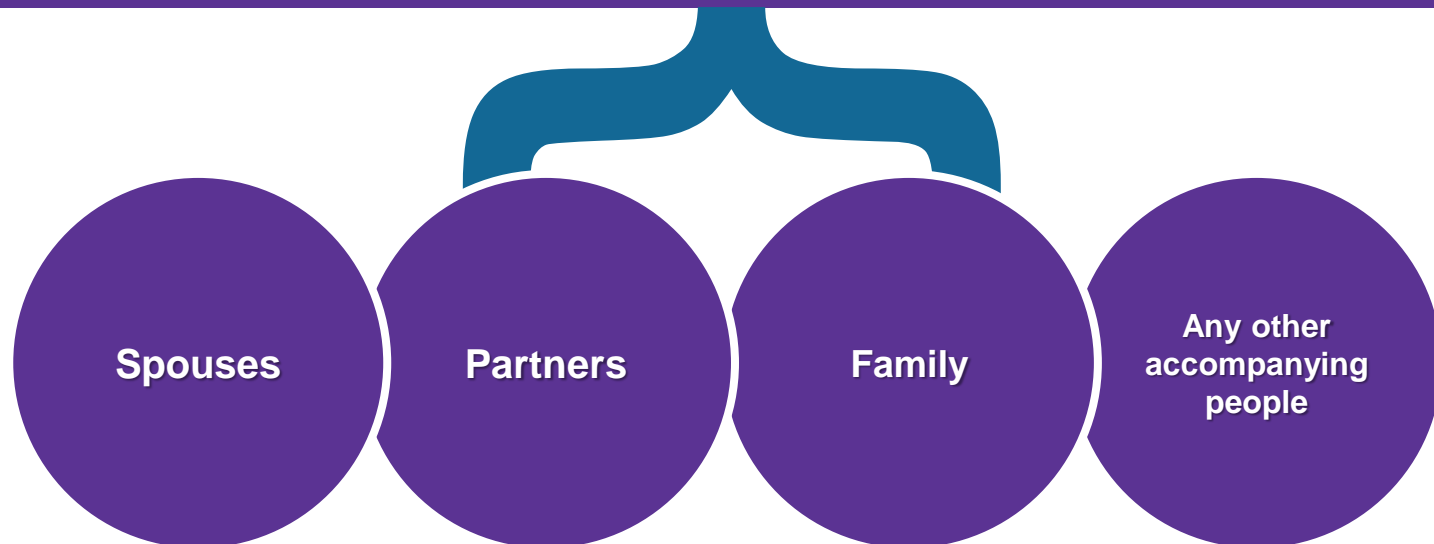
Find out more about the Conference Vetting system at www.ethicalmedtech.eu.



- 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





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.



Q: An HCP has asked you whether your company is going to provide Educational Grants to a medical congress she would like to attend. The medical congress in question is taking place in Majorca, Spain, in late June. What criteria shall apply?

A: The general criteria for events laid down in Chapter 1 of the Code apply to all Events, regardless of whether they are organised by a Member Company or by a Third Party.

Any support for a Third Party Organised Educational Conference (through Educational Grants, satellite symposia or promotional activity) requires **prior approval via the Conference Vetting System**.

Please check www.ethicalmedtech.eu to see if a particular congress has already been assessed.



Q: Your company would like to organise a product training meeting and one of the options is Estoril, Portugal, in January. Should the training be hosted there?



A: YES, provided the Event complies with the general criteria for events laid down in **Chapter 1 of the Code apply to all Events**. These criteria apply regardless of whether they are organised by a Member Company or by a Third Party.

The chosen geographic location should be in or near a city or town which is a **scientific or business centre conducive to exchange of ideas and the transmission of knowledge**.

For European and international events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question, but the Code does not automatically exclude any location based on it being known as a touristic destination.

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

Third Party Organised Educational Event



- Third Party Organised Educational Conferences

- Third Party Organised Procedure Training



- **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

Examples:

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



- **Third Party Organised Procedure Training:**

- Primarily intended to provide HCPs with hands-on 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.
 - Such trainings cannot be linked or be organised around to a Third-Party Organised Conference.

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.



Q. Your company would like to place systems at KOL laboratories so that they can work on the systems, publish results and speak of those results and the performance of the system at conferences. The work done/study undertaken is fully funded by your company. Is this arrangement still acceptable after 1st January 2018?



A: YES. This arrangement would still be acceptable if it happens in the context of a **satellite symposium of a conference**. Member Companies can still invite HCPs to speak in these satellite symposia provided the speaker services are part of a **consulting agreement**.

If the HCP would be a speaker in the main event of the conference his or her support should be done through an Educational Grant to the organiser of the conference.

Please, note that participants in the satellite symposia cannot be sponsored.



Q. Your company has allocated a specific budget to support HCPs to attend Third Party Organised Educational Conferences and support medical education. You are used to select individual HCPs to support their medical education.

Would it be compliant with the new Code after 1st January 2018?



A: NO. After 31 December 2017, Member Companies shall no longer provide support directly to individual HCPs to cover costs of their attendance at Third Party Organised Educational Events. Consequently, companies will no longer be able to select individual HCPs.

You may support individual HCPs to attend Third Party Organised Educational conferences through Educational Grants provided to an HCO.

Company Events

- **Product and Procedure Training and Education Events**

- **Sales, Promotional and Other Business Meeting**



- **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.



- **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 (unless demonstrations of non-portable equipment are necessary)



Q: My company would like to organise a new product demonstration in our factory in Frankfurt, can I still invite doctors from outside Germany?

✓ **A: YES**, it is acceptable to invite HCPs from outside the country where the company event takes place provided the event **complies with all the other requirements of the Code** and if there is a **legitimate business need**.

If the participants are primarily of one country the venue should be in the specific venue involved, if the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected is the residence of at least some of the participants.

Chapter 3 of the Code provides that travel or accommodation support to HCPs can only be provided for **demonstrations of non-portable equipment**, so it shall be assessed whether the product that is going to be presented falls within this category or not.



Q. Your company would like to organise and pay a dinner for a few Healthcare Professionals, unrelated to any Event, as a thank you for key customers. Would it be compliant with the new Code?



A: NO. Member Companies are generally not allowed to invite and pay for individual HCPs to come to a dinner, when this dinner is not connected to any Event.

Such a dinner is to be considered as a Business and Sales meetings, there must be legitimate business purpose and, in any case, it would not be appropriate to facilitate or pay for travel or accommodation support.

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:

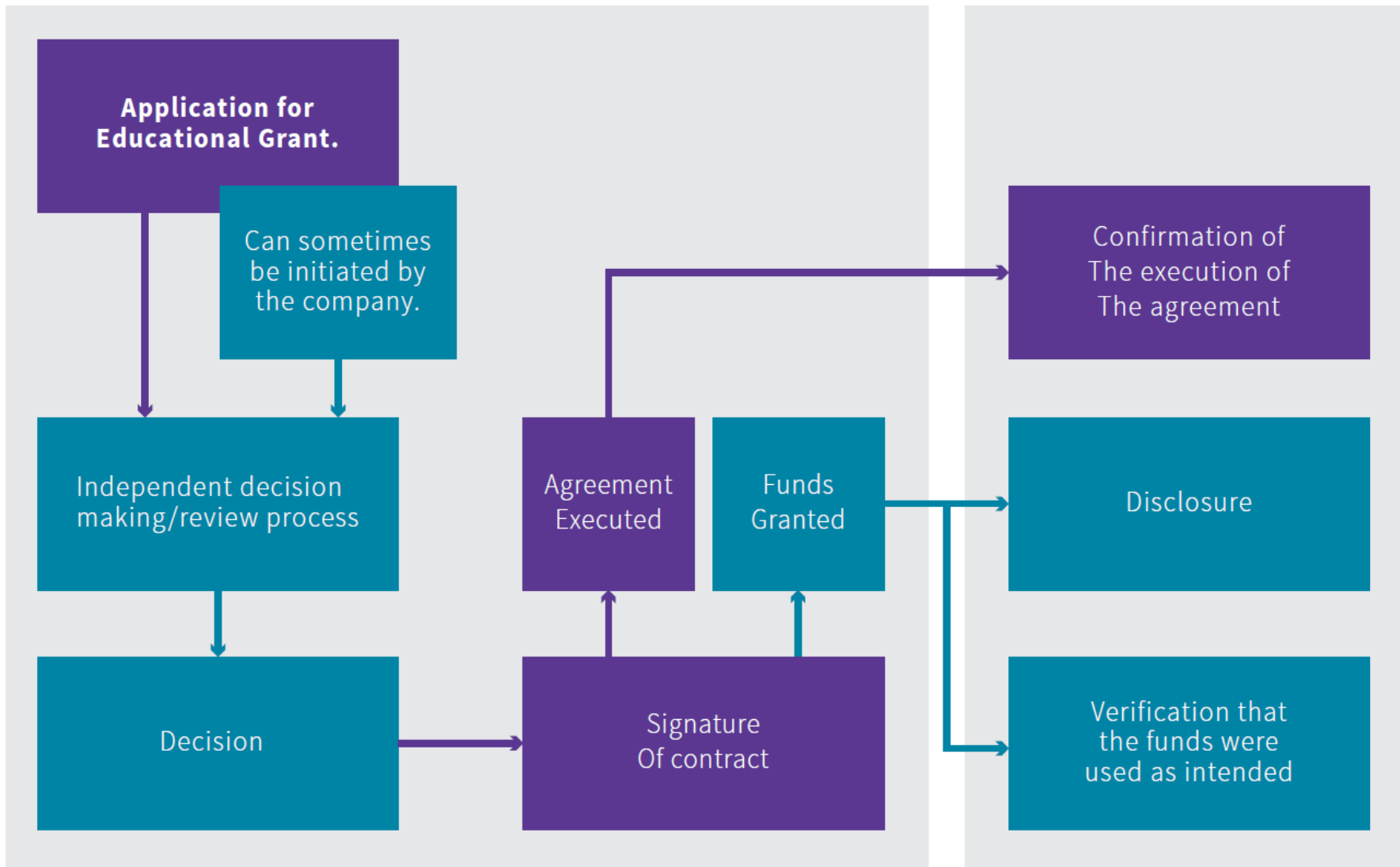
- *Support for HCPs participation*
- *Support for event*

Scholarships and fellowships

Grants for public awareness campaigns

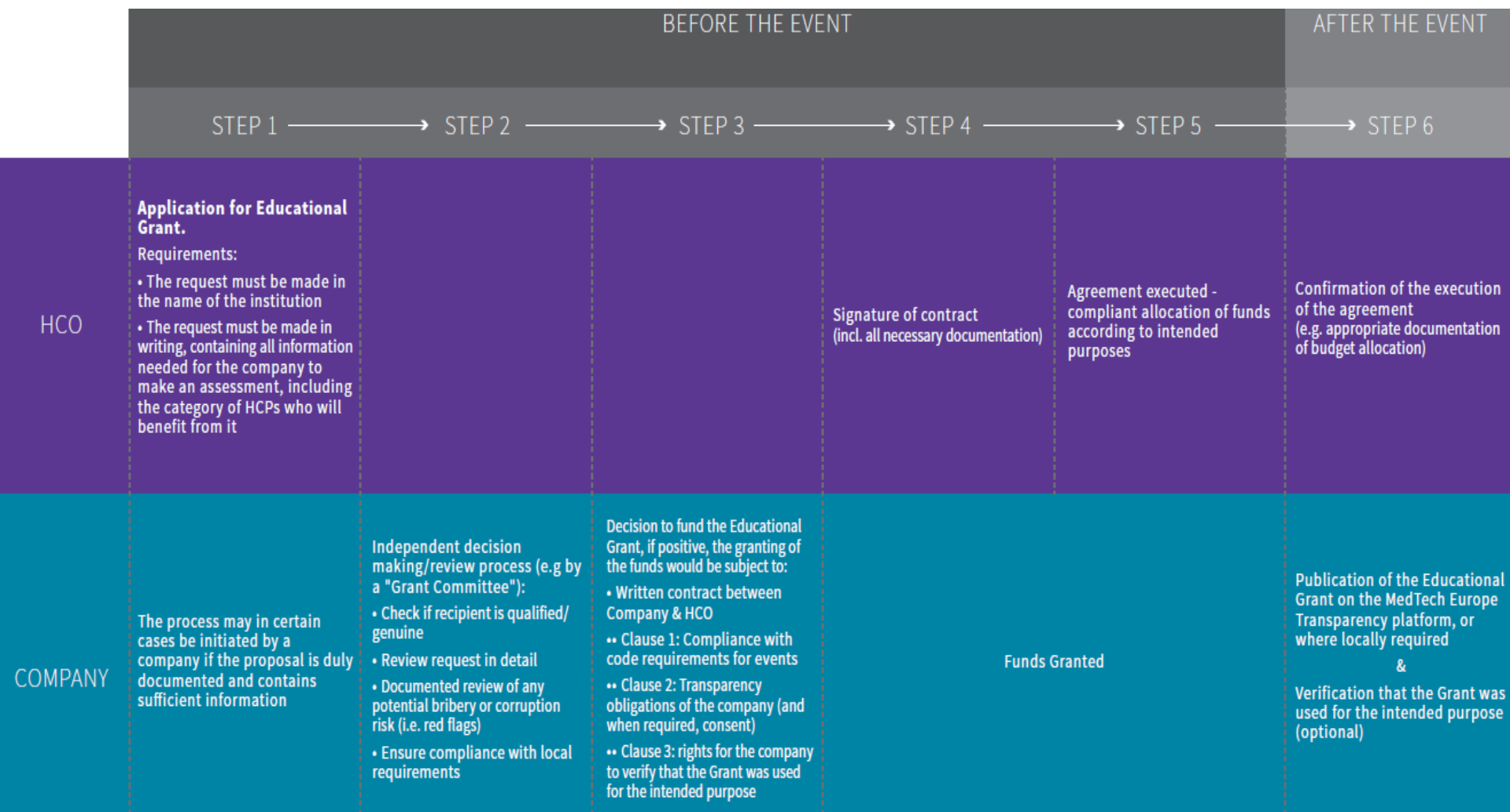


Can only be
provided to
HCOs



BEFORE THE EVENT

AFTER THE EVENT



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



Q: Your company would like to sponsor an Educational Event related to a specific sector in which it is active. Your commercial department has decided to provide an Educational Grant to the local Hospital and identified in the draft Contract some HCPs belonging to the relevant sector.

Is this process compliant with the new Code?



A: NO:

1. According to the **principle of Separation**, an **independent decision making/review process** shall be implemented by Member Companies. Sales' function shall not decide upon and/or approve a decision to provide a Grant or a Charitable Donation. For example, such independent process could be led by a Member Company's Legal, Finance or Compliance functions, according to clear, transparent decision making process.
2. Member Companies shall only provide **restricted Educational Grants**, meaning that companies shall only specify the intended purpose of the Educational Grant, and not select individual HCPs.



Q: A medical society has approached your company asking for support to their annual medical conference. In particular, they would like your company to support the attendance of young physicians. In the past, your company used to select the HCPs individually, will this be possible after 1st January 2018?



A: NO. After 31 December 2017, Member Companies shall no longer provide support directly to individual HCPs to cover costs of their attendance at Third Party Organised Educational Events. Consequently, companies will no longer be able to select individual HCPs.

However, you may provide Educational Grants specifying the category of HCPs that would benefit from it. You may for instance specify that the Educational Grant is intended to cover the attendance costs for young physicians. This is what is known as a “restricted” Educational Grant.



Q: Your company supports the attendance of HCPs to a Third Party Educational Conference.

You would like to tell an HCP that your company has provided an Educational Grant to the HCO organising the conference, is this allowed?

✓ **A: YES**, you may inform the HCP that such Educational Grant is supported by your company. **However**, you shall not contact directly or indirectly the HCO in charge of the selection of HCPs who will benefit from the Educational Grant.

Arrangements with Consultants




- **Member Companies may engage HCPs to provide *bona fide* consulting and other services, e.g.:**
 - Research
 - Participation in 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?





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.



Q: Your company concluded a consultancy agreement with an HCP to conduct post-market research. The HCP asks you if, within the framework of this agreement, it would be possible to cover his costs for travel and accommodation as he will attend a Third Party Organised Educational Conference as speaker in the main program. Is this compliant with the new Code?



A: NO. After 31 December 2017, Member Companies shall no longer provide support directly to individual HCPs to cover costs of their attendance at Third Party Organised Educational Events.

There are two exceptions to this rule:

- Third Party Organised Procedure Training meetings,
- Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium pursuant to a consulting agreement.

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

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

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

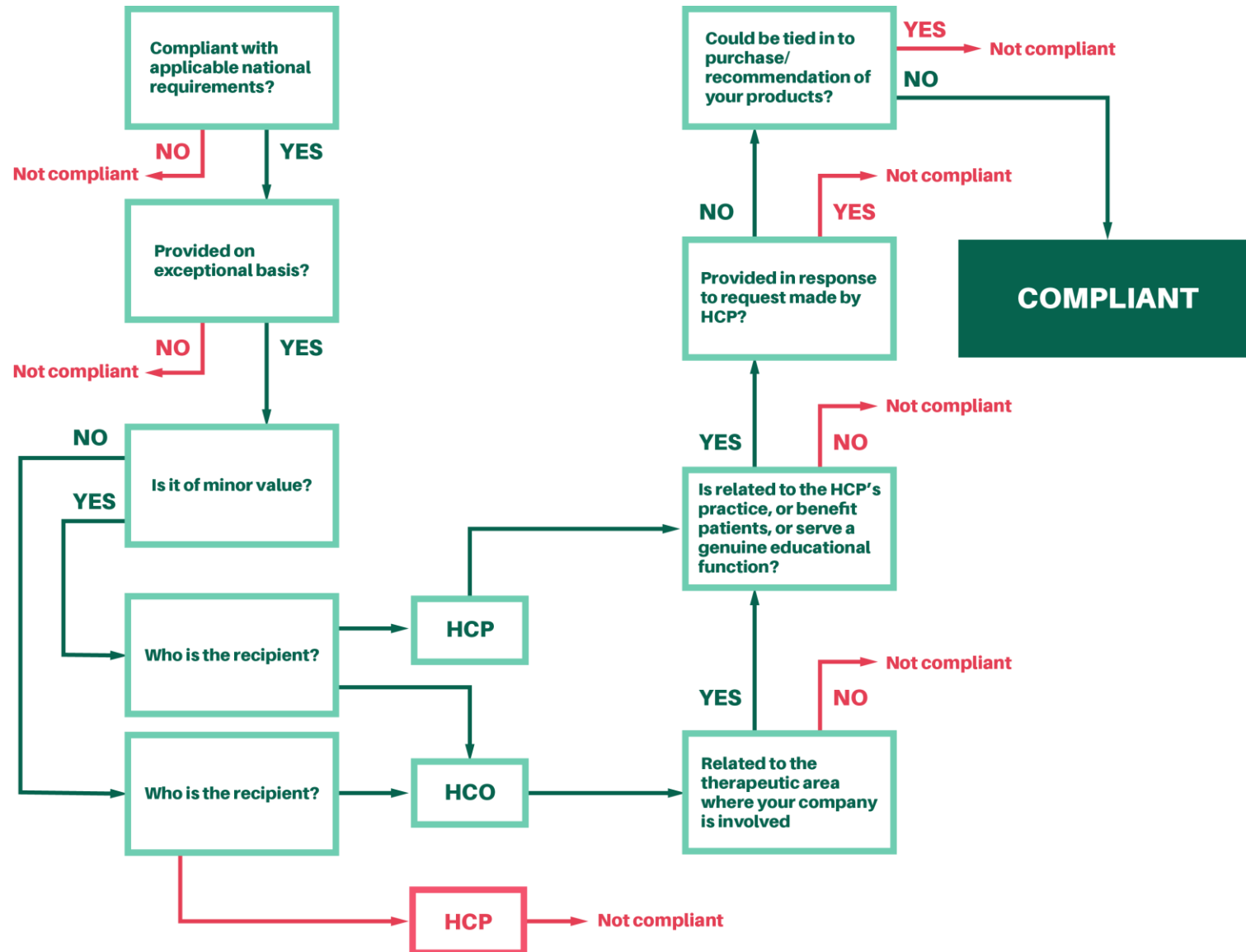
Inexpensive

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

- X** Cash or cash equivalence
- X** Food (e.g. fruit basket; chocolate), alcohol and items which are primarily for use in the home or car
- X** Gifts to mark significant life events e.g. marriage, birth or birthday



Q: An employee of a MedTech 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.



Q: Your company wants to run a raffle at a congress and the prize would be a bottle of champagne. Is this allowed under the new Code?

X **A: NO.** Although raffles are allowed under the new Code, they need to comply with all the requirements of Chapter 8 on Educational Items and Gifts.

Therefore, this raffle would not be compliant with the new Code as:

- 1- The prize is not related to the Healthcare Professionals practice or benefit patients, or serve a genuine medical education function.
- 2- Gifts must not encourage Healthcare Professionals to recommend, prescribe, use, supply or procure the Member Company's products or services.
- 3- It would not be compliant with the Principle of Perception and Image.

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



Demonstration Products	Samples
<p>Provided solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use</p>	<p>Provided in order to enable HCPs to familiarise themselves with the products in clinical use</p>
	<p>Single-use Samples:</p> <ul style="list-style-type: none">- Quantity not exceeding the amount reasonably necessary to acquire adequate experience
	<p>Multiple-use Samples:</p> <ul style="list-style-type: none">- 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



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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