# MedTech Europe
# Code of Ethical Business Practice

## December 2015

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MedTech Europe
from diagnosis to cure

www.medtecheurope.org

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# INTRODUCTION

## Promoting an Ethical Industry

MedTech Europe[1] is the only European trade association representing the medical technology industry from diagnosis to cure. We represent In-Vitro Diagnostics and Medical Devices manufacturers operating in Europe. Our mission is to promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders.

MedTech Europe recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology industry.

The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. 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 and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes. Furthermore, Member Companies must be mindful of the fact that they may be liable for the activities of third party intermediaries who interact with Healthcare Professionals or Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation impose obligations upon the third party (for example, third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives) to comply with provisions set out in the Code or equivalent guidelines[2].

## Key Legislation

The medical technology industry in Europe, in common with other industries, is subject to national and supranational laws which govern many aspects of their business operations. MedTech Europe underlines compliance with the following laws and regulations as having particular relevance to the medical technology industry:

- Safety, Quality and Performance Laws;
- Advertising and Promotion Laws;
- Data Protection Laws;
- Anti-corruption Laws;
- Environmental Health and Safety Laws;
- Competition Laws.

National and European Union (EU) competition legislation applies not only to Members in their business operations, but also to MedTech Europe, each of the alliance's working groups and any sub-group within

***QI:** Is the Code applicable to activities of an Affiliate of a Member Company located outside the MedTech Europe Geographic Area? (Added in September 2018)*

***AI:** "With regards to activities of an Affiliate of a Member Company located outside of the MedTech Europe Geographic Area;*

*The Code is applicable:*
*• whenever they support an Event taking place in the MedTech Europe Geographic Area or*

*• whenever they interact with Healthcare Organisations located, or Healthcare Professionals registered or practising inside the MedTech Europe Geographic Area.*

*The Code is not applicable:*
*• whenever they support an Event taking place outside the MedTech Europe Geographic Area (for the avoidance of doubt and as stated in the above paragraph; except if they are supporting participation of Healthcare Professionals registered or practicing inside the MedTech Europe Geographic Area to attend the Event) or*

*• interact with Healthcare Organisations located, or Healthcare Professionals registered or practising outside the MedTech Europe Geographic Area.*

*However, in the interest of increased transparency, it would always be preferable for the Affiliate of the Member Company based in the MedTech Europe Geographic Area to handle support for Healthcare Professionals attending Events held in the MedTech Europe Geographic Area.*

1) Please note that on 30 November 2016, Eucomed AiSBL and EDMA members have decided to transfer the totality of their assets and liabilities to MedTech Europe and dissolve Eucomed and EDMA. Therefore any reference to EDMA and Eucomed have been deleted in the Code.

2) For further details, please refer to the Eucomed/AdvaMed Third Party SMIs guidance.

the associations, irrespective of size and name. Liability under competition laws may be strict and a Member may become liable for the infringement of such laws by other Members of an association group in which it participates. Accordingly, Members must make every effort to observe EU and national competition laws in all their interactions.

## Aims and Principles of the Code

The interaction between Members and Healthcare Professionals and Healthcare Organisations is an important feature in achieving MedTech Europe's mission to make safe, innovative and reliable technology and related services available to more people. For example:

- Advancement of Medical Technologies
  The development of innovative medical devices, technologies and in vitro diagnostics and the improvement of existing products require collaboration between Member Companies and Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services.

- Safe and Effective Use of Medical Technology
  The safe and effective use of medical technology and related services requires Member Companies to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support.

- Research and Education
  Member Companies' support of bona fide medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction Member Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the industry. To achieve this aim, the Code provides guidance on the interactions of Member Companies with both Healthcare Professionals and Healthcare Organisations, based upon the following underlying principles:

- **The Principle of Image and Perception**: Member Companies should, at all times, consider the image and perception of the medical technology industry that will be projected to the public when interacting with Healthcare Professionals and Healthcare Organisations.

- **The Principle of Separation**: Interaction between industry and Healthcare Professionals/ Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies' products.

***Q1:*** *Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain?*

***A1:*** *No, the definition of Healthcare Professional does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' medical devices for or on behalf of medical or clinical personnel. For example, if a Member Company's medical devices are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall under the Code. However, where the Member Company's medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the Member Company and the responsible purchasing professional will fall under the Code.*

- **The Principle of Transparency**: Interaction between industry and Healthcare Professionals/ Healthcare Organisations must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, Member Companies shall nevertheless maintain appropriate transparency by requiring prior written notification to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.

- **The Principle of Equivalence**: Where Healthcare Professionals are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent a fair market value for, the services performed by the Healthcare Professional.

- **The Principle of Documentation**: For interactions between a Member Company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for or on behalf of a Member Company, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member Company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the Member Company for a reasonable period of time to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

## Interpreting the Code

The use of capital letters indicates that a word or expression is a defined term, the meaning of which is set out in the Glossary.

Any phrase introduced by the terms: including, include, in particular, or any similar expression shall be interpreted as illustrative and shall not limit the sense of the words preceding those terms.

## Administering the Code

The Code operates within a Procedural Framework which includes procedures designed to provide an effective and efficient complaint-handling process, at national and European level, to ensure compliance with the Code. MedTech Europe's dispute handling system is based on the principle that disputes are generally national in nature and are therefore best resolved at national level. For complaints between Member Companies, mediation should be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MedTech Europe level.
The principles outlined in the Procedural Framework aim at supporting Member Associations when setting up or amending their national dispute-resolution mechanisms. They are based on principles of proportionality, speed, due process, fairness and transparency and have been established under the guidance of the MedTech Europe Compliance Panel, acting independently of MedTech Europe.

***Q2:** Must a Member Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO? (added in November 2016)*

***A2:** No. Unless the Member Company's interaction with an HCP entails a transfer of value or raises a potential conflict of interest there is no requirement for Employer Notification. However, Member Companies must comply with any access requirements imposed by HCOs to visiting Member Company personnel.*

The Conference Vetting System is an independently-managed system which reviews the compliance of Third Party Organised Educational Events with the Code.

The Code and the Procedural Framework shall be reviewed when required and at a minimum every five (5) years for the Code and every two (2) years for the Procedural Framework, in accordance with the governance rules of MedTech Europe.

***Q3:** What is the Conference Vetting System (CVS) and, is CVS approval required for all Third Party Organised Educational Events before a Member Company can provide support to these events? (added in November 2016)*

***A3:** The Conference Vetting System (see the Glossary) has been established as the online, binding and centralised decision-making process to help Member Companies review the compliance of relevant Third Party Organised Educational Events with the Code. It is managed independently of the MedTech Europe Secretariat and Members and is under the supervision of the MedTech Europe Compliance Panel. CVS approval is only required for Third Party Organised Educational Events which fall within its scope, as provided here. Where there is a CVS decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Member Companies.*

***Q3bis:** What is a Virtual Third Party Organised Educational Event ("Virtual Event") (added in June 2019)*

***A3bis:** A [stand-alone] Virtual Third Party Organised Educational Event ("Virtual Event") consists of the filming of presentations, panel discussions or live clinical procedures (e.g. hands-on sessions, surgery simulations, live surgeries, etc.) and their broadcasting (whether immediate or deferred) to an audience which is not physically in attendance.*

*A Virtual Event is delineated by the lack of Healthcare Professional ("HCP") attendees, as the only HCPs physically present at a Virtual Event are those involved in its creation, i.e. presentation. As a result, a Virtual Event will not be connected in any way with a physical Third Party Organised Educational Event.*

*Conversely, the filming of presentations, discussions, etc. made during a Third Party Organised Educational Event ("Broadcasted Event"), and its broadcasting to audiences not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event.*

*For avoidance of doubt, Member Companies may provide financial and/or in-kind support (e.g. Member Company products) to Virtual Events in accordance with the rules of the Chapter 2 of the Code.*

***Q3ter:** Are Virtual Events subject to the MedTech Europe Conference Vetting System (CVS)? (added in June 2019)*

***A3ter:** Virtual Events are not subject to CVS. Third Party Organised Educational Events as well as their broadcasting, falling in the scope the MedTech Europe CVS, are subject to CVS. Both Virtual and Broadcasted Third Party Organised Educational Events are subject to the rules of the MedTech Europe Code of Ethical Business Practice.*

# Implementation and Transition Period

This edition of the Code comes into force as follows:

- PART 2: The Dispute Resolution Principles[3] shall enter into force on 1 January 2016; and
- The balance of the Code [i.e. Introduction, PART 1 and PART 3] shall enter into force on 1 January 2017.

For the avoidance of doubt, during the transposition period 1 January 2016 to 31 December 2016, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.

***Q4:** What is the difference between the Transposition period and the Transition Period as defined in the Glossary? (added in November 2016)*

***A4:** Transposition means the process of incorporating the Code within the Member Company's own policy and procedures. This process must be completed by 1 January 2017.*
*Transition Period means the period between 1 January 2016 and 31 December 2017 by the end of which Member Companies must have ceased all financial or in kind direct support to Healthcare Professionals to attend Third Party Organised Educational Conferences. Any exceptions to this rule are outlined in the Code*

**Transition Period to phase out direct support for HCP attendance at Third Party Organised Educational Events and for HCP speakers at satellite symposia**

After the end of the Transition Period (see the Glossary) on 31 December 2017, Member Companies shall no longer provide financial or in kind support directly to individual Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium. This means that support of individual Healthcare Professionals to attend Third Party Organised Educational Events (as provided for at *Chapter 2, Section 3*) shall no longer be permitted under the Code.

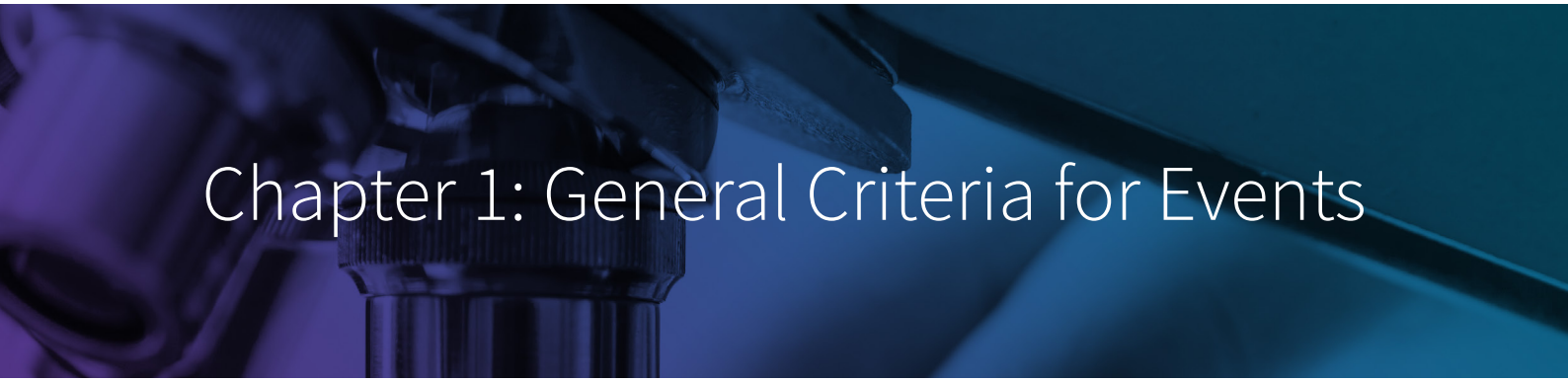
After the Transition Period, Member Companies may provide financial or in kind support to Third Party Organised Educational Events only through Educational Grants or other types of funding in accordance with the rules of Chapter 2: Third Party Organised Educational Events and Chapter 4: Charitable Donations and Grants.

***Q4-bis:** How does the Code apply to members with company structures that include different business units e.g., medical devices, pharmaceuticals, research only products? How can educational grants be applied in such organizational structures? (amended in April 2018)*

***A4-bis:** The Code applies to all Member Companies regarding their interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with structures combining different business units, however Member Companies are required to comply with the Code as a minimum standard for all interactions linked to Medical Technologies independent of their organizational set up. For example, if a member were to have Medical Devices or In Vitro Diagnostics marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to these medical technologies would be governed by the Code irrespective of the business unit that pays for or manages the interaction. In this respect, the Member Company cannot circumvent the Code's requirements by using its pharmaceutical business/affiliate to directly support a Healthcare Professional to attend a medical technology-related Third Party Organised Educational Conference as this would amount to a violation of the Code. For the avoidance of doubt, the Code will not apply to Member Companies' interactions linked exclusively to non- Medical Technology products or services such as medicinal products or research only products, without any link to Medical Technology products. However, this does not mean that different business units can be used to circumvent Code requirements as explained above. In case an interaction or activity is linked in part to Medical Technology products, the Code shall apply.*

3) The Dispute Resolution Principles were replaced by the Procedural Framework in October 2016. Please visit www.medtecheurope.org to find the latest version.

# PART 1
# Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations



# Chapter 1: General Criteria for Events

Member Companies may invite Healthcare Professionals to Company Events and Third Party Organised Educational Events. The principles and criteria set out in this Chapter 1 shall apply to all such Events supported in any way by Member Companies, irrespective of who organises the Event.

**1. Event Programme**

The Event programme should directly relate to the specialty and/or medical practice of the Healthcare Professionals who will attend the Event or be sufficiently relevant to justify the attendance of the Healthcare Professionals. For Third Party Organised Educational Events, the agenda should be under the sole control and responsibility of the third party organiser.

A Member Company shall not organise Events which include social, sporting and/or leisure activities or other forms of Entertainment, nor support such elements where part of Third Party Organised Educational Events. For Third 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.

***Q5:** What is meant by "legitimate" or "genuine" as used in the definitions of 'Company Event' and 'Third Party Organised Educational Conferences'?*

***A5:** Any Event should be relevant to the Healthcare Professional attendees; the detailed programme should be available sufficient time prior to the Event; present a clear schedule with no gaps during the sessions, (e.g., the minimum duration for a full day Event should be 6 hours or 3 hours for a half day Event including refreshment breaks). If it is a Third Party Organised Educational Event the Faculty must be identified. It is also important that all supporting materials (e.g. flyers, brochures and website) are consistent with the scientific or promotional nature of the programme content, as the case may be.*

***Q6:** Can a Member Company organise or support an Event at a hotel or resort that offers significant leisure facilities such as golf, casino or ski/water sports?*
*(Amended in June 2017)*

***A6:** In principle no. It is not appropriate for a Member Company to organise or support Events at hotels or resorts renowned for their entertainment facilities or centred around recreational or sporting activities such as golf, private beach or ski/water sports.*

*Exceptions might be considered for venues well adapted to business meetings in an otherwise compliant geographic location where there is a compelling need to use the chosen venue, for example, a lack of alternative venues or genuine safety or security issues. In certain circumstances, hotel accommodation separate from the Third-Party Organised Event venue might be required for compliance.*

- 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.

*Where an exception is considered, the Event's promotional material should not feature the on-site leisure aspects of the conference venue as a key attraction and the Event's agenda should be arranged in such a way that attending Healthcare Professionals would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to use the leisure or sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.*

*For reasons of perception, cruise ships or hotels with on-site casinos are under no circumstances compliant with the Code, either as an Event venue or for accommodation for Healthcare Professionals.*

***Q7:** Under the Code, what is meant by "ease of access" in relation to Event location and venue?*

***A7:** When originating location of the majority of attendees is considered, Event location and venue need to be in close proximity to an airport and / or train station with appropriate international connections, with associated reliable ground transportation infrastructure to the venue.*

***Q8:** Under the Code, how does the "season" impact evaluation of Event location? (Amended in March 2019)*

***A8:** Even assuming a location or venue meets all other applicable requirements under the Code, geographic locations renowned primarily as seasonal vacation or holiday destinations (for example, ski-, island-, or beach resorts) are still not appropriate locations during the season in question. For this purpose, in Europe, the ski season is considered to run from December 20 - March 31 and the summer season from June 15 - September 15. Equivalent, seasonally adjusted dates apply in other regions of the world. Member Companies must not support or organise Events at these locations if they take place during those seasons, even if only in part.*

**3. Guests**

Member Companies are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for Guests of HealthcareProfessionals, or for any other person who does not have a bona fide professional interest in the information being shared at the Event.

***Q9:** What does the term "facilitate" mean where used in connection with the Guest expenses?*

***A9:** The term "facilitate" refers to the prior arrangement, organisation or booking of meals, travel or accommodation by or on behalf of a Member Company on behalf of the Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in his/her own right, irrespective of who pays. Such actions are open to misinterpretation. If Healthcare Professionals attending the Event wish to be accompanied by a Guest who does not have a professional interest in the information being shared, the Healthcare Professional must take sole responsibility for the payment and organisation of the Guest's expenses.*

***Q10:** In the event that a Healthcare Professional is accompanied by a Guest at the Event, may this Guest be admitted to any Company Event, or Third Party Organised Educational Events?*

***A10:** It is not appropriate for a Guest of a Healthcare Professional to attend either Company Events (including Satellite Symposia) or Third Party Organised Educational Events (unless the individual qualifies as a participant in their own right), nor is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest's expenses.*

*Member Companies, however, may financially support Third Party Organised Educational Events which offer extra-curricular programmes/activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), always provided that such an extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, facilitated or reimbursed by, a Member Company.*

**4. Reasonable Hospitality**

Member Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events and Third Party Organised Educational Events but any hospitality offered must be subordinate in time and focus to the Event purpose. Member Companies must in any event meet the requirements governing hospitality in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the Event is being hosted.

The Code seeks to find a balance between the courteous and professional treatment of Healthcare Professionals by Member Companies, with the desire to avoid even the appearance that hospitality may be used by Member Companies as a means to induce Healthcare Professionals to purchase, prescribe or recommend Member Companies' products.

Accordingly, Member Companies must assess what is "reasonable" in any given situation and regional variations will apply. As a general guideline, "reasonable" should be interpreted as the appropriate standard for the given location and must comply with the national laws, regulations and professional codes of conduct. The term "hospitality" includes meals and accommodation and it is important that Member Companies differentiate between "hospitality" which is permitted and Entertainment which is not. Please refer to the Glossary for the definition of Entertainment.

Member Companies may not pay for or reimburse Healthcare Professionals' lodging expenses at top category or luxury hotels. For the avoidance of doubt, if the Event venue is a hotel which complies with the requirements of the Code, it would be acceptable for Member Companies to offer participants meals and accommodation at the same hotel. However, accommodation and/or other services provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

***Q11:** Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Healthcare Professional for a specific amount to cover all or part of the Healthcare Professionals' travel or accommodation expenses for attendance at the Event?*

***A11:** It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively Member Companies may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.*

**5. Travel**

Member Companies may only pay or reimburse for reasonable and actual travel. Travel provided to Healthcare Professionals should not cover a period of stay beyond the official duration of the Event.

For air travel, in principle, this means that Member Companies can only pay or reimburse economy or standard class unless the flight time is of a duration of greater than 5 hours including connection flights, in which case business class can be considered. First class is never appropriate.

***Q12:** May Member Companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the Event programme attended?*

***A12:** Generally, travel and accommodation support offered by Member Companies to Healthcare Professionals should be tailored to the duration of the Event. Member Companies must always keep in mind the impression which may be created by the arrangements for any meeting.*

**6. Transparency**

Member Companies must ensure full compliance with national laws with regard to the disclosure or approval requirements associated with such financial support and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, as a minimum, by requiring Employer Notification (as defined in the Glossary) is made prior to the Event.

***Q13:** Under the Code, is Employer Notification required for each interaction with a Member Company? For example, is such notification required each time a Member Company pays for a reasonably priced meal or gives a Healthcare Professional a gift, which is otherwise in line with the requirements of the Code?*

***A13:** Employer Notification is required whenever a Member Company engages a Healthcare Professional or whenever a member makes a financial contribution to the Healthcare Professional's medical education. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest gifts related to the Healthcare Professional's practice, do not require Employer Notification.*

***Q14:** Are members required to provide additional written notification under the Code to the hospital administration, Healthcare Professional's superior (or other locally-designated body) for Member Company/ Healthcare Professional interactions in countries where there are compulsory notification systems already in place?*

***A14:** No. Only the compulsory notification is required. Additional notification under the Code is not required in countries where specific notification requirements of law or regulation govern the transparency of interactions between industry and Healthcare Professionals. The transparency provisions of the Code apply only in countries where there is an absence of national transparency laws and regulations.*

***Q15:** When making Employer Notification, are Member Companies required to provide details of the proposed financial contribution Member Companies will make to the Healthcare Professional in exchange for the services rendered?*

***A15:** The written notification must comply with national laws, regulations and professional codes of conduct. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the Code, Member Companies must ensure that the level of remuneration is commensurate with the services provided and not greater than a fair market value. However, the purpose of the Employer Notification is to provide transparency on the nature of the interaction between the Member Company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.*

# Chapter 2: Third Party Organised Educational Events

Member Companies may provide financial and/or in kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of this Code. Such Events include:

- Third Party Organised Educational Conferences; and
- Third Party Organised Procedure Training meetings.

**1. Third Party Organised Educational Conferences**

Member Companies may support in cash and/or in kind Third Party Organised Educational Conferences (see the Glossary) which comply with:

- Chapter 1: General Criteria for Events; and
- Where applicable, has approval via the Conference Vetting System (see the Glossary)[4].

Where permitted under national laws, regulations and professional codes of conduct, Member Companies may provide financial and/or in kind support to Third Party Organised Educational Conferences (always provided that the Third Party Organised Educational Conference has been approved via the Conference Vetting System, where appropriate) through grants and other types of funding, such as:

**a. Educational Grants**

Please refer to Chapter 4: Charitable Donations and Grants for guidance on Educational Grants.

**b. Promotional Activity**

Member Companies may purchase packages that may include promotional and advertising services, for example, advertisement space and booth space for company displays. Member Companies should ensure that the overall image projected by the promotional activity at Third Party Organised Educational Conferences is perceived as professional at all times. It should never bring discredit upon or reduce confidence in the medical technology industry.

***Q16:** What is meant by "in kind support" as used in Chapter 2, Section 1 of the Code in connection with "Third Party Organised Educational Conferences"? (amended in January 2018)*

***A16:** "In kind support" can be provided to the Healthcare Organisation (HCO) and Member Companies should take care to ensure that any such in kind support does not, nor is perceived to, circumvent the prohibition of Member Companies providing direct financial support to identifiable Healthcare Professionals (HCPs) to attend Third Party Organised Educational Conferences. For example, after the Transition Period, it would not be appropriate for Member Companies to directly handle the conference registration, travel, or accommodation arrangements for individual (and identifiable) HCP delegates at a Third Party Organised Educational Conference. Examples of "in kind support" which Member Companies may provide could include modest secretarial and/or logistical support to assist with meeting arrangements.*

***Q17:** Please provide examples of appropriate booth activities which will be perceived as professional?*

***A17:** Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies' products and services and related literature. Therefore, other activities should be limited and reasonable and in principle, only soft drinks and snacks should be served.*

***Q18:** Can a Member Company for example be present via a satellite symposium, rent booth space at a Third Party Organised Educational Conference which was assessed as non-compliant by the Conference Vetting System (CVS)? (Amended in November 2016)*

***A18:** Please refer to Annex I for a detailed visualisation of the scope of CVS and its impact on commercial activities.*

4)For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

### c. Satellite Symposia

Member Companies may purchase satellite symposia packages at Third Party Organised Educational Conferences and provide presentations on subjects that are consistent with the overall content of the Third Party Organised Educational Conference. Member Companies may determine the content of these satellite symposia and be responsible for speaker selection.

***Q19:** Can Member Companies directly support attendance by Healthcare Professionals engaged to speak only at satellite symposia at Third Party Organised Educational Conferences, e.g. registration fee, travel and/or accommodation? (Amended in June 2017)*

***A19:** Member Companies must ensure all aspects of the arrangement comply with the Code, including entering into a consulting agreement with Healthcare Professionals engaged to speak at satellite symposia. The consulting agreements may provide for payments to be made in respect of travel and/or accommodation for the purpose of delivering the speaker services. Where payment of a registration fee is required in order for speakers to access satellite symposia, Member companies may also pay for the registration fee.*

## 2. Third Party Organised Procedure Training

Member Companies may support Third Party Organised Procedure Training either via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants) or by providing financial support directly to individual Healthcare Professionals to cover the cost of attendance at Third Party Organised Procedure Training sessions in accordance with the following rules:

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. Member Companies may therefore pay travel, hospitality and the registration fee.
- Where applicable, the Third Party Organised Procedure Training has approval via the Conference Vetting System (see the Glossary) [5].
- For financial support to Third Party Organised Procedure Training meetings Member Companies must apply the requirements governing conduct and attendance at such meetings in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted.

***Q20:** What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings? (added in November 2016)*

***A20:** Both Third-Party Organised Educational Conferences (see the Glossary) and Procedure Trainings (see the Glossary) are a type of Third Party Organised Educational Events. Therefore, they must comply with Chapter 1. General Criteria for Events; and, where applicable, are subject to the Conference Vetting System (see the Glossary). However, unlike Third Party Organised Educational Conferences, Third Party Organised Procedure Trainings are not subject to the phase out of direct support for the attendance of HCPs. Nonetheless, for Third Party Organised Procedure Trainings the following three criteria shall apply:*

*• Programme: Unlike Third Party Organised Educational Conferences which are theoretical in nature, Third Party Organised Procedure Trainings consist of practical, hands-on trainings, generally involving more than one provider/manufacturer/sponsor.*
*This must be evident by the programme of the Event. The programme, which is often referred to as a "course", rather than a conference or seminar, must be focused on acquiring specific medical skills relevant to certain medical procedures (rather than products, or medical technologies). Examples may include courses aimed at acquiring or improving the Healthcare Professional's skills in minimally invasive surgery; orthopaedic trauma surgery; or the implantation of cardiac rhythm devices; etc.*
*The programme must also include practical demonstrations (and/or actual live surgeries, where allowed). Examples of practical demonstrations may include surgery simulations where technologies are used on cadavers; skin models; synthetic bones; cath labs; etc.*

*• Venue: Third Party Organised Procedure Trainings are typically organised in a clinical environment, as opposed to, e.g., a classroom setting. For the avoidance of doubts, the adjective "clinical" includes places suitable for the simulation of medical procedures, rather than just the medical treatment of real patients.*
*Examples of clinical environment include hospitals or clinics, where medical treatment on real patients may be given; as well as conference rooms which are appropriately set up to simulate medical procedures, for example with the presence of medical technologies to be used on cadavers; skin models; synthetic bones; etc.*

*• Stand-alone event: Third Party Organised Procedure Trainings must stand-alone. Where the majority of the Training is not given in a clinical environment, for example, where the Training is organised in connection, adjacent to or at the same time as a larger Third Party Organised Educational Conferences, that Training will not qualify as a Third Party Organised Procedure Training, as defined in the Code.*

5)For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

***Q21:*** *In the definition of Third Party Organised Procedure Training, what is meant by "Proctorship" and "Preceptorship"? Further, do Proctorships and Preceptorships require CVS approval before they can be provided and/or supported by a Member Company? (added in November 2016)*

***A21:*** *For the purpose of the Code both Proctorship and Preceptorship are types of clinician-to-clinician training funded by a Member Company.*
*Proctorship is where the trainee clinician performs a procedure under the supervision of another clinician and where the trainee clinician has primary responsibility for the patient undergoing the procedure.*
*Preceptorship is where the supervising clinician oversees the procedural training of the trainee clinician and the trainee does not have primary responsibility for the patient undergoing the procedure.*
*Such Proctorships and Preceptorships normally take place on HCO premises and are not subject to CVS approval as it is not considered to be either a Third Party Organised Educational Event or a Third Party Organised Procedural Training.*

**3. Transition Period: Support of Individual Healthcare Professionals to Third Party Organised Educational Events**

Member Companies may provide financial support directly to individual Healthcare Professionals to cover the costs of attendance at Third Party Organised Educational Events where this is permitted under national laws, regulations and professional codes of conduct. Such support shall be in accordance with the following rules:

- Financial support must comply with the criteria provided in Chapter 1: General Criteria for Events. In addition Member Companies may pay the registration fee.
- Where applicable, the Third Party Organised Educational Event has approval via the Conference Vetting System (see the Glossary).
- For financial support to Third Party Organised Educational Events Member Companies must apply the requirements governing conduct and attendance at such Third Party Organised Educational Event in the country where the Healthcare Professional carries on their profession and give due consideration to the requirements in the country where the meeting is being hosted.

# Chapter 3: Company Events

**1. General Principles**

Member Companies may invite Healthcare Professionals to Company Events. Such events include, as defined in the Glossary:

- Product and Procedure Training and Education Events
- Sales, Promotional and Other Business Meetings

Company Events should comply with the principles mentioned in Chapter 1: General Criteria for Events.

Where there is a legitimate business purpose, Company Events may include or take place in Member Company's manufacturing plant or Healthcare Organisations, used by the Member Company as reference centres.

***Q22** Is it appropriate for Member Companies to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?*

***A22** Yes, it is appropriate for Member Companies to invite Healthcare Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the Code in all respects.*

**2. Product and Procedure Training and Education Events**

Where appropriate, in order to facilitate the safe and effective use of medical technologies, therapies and/or services, Member Companies should make product and procedure training and education available to relevant Healthcare Professionals.

Member Companies shall ensure that personnel conducting the Product and Procedure Training and Education Events have the appropriate expertise to conduct such training.

***Q23** Can Member Companies directly support travel and/or accommodation or other expenses of individual Healthcare Professionals for attendance as delegates at Company Organised Events, happening during or around a Third-Party Organised Educational Event? (Amended in January 2020)*

***A23:** No, as of 1 January 2018, Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating as delegates in Company Organised Events which take place during, around, or at the same time and in the same approximate location as a Third-Party Organised Event.*

*However, company Organised Events—including fee-for-service arrangements like Advisory Boards and Clinical Investigator meetings—may be organised at or around a Third Party Organised Educational Event for reasons of convenience and efficiency, given the attendance of Healthcare Professionals at that Third-Party Organised Educational Event. If such an event overlap occurs, the Member Company may only pay for the contractual remuneration and expenses agreed for the provision of the services by the Healthcare Professional at the Company Organised Education Event itself. Under no circumstances may a Member Company pay for incremental costs relating to the Healthcare Professional's attendance at the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel or accommodation. Member Companies may provide flexibility in the Healthcare Professionals' travel arrangements—provided there is no additional or incremental cost involved (i.e. registration, hospitality, additional accommodation or travel). Moreover, the Healthcare Professionals must have an active role at such a Company Organized Event, rather than being mere passive attendees. [E.g. no support shall be provided by Member Companies to Healthcare Professionals attending a Company Organised Educational Event as a delegate or trainee where this is organised at or around a Third Party Organised Educational Event.]*

*Specific examples of support which can and cannot be provided could include the following:*

- *For an advisory board or a clinical investigator meeting organized at or around a Third-Party Organised Educational Event:*
  - *the registration fee of the Healthcare Professional to the Third-Party Organised Educational Event shall in no circumstances be covered by the Member Companies - as this would not be related to the services to be provided.*

- *the flight and accommodation costs can be covered pursuant to the services provided, with the flexibility caveat noted above.*

• *For a satellite symposium or a booth speaker engagement taking place during the Third-Party Organised Educational Event (i.e. as part of that Third-Party Organised Educational Event):*

- *the Healthcare Professional's registration fee for the Third-Party Organised Educational Event may be covered only if the Healthcare Professional's access to the satellite symposium or booth at the Third-Party Organised Educational Event is conditional upon the payment of the registration fee. Where this does apply, the registration fee must, where possible, be prorated to the actual attendance required in order to deliver the required services. E.g. if the satellite symposium is held on a single day of the three-day event, and it is possible to choose a one-day registration, that option should be selected.*

- *the flight and accommodation costs can only be covered if the Healthcare Professional is not already benefiting from an educational grant covering his/her attendance to the event.*

• *If a Member Company wishes to organise a legitimate business or scientific meeting which includes lunch or dinner with selected Healthcare Professionals in the context of a Third Party Organised Educational Event, the following conditions must be met before the Member Company may cover the hospitality costs :*

- *The meeting should have a legitimate business or scientific purpose and the lunch or dinner must not be the primary purpose of the invitation but must instead be only subordinate to the purpose of the meeting ;*

- *The invitation to the lunch or dinner should be made to a small number of participants, in order to ensure effective contribution by way of transfer of knowledge, discussion and exchange among the participants in line with the meeting's legitimate business or scientific purpose . In no case can a Member Company issue a blanket invitation to all the participants at the Third Party Organised Educational Event . Any such invitation should have regard to Q&A 38.*

- *The Member Company must ensure that the hospitality provided complies with all local laws and regulations, and with the MedTech Europe Code of Ethical Business Practice, more particularly Chapter 1 (General Criteria for Events).*

*In all cases, Member Companies should pay special attention to instances where Healthcare Professionals may be benefiting from an Educational Grant which already covers all forms of hospitality; and be mindful of the impact that their interactions with Healthcare Professionals may have on the image and perception of the industry as a whole.*

### ***Q24** Under the Code, Chapter 3, Point 2, what is meant by "Company Organised Educational Event"? (added in November 2016)*

***A24** "Company Organised Educational Event" is a Company Event as defined in the Glossary, whose objective is genuine and bona fide medical education, and the enhancement of professional skills. "Educational" means communicating information directly concerning or associated with the use of Member Companies' medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations. In all cases the information and/or training must directly concern a Member Company's medical technologies, therapies and/or related services. This means that a Member Company must meet the following tests when organizing such an Event in order to be compliant with the MedTech Europe Code:*

*The entire Event must comply with the criteria of Chapters 1 and 3;*

*a) The programme must be rigorous from a scientific and/or educational point of view. This means that its content must include current scientific information of a nature and quality which is appropriate to the Healthcare Professionals who are attendees at the Event.*

*b) The programme must be genuine and bona fide educational, and therefore cannot have a primary sales and marketing objective. This means that the Education part must fill most of the Program.*

*c) Information on the programme, clearly indicating the name of the Company organising the Event, should be made available sufficiently in advance in order for invited Healthcare Professionals to be able to make a reasoned judgment as to the rigor and quality of the programme, provided however that subsequent changes, deletions and additions to the programme are acceptable to the extent that such changes, deletions and additions are reasonable and do not significantly modify the quality or nature of the programme.*

*d) The programme should in principle involve full days, with the majority of the morning and afternoon parts dedicated to scientific and/or educational sessions, unless the Event is a half day event, commences or ends on a mid-day or lasts less than half a day. Such half-day or less sessions are permissible, but there should not be any non-scientific or non- educational events or activities organized for the other part of the day. Furthermore, there should be no significant gaps in the programme which would permit Healthcare Professionals to engage in non-scientific or non-educational activities. For example, early morning sessions should not be followed by late afternoon or evening sessions with large blocks of free time in between.*

***Q25** Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Education Events?*

***A25** No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used. Appropriate examples include hospital, clinic or surgical centre laboratory, educational, conference, or other appropriate settings, including Member Companies' own premises or commercially available meeting facilities, that are conducive to effective transmission of knowledge and any required "hands on" training.*

### 3. Sales, Promotional and Other Business Meetings

Where it is appropriate, Member Companies may organise Sales, Promotional and Other Business Meetings where the objective is to discuss product and related services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles laid down in the Chapter 3, Section 1, Sales, Promotional and Other Business Meetings should also comply with the following more stringent requirements:

- Such meetings should, as a general rule, occur at or close to the Healthcare Professional's place of business;
- It is not appropriate for travel or accommodation support to be provided to Healthcare Professionals by Member Companies, except where demonstrations of non-portable equipment are necessary.

***Q26** What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Education Events?*

***A26** If the participants are primarily of one country, the venue should be in the specific country 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 of the Product and Procedure Training and Education Event.*

***Q27** Can a Member Company use a meeting venue outside Europe?*

***A27** Yes, provided the participants are from multiple countries outside Europe. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) is the residence of at least some of the participants of the Product and Procedure Training and Education Event.*

***Q28** Can Member Companies directly support travel and/or accommodation of individual Healthcare Professionals at Company Events, which include new product launches, even if only portable equipment or solutions are being demonstrated? (Added June 2017)*

***A28** Member Companies can pay for travel and/or accommodation of individual Healthcare Professionals to attend Company Events which include product launches provided that such Events fall within the scope of Chapter 3, Section2, of the Code ("Product and Procedure Training and Educational Events").*

# Chapter 4: Grants and Charitable Donations

**1. General Principles**

**a.** Grants and Charitable Donations (see the Glossary) shall not be contingent in any way on past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services. It is important that support of charitable and/or philanthropic programmes and activities by Member Companies is not viewed as a price concession, reward to favoured customers or as an inducement to purchase, lease, recommend, prescribe, use, supply or procure Member Companies' products or services.

**b.** A Member Company shall not provide Grants or Charitable Donations to individual Healthcare Professionals. Grants and Charitable Donations must be provided directly to the qualifying organisation or entity, as the case may be. Grants and Charitable Donations shall not be provided in response to requests made by Healthcare Professionals unless the Healthcare Professional is an employee or officer of the qualifying organisation or entity and submits the request in writing on behalf of the qualifying organisation or entity.

**c.** The payment (or provision of other support) by way of any Grant or Charitable Donation shall always be made out in the name of the recipient organisation and shall be paid directly to the organisation. A Member Company shall not provide Grants or Charitable Donations in the name of any Healthcare Professional. In addition, all Grants and Charitable Donations shall identify the Member Company as the provider of the Grant or Charitable Donation.

**d.** It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit from the particular type of Grant/Charitable Donation.

**e.** Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with the provision of a Grant or a Charitable Donation to a specific prospective recipient. This process shall include a documented, prior evaluation of any such associated risks and of the relevant information concerning the intended recipient organisation or entity.

***Q29** Under the General Principles in Chapter 4. Grants and Charitable Donations, what is meant by an "independent decision-making/review process"?*

***A29** In accordance with the Principle of Separation, an "independent decision-making/review process", is a process where the decision-making criteria are not primarily sales-driven and where the Member Company's sales function does not decide upon and/or approve a decision to provide a Grant or Charitable Donation. For example, such a process could be led by a Member Company's legal, finance or compliance functions, operating within a robust governance framework and according to clear, consistent and transparent criteria for review and decision-making.*

***Q30** Under the Code, what is meant by "prior evaluation of any associated risks and of the relevant information" relating to a Grant or a Charitable Donation?*

***A30** Prior to deciding to provide a Grant or a Charitable Donation, the Member Company must evaluate the appropriateness of the award of the proposed Grant or Charitable Donation to the proposed recipient. Such an evaluation shall consider all the circumstances including, but not limited to, consideration of the legal status and structure of the requesting ( i.e. prospective recipient) organisation as well as of the nature and scope of its activities and the terms and conditions to which the Grant or Charitable Donation will be subject. The evaluation shall be documented and shall be based on information available to the Member Company, such as information or documentation available from public sources.*

*For Educational Grants provided in relation to Third Party Organised Educational Events, this may also include information of how the funds have been applied by the recipient in relation to previous equivalent Events and whether funds have been spent in accordance with the terms and conditions of any previous Grant*

***Q31** What does "sufficient information" mean where used in connection with documentation of Grants and Charitable Donations?*

***A31** The written request by a requesting organisation should include as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is the object of the Grant or Charitable Donation. It shall also contain a description of the proposed recipient, its legal status and structure, and where relevant, a budget.*

**f.** All Grants and Charitable Donations must be appropriately documented by the Member Company. Moreover, Grants and Charitable Donations shall only be provided in response to a written request submitted by the requesting organisation or documented initiative from a Member Company containing sufficient information to permit an objective evaluation of the request to be carried out by the Member Company. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.

**g.** This section of the Code (Chapter 4: Grants and Charitable Donations) is not intended to address the legitimate practice by Member Companies of providing appropriate rebates, additional product and/or service offerings, including free of charge, or other comparable pricing incentive mechanisms ("value adds") which are included in competitive and transparent centralised purchasing arrangements, such as, for example, tenders.

**2. Charitable Donations**

Member Companies may make unrestricted Charitable Donations for genuinely charitable or other philanthropic purposes. "Unrestricted" in this context means that Member Companies shall have no control over the final use of funds (or other support) they provide as Charitable Donations beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes.

Charitable Donations may be made only to charitable organisations or other non-profit entities which have charitable and/or philanthropic purposes as their main purposes and which are objectively engaged in genuine charitable or philanthropic activities.

Charitable Donations shall always be made in accordance with the general principles set out in Chapter 4: Grants and Charitable Donations.

Restricted Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (see Glossary), when Charitable Donations serve exclusively the benefit of the patient, are limited in value, or explicitly permitted by applicable national laws.

This section of the Code (Chapter 4: Grants and Charitable Donations– Charitable Donations) is not intended to address legitimate commercial transactions by Member Companies in the form of leasing of stands or booth space at Third Party Organised Educational Events and/or at any conference or event organised by a charity or other philanthropic organisation. Such activity is considered to be part of Member Companies' normal marketing activity. Member Companies should, however, always consider the appropriateness of the location, venue and the general arrangements for any such events and the impression that may be created by the arrangements in order not to bring the industry into disrepute.

***Q32** Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?*

***A32** No, a Member Company cannot make available a Charitable Donation to support the general running of a hospital or other Healthcare Organisation. A Charitable Donation shall only be given to a legal entity or body which has charitable and/or philanthropic purposes as its main purposes. For the purpose of the Code and irrespective of their legal status, hospitals and Healthcare Organisations are considered to generally have health functions as their main purposes and accordingly are not generally considered to have charitable and/or philanthropic functions as their main purposes. It is not therefore appropriate to provide Charitable Donations to support their general running.*

***Q33** Is it permissible for a Member Company to specify restrictions in relation to the final use of a Charitable Donation where a Member Company wishes its Charitable Donation to be applied as part of a specific aid programme or as part of the relief effort following a specific natural disaster, such as a major earthquake in a particular country? (added in November 2016)*

***A33** Under the Code it is not appropriate for a Member Company to apply conditions or restrictions to the final use of a Charitable Donation which go beyond general restrictions to ensure that the funds (or other support) are applied for charitable and/or philanthropic purposes. Member Companies may therefore impose general restrictions concerning the final use, such as the relief of a specific disaster in a particular country (e.g. for use to aid reconstruction and/or re-equipping of healthcare facilities following the earthquake in that country). However, Member Companies must take care that such general restrictions are not so specific that the Charitable Donation is no longer unrestricted. The Charitable Donation must not be misused or be perceived to influence through undue or improper advantages, purchasing decisions, nor should such Donation be contingent upon sales transactions or use or recommendation of Member Companies' products*

***Q34** Is it permissible for a Member Company to make a Charitable Donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the Member Company to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the Member Company?*

***A34** No. Under the Code it is not appropriate for a Member Company to support the favourite charity of a Healthcare Professional in response to a request by that Healthcare Professional irrespective of the underlying reasons. No exception can be made for sport events, such as payment of the registration charge to participate in a charity run.*

***Q35** Under the Code, may a Member Company make a Charitable Donation such as the purchase of a table of dinner invitations at a fundraising dinner or entries to participate in, or attend at, a fundraising sports or other event?*

***A35** Yes, Charitable Donations made by Member Companies may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charitable or other non-profit philanthropic organisation. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company should not invite Healthcare Professionals to attend such an event at the Member Company's expense. Furthermore, the Member Company is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the Member Company's table.*

### 3. Educational Grants

Member Companies may provide restricted Educational Grants (see the Glossary) for the advancement of genuine medical education. "Restricted" in this context means that Member Companies shall specify the intended purpose of the Educational Grant in the Grant agreement. A Member Company shall also ensure that the Educational Grant agreement with the recipient organisation includes rights to enable it to verify that the Grant is in fact used for the agreed intended purpose.

Member Companies shall document and publicly disclose all Educational Grants in accordance with the Code's Disclosure Guidelines, and publication shall commence no later than the end of the Transition Period.

Member Companies may provide Educational Grants for the following (non-exhaustive) purposes:

**a. Support for Third Party Organised Educational Events:**

As a general principle, any Third Party Organised Educational Event supported by way of an Educational Grant from a Member Company to a Healthcare Organisation must:

- Comply with Chapter 1. General Criteria for Events; and
- Where applicable, have approval via the Conference Vetting System (see the Glossary)[6]

***Q36** Can a small sized Healthcare Organisation (HCO) receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events? (added in November 2016)*

***A36** Yes, in principle. There are no size limits for HCOs to receive Educational Grants; however, Member Companies must ensure that the final beneficiaries of the Educational Grant cannot be identified beforehand. For example, HCOs composed of a single Healthcare Professional will in practice not be allowed to receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events, as the final beneficiary is known upfront.*

6) For scope of application of CVS please refer to: http://www.ethicalmedtech.eu

***Q36-bis** Can an Educational Grant or funds earmarked for education be provided to a specific hospital or department or specify individual hospital or department as criteria for HCOs and/or PCOs? (added January 2018)*

***A36-bis** One of the guiding principles in the Code is that companies should not receive or be able to determine the names of the ultimate HCP beneficiaries and the inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However, companies should bear in mind that the smaller the hospital or department the greater will be the risk that companies will be able to make such a determination making the use of such a criterion inappropriate under the Code. In addition, companies should be mindful of any proximate or ongoing tender proceedings with that specific hospital, as such tenders may raise additional red flags.*

**1) Support for HCP Participation at Third Party Organised Educational Events:**

Where the Educational Grant is provided for the purpose of supporting Healthcare Professionals' attendance at Third Party Organised Educational Events, the Healthcare Organisation receiving the Grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written Grant agreement.

***Q37** How can Member Companies in practice ensure that Educational Grants made available for Third Party Organised Educational Events which are subject to the Conference Vetting System, are positively reviewed by CVS?*

***A37** It is the responsibility of Member Companies to individually ensure compliance with this Code obligation. For example, Member Companies may themselves consider submitting relevant Third Party Organised Educational Events for CVS review or they may decide to include appropriate contractual obligations making it a pre-condition for an Educational Grant that the Third Party Organised Educational Event be submitted and positively assessed via the CVS, for example by the prospective Grant recipient or by a third party.*

***Q37-bis** Can Member Companies give criteria for HCOs and/or PCOs to allocate their Educational funds?*
*(added in January 2018)*

***A37-bis** Yes, objective criteria for a HCOs and/or PCOs to select HCPs to benefit from Educational funds may be given as long as such selection criteria are relevant to the HCPs' educational needs and are not so specific that it would effectively select individual HCPs. Examples of criteria for selecting Educational Grant Recipients are Healthcare Professionals' specialty, years of practice, country, city/region of practice and/or academic criteria such as number of publications, participation in clinical trials in a given pathology.*

**2) Support for Third Party Organised Educational Events:**

Where the prospective beneficiary of an Educational Grant is the organiser of the Third Party Organised Educational Event and is also a Healthcare Organisation, the recipient Healthcare Organisation shall be solely responsible for:

- The programme content;
- The selection of Faculty; and
- The payment of Faculty honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of Faculty (see Glossary) and this shall be reflected in the written Grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

***Q38** Is it appropriate for a Member Company that has provided an Educational Grant to support Healthcare Professional attendance at a Third Party Organised Educational Event to receive the names of the Healthcare Professionals benefiting from the Educational Grant? (Added in June 2017)*

***A38** A Member Company should not proactively seek to receive the names of the Healthcare Professionals benefiting from its Educational Grant. Generally, when a Third Party Organised Educational Event is supported by more than one company, all companies should receive the same attendance list, from which it should not be possible to identify which Healthcare Professionals have benefited from a particular Member Company's Educational Grant.*

*However, where required by law, a Member Company may, in accordance with the applicable legal requirements, request and obtain the names of the Healthcare Professionals participating in the Event, who are benefiting from that Company's Educational Grant.*

*For purposes of auditing, compliance and monitoring by relevant Company functions, it may be necessary for a Member Company to request and receive the names of the Healthcare Professionals who have benefited from the Educational Grant provided by the Member Company after the Event has taken place.*

*In either of the above cases, unless required by law, such Healthcare Professional names should never be received by the Member Company until the Educational Grant agreement has been signed and the independent selection process of the Healthcare Professionals has been completed.*

***Q38-bis** Can a Member Company provide funds to a commercial organisation where the commercial organisation will be responsible for the management of the Educational Grant (i.e., selection of HCPs, arrangement of conference attendance, travel and accommodation) but is not the organiser of the event (or all of the events) in question? (Amended in November 2018)*

***A38-bis** In principle yes, however Member Companies must bear in mind that certain compliance risks may rise from working with intermediary companies for the management of Educational Grants, and must also take all necessary actions to mitigate them. In particular, Member Companies must ensure that any company receiving funds for the management of Educational Grants manages those funds in accordance with the Code. To the extent the managing company will select particular HCPs to benefit from the grant, the Member Company must ensure that the managing company has the experience and expertise sufficient to make an appropriate selection. Additionally, Member Companies must include appropriate and specific compliance-related criteria in all contractual arrangements relating to management of Educational Grants, to ensure that the funds are used appropriately and in accordance with ethical standards and local rules and regulations. The contractual arrangements should include appropriate provisions to provide the Member Companies the right to monitor and audit the activity of the companies managing the Educational Grants. However, Member Companies may not provide an Educational Grant or Educational funds to a Third Party Travel Agency directly. For the avoidance of doubt, a Member Company may provide an Educational Grant to a Healthcare Organisation (HCO) or funds earmarked for education to a Professional Conference Organizer (PCO) which is structured so that payments for travel, accommodation [and registration] are remitted directly by the Member Company to a third party travel agency on behalf of the HCO / PCO, which is the recipient of the Educational Grant or the funds earmarked for education. In these circumstances the Member Company may choose to establish a tri-partite contract, with the HCO/ PCO and the third party travel agency. Such a third party travel agency could in principle include a third party travel agency also used by the Member Company for its own internal travel arrangements provided this is not a Company-internal function or Company-owned entity. In any event, where a Member Company decides to use any such arrangement involving funding for, or payments to, a third party travel agency to arrange travel, accommodation [and/or registration] it is important that the Member Company carries out appropriate, prior due diligence on a country-by-country and case-by-case basis in order to evaluate and mitigate the particular compliance risks and practicalities where such an arrangement is considered.Additionally, the Member Company must include in all of the contractual arrangements appropriate and specific compliance-related criteria and conditions for the HCO/ PCO to outsource travel arrangements to a third party travel agency, which should include appropriate provisions to allow the monitoring and controlling the activity of the third party travel agency.*

***Q39** Does Chapter 4: Donations and Grants – Educational Grants of the Code apply to requests received by Member Companies in the context of public procurement processes for educational support for Third Party Organised Educational Events from Healthcare Organisations and purchasing bodies?*

***A39** No. Such requests and any subsequent financial or other support provided by a Member Company are not considered to be Educational Grants for the purpose of the Code. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.*

***Q40** In the event that a commercial organisation, such as a Professional Conference Organiser (PCO), organises a Third Party Organised Educational Event independently of any Healthcare Organisation (HCO), is it appropriate for Member Companies to sponsor such events and what rules shall apply? (modified in November 2016)*

***A40** Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser organising a Third Party*

*Organised Educational Event independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organiser are for-profit organisations. Sponsorship arrangements are therefore commercial in nature and Member Companies should consequently document these in a written commercial agreement in accordance with normal business practice and the requirements of the Code (Chapter 2: Third Party Organised Educational Events). In addition, where a Member Company provides funds earmarked for the advancement of genuine educational purposes to a Professional Conference Organiser, acting independently of any Healthcare Organisation, , all the Code provisions governing Educational Grants shall also apply. For example, if a Member Company provides funding to a Professional Conference Organiser to fund Healthcare Professional delegate places and expenses at a Third Party Organised Educational Conference, such Event, where applicable, must have CVS approval and the Member Company shall publicly disclose such funding in accordance with the Code's Disclosure Guidelines.*

**b. Scholarships and Fellowships**

Member Companies may provide Educational Grants on a restricted basis in the form of Grants for Scholarships and Fellowships to support advancement of genuine medical education of Healthcare Professionals (see the Glossary). Only Healthcare Organisations where Healthcare Professionals are in training shall be eligible to request and/or receive such Educational Grants.

A Member Company shall not provide Educational Grants to support Scholarships and Fellowships upon request of individual Healthcare Professionals. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written Grant agreement between the Member Company and the recipient HCO.

***Q41** Can a Member Company pay for or reimburse travel costs to a Third Party Organised Educational Event for a Scholar or Fellow?*

***A41** No, a Member Company cannot additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised Educational Event. Such costs shall be included in the Educational Grant supporting the Scholarship or Fellowship if it is intended that the Grant should extend to such attendance.*

***Q42** Can Member Companies support professional training of Healthcare Professionals on general medical education topics, such as courses on health economics/health technology appraisal, good laboratory practice or similar topics that promote patient care? (Added in June 2017)*

***A42** Member Companies can support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with Chapter 4 of the Code.*

*Member Companies can also support genuine medical training on general healthcare-related topics through company-organised "Product and Procedure Training and Education Events" as long as the information directly concerns the Member Company's medical technologies, therapies, and/or related services. The Event must be conducted in accordance with, and meet the other requirements of, Chapter 3, Section 2 of the Code.*

**c. Grants for Public Awareness Campaigns**

Member Companies may also provide Educational Grants on a restricted basis to Healthcare Organisations for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved.

***Q43** What are examples of relevant disease awareness and health education for patients, carers and the general public for which a Member Company may legitimately provide an Educational Grant?*

***A43** A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific HCOs, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations.*

**4. Research Grants**

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide restricted Research Grants (see the Glossary) to support clearly defined third party-initiated research studies for clinical or non-clinical research programmes in therapeutic areas in which the Member Company is interested and/or involved. Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research.

Member Companies providing Research Grants shall ensure that they do not influence the research. However, in order to ensure that Research Grants are provided on a "restricted" basis, Member Companies shall clarify the intended research scope and purposes for which the Grant is requested and shall ensure that the written Grant agreement with the recipient organisation includes rights for the Member Company to verify that the Grant is applied solely for the agreed intended research use. Such verification may include a request for study-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the study report upon completion or earlier termination of the research.

All requests for Research Grants from prospective Grant beneficiaries must be in writing and must detail, as a minimum, the type, nature and objectives of the research activity, the milestones and budget, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorisations or approvals.
A Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project but shall not take any final decision regarding the Grant request unless and until the research receives formal ethics committee approval.

Research Grant agreements shall include provisions relating to adverse event reporting where appropriate, and shall require full disclosure of the Member Company and of the Grant by the Grant recipient organisation and the lead-investigator in all oral or written presentations of the results.

For guidance on how Member Companies may undertake Member Company-initiated research please refer to Chapter 6: Research: Member Company-Initiated Research.

***Q43-bis** Can Member Companies support the participation of Poster or Abstract Presenters in Third Party Organised Educational Conferences? (Added in March 2019)*

***A43-bis** Poster or Abstract Presenters at Third Party Organised Educational Conferences are not to be considered as Speakers, as defined in the Code ("Glossary"). As such, if Member Companies want to support their participation in the Conference, such support may be provided through an Educational Grant (if it complies with the requirements of the Code, specifically those of Chapter 4). Alternatively, the support can be included in a Research Agreement, whether it relates to Company Initiated or Third Party Initiated Research.*

*However, if the support is included in a Research Agreement, Companies may only support attendance of Poster and Abstract presenters to Third Party Organised Educational Conferences provided the following considerations are met:*

*- The selection of the Poster or Abstract Presenters is done independently by the Third Party Organiser of the Event,*
*- The support envisioned must be specific and detailed in the Research Agreement between the Member Company and the Healthcare Organisation, and*

*- The Company is not directly involved in the selection of the specific investigator who would benefit from the support (for the avoidance of doubt principal investigators with whom a company might have a direct relationship would be eligible to receive support for the dissemination of the research results).*

*Companies should also consider including in the Research Agreement a clause which stipulates that funds will be made available only once the Poster or Abstract Presenter has been selected independently by the Third Party Organiser of the Event.*

# Chapter 5: Arrangements with Consultants

**1. General Principles**

Member Companies may engage Healthcare Professionals as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, consulting arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practise and be consistent with applicable professional codes of conduct in that country.

The principles in this chapter are applicable to all consulting arrangements between Healthcare Professionals and Member Companies including where a consultant Healthcare Professional declines a fee for provision of their services.

Consulting arrangements shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the Member Company's products or services.

When selecting consultants, Member Companies shall implement an independent decision-making/review process to identify, prevent and mitigate against potential bribery and corruption risks arising in connection with use of consultants. This process shall include a documented, prior evaluation of any such associated risks and of the relevant background information concerning each prospective consultant.

**2. Criteria for genuine consulting arrangements**

In addition to the general principles above, the arrangements which cover genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

**a.** Consulting arrangements must be entered into only where a legitimate business need for the services is identified in advance.

**b.** The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.

**c.** Selection of consultants must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by a prospective consultant or the Healthcare Organisation where s/he performs her/his professional activity is not a relevant criterion.

**d.** Consulting arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the nature of the services to be provided and the basis for payment for those services.

**e.** The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

**f.** The remuneration for the services rendered must be reasonable and reflect the fair market value of the services provided.

**g.** Member Companies must maintain records of the services, and associated work products, provided by the consultant Healthcare Professionals and of the use made of those services by the Member Company.

**h.** The venue and other arrangements (e.g. hospitality, travel etc.) for Member Company meetings with consultants shall follow the rules for Events set out in Chapter 1: General Criteria for Events.

### 3. Remuneration and Fair Market Value

The remuneration paid to Healthcare Professionals engaged as consultants by Member Companies shall reflect fair-market-value for the services provided. It shall not be in any way contingent upon the value of products or services which consultants may purchase, lease, recommend, prescribe, use, supply or procure in the course of their own professional practice or that may be purchased, leased, recommended, prescribed, used, supplied or procured by HCOs where they carry on their professional activities.

All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for expenses reasonably incurred by consultants in providing the services which are the subject of the consulting agreement including reasonable travel, meals and accommodation expenses incurred by consultants if attending meetings with, or on behalf of Member Companies. The written consulting agreement must detail which expenses can be claimed by the consultant in relation to the provision of the services and the basis for payment of these by the Member Company.

***Q44** What is meant by fair market value (FMV) in the context of consulting arrangements?*

***A44** Fair-market-value is the value of the specified consultancy services which would be paid by the Member Company to the consultant, each dealing at arm's length in an open and unrestricted market, and when neither party is under any compulsion to buy or sell, and both parties have reasonable knowledge of the relevant facts.*

***Q45** How should Member Companies determine FMV for a service?*

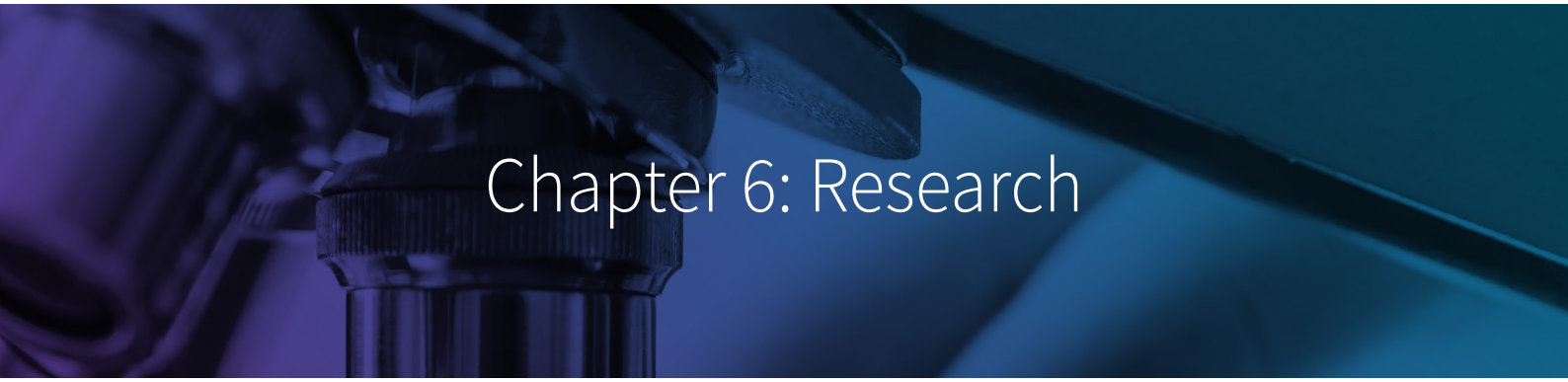
***A45** A Member Company must be able to demonstrate internal methodology to determine fair market value. Amongst other matters this shall take account of the consultant's qualifications, expertise and experience as well as the actual services to be provided to the Member Company.*

**4. Disclosure and Transparency**

Member Companies shall ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring any publication, disclosure or approval in connection with the use by Member Companies of Healthcare Professionals as consultants.

All required consents and approvals shall be obtained, including from the hospital or other Healthcare Organisation administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable. Where no such national requirements apply, Member Companies shall nevertheless maintain appropriate transparency by requiring the relevant Employer Notification which shall disclose the purpose and scope of the consultancy arrangement.

Member Companies shall also include appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and his/her involvement in the research for, or the preparation of, material for scientific publication is disclosed at the time of any publication or presentation.



# Chapter 6: Research

**1. Member Company-Initiated Research**

Where there is a legitimate business need to do so, Member Companies may initiate, conduct, manage and finance scientifically valid research to generate data, whether pre- or post-market. In this context, legitimate business needs for data include medical needs, including patient safety; research and development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Where a Member Company uses a Healthcare Professional as a consultant, for example to lead a study on the Member Company's behalf (i.e. act as Principal Investigator), the Member Company shall ensure that such consulting arrangements comply fully with Chapter 5: Arrangements with Consultants.

In accordance with the Documentation Principle, any arrangements made by a Member Company to procure research-related services shall be set out in a written agreement which shall reference a written research protocol; written schedule of work and provide for all required consents, approvals and authorisations to be obtained prior to the commencement of the study.

Member Companies must ensure that their research activities comply with all applicable national laws, regulations and researchers' own professional codes of conduct, as well as with applicable Good Clinical Practice guidelines, if relevant.

In accordance with the Principles set out in the Introduction: Aims and Principles of the Code, Member Companies shall also ensure appropriate clinical trial transparency in relation to their research activities and results. This shall include appropriate disclosure of information about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals.

Where Member Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the research conducted by these third parties on behalf of the Member Company is carried out in accordance with all applicable legal and ethical requirements, including the applicable requirements of the Code.

***Q46** What is an example of an external public registry for clinical trial transparency?*

***A46** Examples of an external public register for clinical trial transparency are www.clinicaltrials.gov or www.who.org*

**2. Member Company Post-Market Product Evaluation**

Where there is a legitimate business need to do so, Member Companies may initiate, post-market third party evaluation of their products, therapies and/or related services and may therefore provide Evaluation Products under a written contract for services in order to obtain defined user evaluation by Healthcare Organisations in relation to the Evaluation Products. Evaluation Products may be provided on a no charge basis in return for the requested user feedback from Healthcare Professionals at the Healthcare Organisation, which shall be formally described in a written protocol or questionnaire forming part of the contract.

Where the Evaluation Products are multiple-use Evaluation Products the defined period of time necessary for the evaluation and feedback to occur will depend on the frequency of anticipated use; the nature of the user evaluation feedback requested; the duration of any required training and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Evaluation Products and that they have a process in place for promptly removing such multiple use Evaluation Products and/or any unused single-use Evaluation Products from the Healthcare Organisation's location at the conclusion of the evaluation period unless these are purchased by the Healthcare Organisation.

Provision of Evaluation Products and/or related services 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 Evaluation Products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

**3. Third Party-Initiated Research**

Please refer to Chapter 4: Charitable Donations and Grants: Research Grants.

# Chapter 7: Royalties

Healthcare Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or medical technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement.

A royalty arrangement between a Member Company and a Healthcare Professional should be entered into only where the Healthcare Professional 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 Healthcare Professional would be considered to be the sole or joint owner of such intellectual property under applicable laws and regulations. The foregoing is without prejudice to Member Companies' obligations to comply with any applicable obligations to pay royalties which may arise under applicable laws and regulations in some countries. Arrangements involving the payment of royalties by or on behalf of Member Companies to a Healthcare Professional must be set out in a written agreement providing appropriate and reasonable remuneration in accordance with applicable laws and regulations. For example, royalties paid in exchange for intellectual property should not be conditional on:

- A requirement that the Healthcare Professional purchase, order or recommend any product, services or medical technology of the Member Company or any product or technology produced as a result of the development project; or
- A requirement to market the product or medical technology upon commercialisation.

Subject to national regulations and requirements, Member Companies should exclude from the calculation of royalties the number of units purchased, prescribed, used, or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice or Healthcare Organisation.

# Chapter 8: Educational Items and Gifts

Member Companies exceptionally may provide inexpensive educational items and/or gifts, in accordance with national laws, regulations and industry and professional codes of conduct of the country where the Healthcare Professional is licensed to practise. Member Companies may only provide such educational items and/or gifts in accordance of the following principles:

**a.** Educational items and/or gifts may be provided but these must relate to the Healthcare Professional's practice, or benefit patients, or serve a genuine educational function.

**b.** No educational items and/or gifts should be provided in response to requests made by Healthcare Professionals.

**c.** Educational items and/or gifts must not be given in the form of cash or cash equivalents.

**d.** Educational items and/or gifts must be modest in value, and can be branded or non-branded items.

**e.** A Member Company may occasionally provide educational items of greater value to a Healthcare Organisation always provided that the item serves a genuine educational function for the Healthcare Professionals at that Healthcare Organisation and is of benefit to patients. Such items shall not be provided to Healthcare Professionals for their personal use. The item shall also be related to the therapeutic areas in which the Member Company is interested and/or involved. For higher value educational items, Member Companies must maintain appropriate records of their provision of such educational items to Healthcare Organisations. Such items should not be part of the Healthcare Organisation's normal overheads or routine costs of operation.

**f.** Provision of educational items and/or gifts must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.

Member Associations shall provide guidelines on appropriate limits for gifts, in accordance with the principles above.

Prize draws and other competitions at Events are permissible if the prize awarded complies with Chapter 8. Educational Items and Gifts. In addition, it must comply with national laws, regulations and industry and professional codes of conduct.

This Chapter is not intended to address the legitimate practice of providing appropriate Evaluation Products, Demonstration products or Samples. For guidance on how Member Companies may provide Evaluation Products, Demonstration products or Samples, please refer to Chapter 6: Research and Chapter 9: Demonstration Products and Samples, as applicable.

***Q47** Under Chapter 8, what are examples of items of modest value that are "related to the Healthcare Professional's practice or for the benefit of patients".*

***A47** Stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that could be appropriately provided as gifts to Healthcare Professionals provided their value falls within the maximum value prescribed under national laws, regulations and industry and professional codes of conduct. Food, alcohol and items which are primarily for use in the home or car are not appropriate as they are not related to the Healthcare Professional's practice nor are they for the benefit of patients.*

***Q48** May a Member Company provide a small gift to a Healthcare Professional to mark significant life events such as a marriage, birth, birthday or death?*

***A48** The Code restricts the types of gift that may be given to a Healthcare Professional and it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of death, it is for each Member Company to determine the appropriateness of making a tasteful gift as a mark of respect.*

***Q49** Where Healthcare Professionals engaged by Member Companies as consultants or speakers decline a professional fee for their services, would it be appropriate for the Member Company to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers?*

***A49** No, it would not be acceptable for the Member Company to make such a gift because to do so could be open to misinterpretation and would be likely to breach the Principle of Image and Perception. Moreover such gifts would not comply with Chapter 8.Educational Items and Gifts as they neither relate to a Healthcare Professional's practice nor serve an educational function.*

***Q50** Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?*

***A50** Examples of educational items of greater value that can be provided may include medical textbooks or anatomical models, but only if those relate to the therapeutic areas in which the Member Company is interested and/or involved.*

# Chapter 9: Demonstration Products and Samples

**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 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 unsterilised 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.

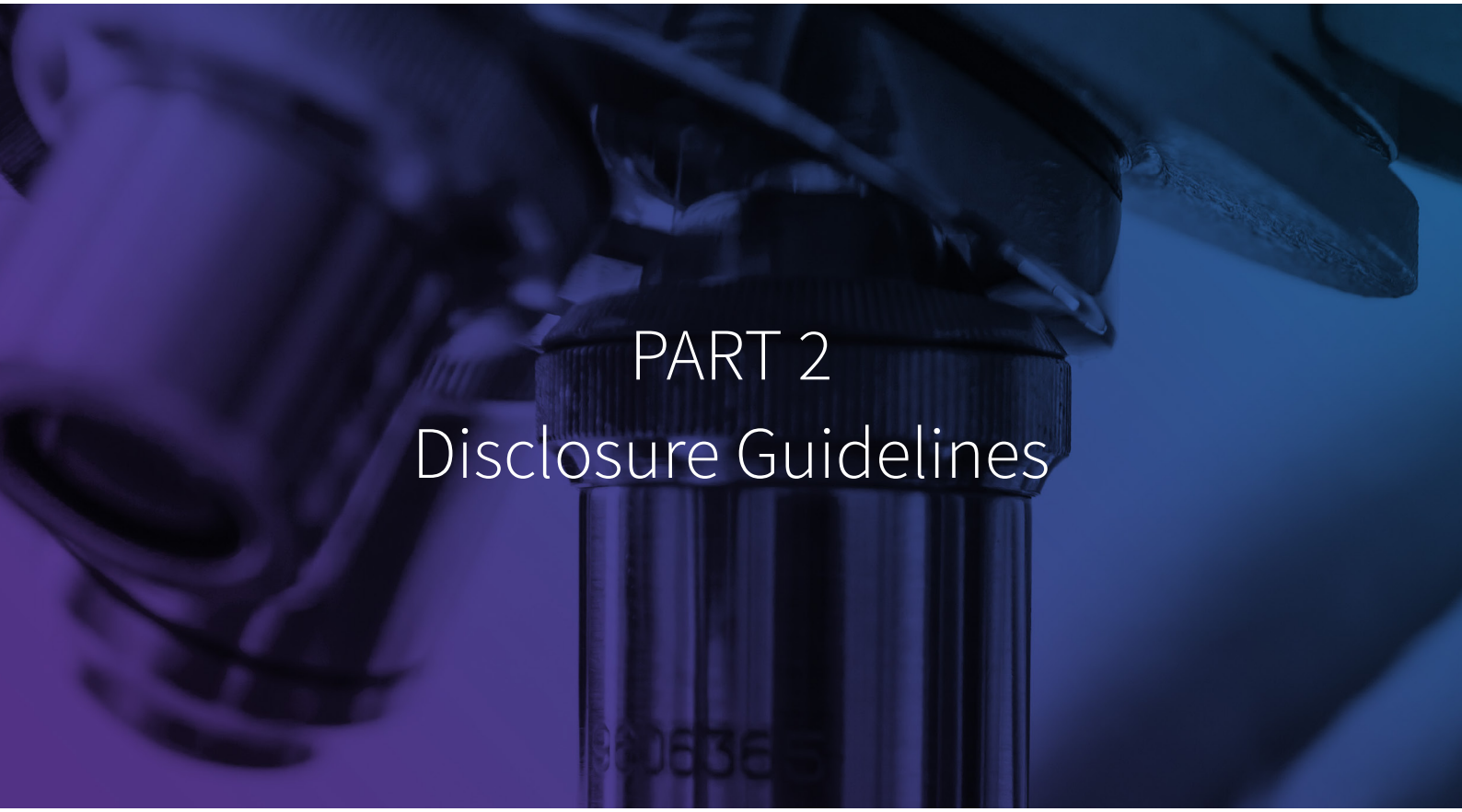
Demonstration Products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Member Companies shall clearly record in the Member Company's records as well as clearly disclose to Healthcare Professionals and/or Healthcare Organisations the no-charge basis and other conditions applicable for the supply of such Demonstration Products no later than the time of the supply. It is recommended that the disclosure to Healthcare Professionals and Healthcare Organisations be in writing.

**3. Samples**

Member Companies may provide a reasonable number of Samples at no charge to allow Healthcare Professionals and/or Healthcare Organisations to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

For Samples, which are single-use products, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the Healthcare Professionals/Healthcare Organisation to acquire adequate experience in dealing with the products.

For Samples, which are multiple-use products, the specific length of time necessary for a Healthcare Professional to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of Healthcare Professionals who will need to acquire experience in dealing with the product and similar considerations. Member Companies shall in all cases ensure that they retain title to multiple-use Samples and that they have a process in place for promptly removing such multiple use Samples from the Healthcare Professional's location at the conclusion of the familiarisation period.



# PART 2
# Disclosure Guidelines

# Preamble

Under the MedTech Europe Code of Ethical Business Practice (the "Code"), Member Companies may support Healthcare Professionals' independent Medical Education, including participation at Third Party Organised Educational Conferences, through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants.
Specifically, Section 3 of Chapter 4 of the Code states that Member Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code, and need to be interpreted as such.

For the avoidance of doubt, all funds provided by a Member Company for the advancement of genuine educational purposes to a Professional Conference Organiser ("PCO"), acting independently of any Healthcare Organisation, fall under the scope of these Disclosure Guidelines and are subject to the same conditions as Educational Grants. Whenever these Disclosure Guidelines refer to Healthcare Organisations, these shall also include Professional Conference Organisers.

All capitalised concepts used in the Guidelines are concepts defined in the Code.

# Chapter 1: Applicability of these Guidelines

## 1. Scope

These Disclosure Guidelines apply to Member Companies in their interactions with Healthcare Organisations based or registered in the MedTech Europe Geographic Area[1], excluding the countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, which are currently not in the scope of these Disclosure Guidelines.

Separate entities belonging to the same multinational company ("Affiliates") – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – shall be deemed to constitute a single company, and are as such committed to compliance with these Disclosure Guidelines.

Transfers of value that are not included in the definition of Educational Grants (as described in Chapter 4, Section 3 of the Code) and that consequently cannot be allocated to any of the categories set forth in Section 2.2 Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

***Q1** Does the Disclosure Guideline's definition of "Affiliate" include legal entities belonging to the same parent Member Company but registered outside Europe?*

***A1** Yes. Educational Grants made by Affiliates (parent companies are included in the definition of Affiliates to the effect of the Disclosure Guidelines) incorporated outside of Europe to Healthcare Organisations registered in Europe are within the scope of these Disclosure Guidelines. Any of the Affiliates registered in Europe can disclose these Educational Grants. Each Member Company can choose which Affiliate will report these Educational Grants made by non-European Affiliates.*

***Q2** Are these Disclosure Guidelines applicable to third party intermediaries who interact with Healthcare Organisations in connection with the sale, promotion or other activity involving Member Companies' products?*

***A2** No, these Disclosure Guidelines are not applicable to third parties such as third party sales & marketing intermediaries (SMIs), consultants, distributors, sales agents, marketing agents, brokers, commissionaire commercial agents and independent sales representatives (list not exhaustive). Nevertheless, it is recommended to document arrangements concluded between Member Companies and third parties intermediaries in order to comply with the provisions set out in the Code.*

## 2. Applicability of these Disclosure Guidelines

Member Companies do not need to report the same information twice, in case of national laws, regulations or professional codes imposing disclosure obligations regarding Educational Grants (as described in Chapter 4, section 3 of the Code) equivalent to the ones imposed by these Disclosure Guidelines.

***Q3** Where a national professional code already imposes disclosure obligations in a given country, where may Corporate Members disclose the Educational Grants?*

***A3** Where a national professional code imposes disclosure obligations regarding Educational Grants (as regulated in Chapter 4, Section 3 of the Code) to the same extent as regulated by these Guidelines, Corporate Members, who are not a member of the National Association responsible for that national professional code, may choose either:*

- *To disclose only on the MedTech Europe platform; or*
- *To disclose on the national platform, if that possibility is provided for.*

*Corporate Members who are bound by this national professional code may choose either:*

- *To disclose only on the national platform or*
- *To disclose both on the MedTech Europe platform and the national platform.*

*This selected option shall be included in the Methodology Note.*

1)The MedTech Europe Geographic Area currently includes: Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, the countries where Mecomed is active, the Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom as countries with National Associations, and Croatia, Cyprus, Estonia, Iceland, Latvia, Liechtenstein Lithuania, Luxembourg and Malta as countries party to the European Economic Area agreement without a MedTech Europe National Association.

***Q4** How will it be decided if a national law, regulation or professional code imposes disclosure obligations regarding Educational Grants equivalent to the ones imposed by the Disclosure Guidelines?*

***A4** The decision-making process is as follows: Members, both National Associations and Member Companies, can at any time submit any information or documentation, to request a "equivalence" assessment to the MedTech Europe Secretariat. In addition, the Secretariat shall conduct a yearly assessment of the equivalence of national laws, regulations and/or professional codes imposing disclosure obligations with the MedTech Europe Transparency Obligations (as regulated in Chapter 4, Section 3 of the Code).*

*The Secretariat shall submit any request for equivalence to the MedTech Europe Transparency Task Force, who will analyse the proposal. If the MedTech Europe Transparency Task Force agrees with the proposal, it will be submitted for approval to the MedTech Europe Compliance Network.*

*If the disclosure obligations imposed by a national law, regulation or professional code are deemed equivalent to the ones imposed by the Disclosure Guidelines, the assessment will be made public on the MedTech Europe Transparency website.*

# Chapter 2: Disclosure Obligation

## 1. General Obligation

Subject to the terms of these Disclosure Guidelines, each Member Company shall document and disclose all payments related to Educational Grants (as described in Chapter 4, section 3 of the Code) that it makes to a Healthcare Organisation based or registered in Europe, without limitation of value.

This also applies to payments of funds earmarked for education made to Professional Congress Organisers, in accordance with Q&A 38bis of the Code.

In case of Educational Grants or funds earmarked for education as described in Chapter 4, Section 3, para. a) (Support for HCP Participation at Third Party Organised Educational Events and Support for Third Party Educational Events), the entity shown as beneficiary of the funds should be, whenever possible, the organiser of the Event or the Healthcare Organisation to which the Healthcare Professional is assigned to or work for. In all other cases, the entity shown as beneficiary should be the one that according to the contract received the funds.

The disclosure of Educational Grants provided by Affiliates of the Member Company described above, but which are not registered in the MedTech Europe Geographic Area under these Guidelines shall be made by any of the Affiliates comprising said Member Company that are registered in the MedTech Europe Geographic Area.

***Q5** Which Affiliate should disclose a particular Educational Grant?*

***A5** A Member Company may choose to use any internal arrangement of its choice to report the aggregated sum in relation to Educational Grants made by each legal entity composing the company (Affiliates) to a particular Healthcare Organisation during a disclosure period.*

*To facilitate the reporting of Educational Grants, it is recommended that Member Companies disclose through a single account, instead of having different Affiliate accounts, but this is a Company decision.*

## 2. Aggregate Disclosure

Educational Grants shall be disclosed on an aggregate basis. Each Member Company shall disclose, for each clearly identifiable and separate recipient, the amounts paid as Educational Grants to such recipient in each Reporting Period[2] which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, but itemised disclosure shall be made available upon request by the Member Company, as deemed necessary, to (i) the relevant recipient, and/or (ii) the relevant authorities.

Member Companies shall disclose an aggregate amount related to any of the categories set forth below:

a. Educational Grants to support Third Party Organised Events (including Support for HCP Participation at Third Party Organised Educational Events) and,

b. Other Educational Grants to Healthcare Organisations (including Scholarships, Fellowships and/or Grants for Public Awareness Campaigns).

***Q5bis (Added in June 2019)** Should the reported amounts include VAT, when relevant?*

***A5bis** No, the reported amounts should not include VAT, even in those cases when VAT has been paid.*

## 3. Optional Object Specification

If desired, Member Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth in *Section 2.2* Aggregate Disclosure.

2) Reporting Period means a full calendar year (starting on the 1st of January and ending in the 31st of December).

# 4. Methodology

Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category described in Section 2.2 Aggregate Disclosure. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This methodology note shall be made available upon request by an interested party.

***Q6** When should a Methodology Note be made available?*

***A6** Member Companies should create a comprehensive Methodology Note that would allow any Healthcare Organisation directly affected by a disclosure to understand how the amount disclosed was aggregated. The Methodology Note should therefore be made available upon specific request to Healthcare Organisations concerned about a particular disclosure that directly affects them.*

***Q6bis (Added in June 2019)** Are in-kind Educational Grants reportable under these Guidelines?*

***A6bis** In-kind Educational Grants, or the provision of in-kind support for educational purposes, such as Samples or Demonstration Products do not need to be reported.*

# Chapter 3: Form of Disclosure

## 1. Reporting Period

Disclosures shall be made on an annual basis and each Reporting Period shall cover a full calendar year.

***Q7** When will the first Reporting Period start?*

***A7** Chapter 4, Section 3 of the MedTech Europe Code of Ethical Business Practice establishes that the first disclosure shall occur no later than the end of the Transition Period. The Transition Period ends on the 31st December 2017. As a consequence, the first Reporting Period is the calendar year 2017, starting on the 1st January 2017, and ending on 31st December 2017.*

## 2. Time of Disclosure

Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period.

## 3. Time of Publication

The disclosures shall be made public at the time of publication. The time of publication is the 31st August of the year of the relevant time of disclosure.

## 4. Template and Language of Disclosure

For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in English using the template set forth in the Annex, without prejudice of the names of the recipients being in their original language.

***Q8** In what currency should the amounts paid be disclosed?*

***A8** Disclosed amounts should be in the currency used in the payment. In the event the aggregate amount includes Educational Grants made in different currencies, the reporting company may choose in which currency they wish to disclose the aggregate amount, and keep appropriate record of the exchange rate used to convert the different currencies. This information will then be included in their Methodology Note.*

## 5. Platform of Disclosure

Disclosures shall be made on the EthicalMedTech website unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Section 1.2 Applicability of these Disclosure Guidelines. Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, MedTech Europe shall not be held liable for (i) maintaining, correcting, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

## 6. Retention and Modification of the Disclosures

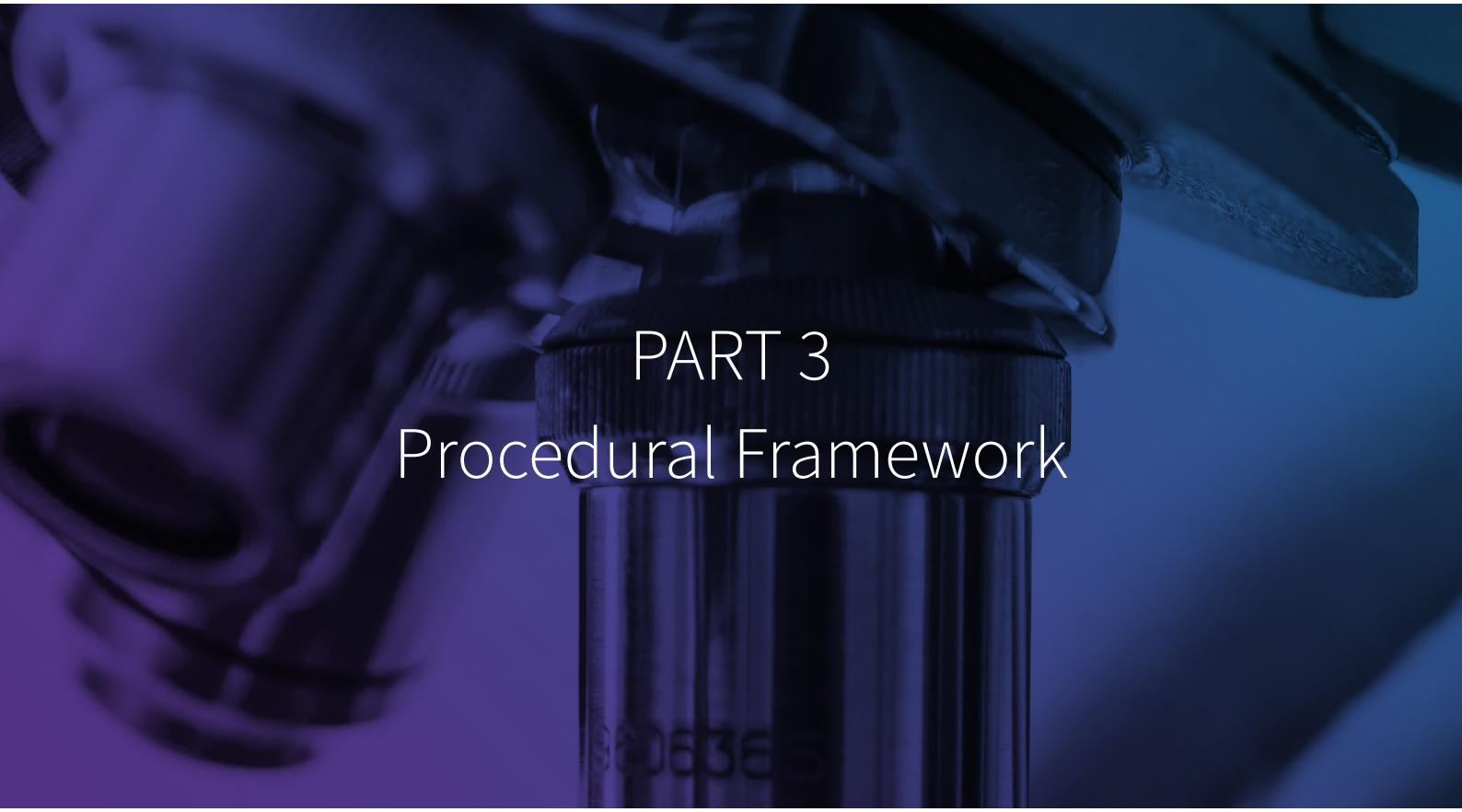
Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

## 7. Enquiries Regarding Reported Disclosures

Member Companies shall make available to Healthcare Organizations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the disclosed information remains in the public domain as stated in Section 3.3 Time of Publication.

## Disclaimer

Please note that Part 3 below is an integral part of the MedTech Europe Code of Ethical Business Practice (the “Code”) and is included here to ensure a coherent and harmonised framework of concepts and definitions while implementing these Disclosure Guidelines.



# PART 3
# Procedural Framework

# 1. Preamble

**1.1** The principles set out below are intended to design an effective and efficient complaint-handling process, the object of which is to ensure compliance with the MedTech Europe Code of Ethical Business Practice ("the Code") by Member Companies and the codes of conduct adopted by the Member Associations. It is based on principles of proportionality, speed, due process, fairness and transparency. This Procedural Framework shall be reviewed when required and at a minimum every 2 years. This Procedural Framework shall be amended in accordance with the MedTech Europe Statute.

# 2. Transposition Obligations

**2.1** Member Companies shall transpose the provisions of this Code internally between 1 January 2016 and 31 December 2016 at the latest. No later than 1 January 2018, Member Companies shall cease direct financial and in kind support to individual HCPs to cover the costs of their attendance at Third Party Organised Educational Events. New Members of MedTech Europe will be subject to the same obligations as current Members.

As soon as a Member Company transposes the Code internally it shall notify the MedTech Europe Secretariat, specifying the date on which such transposition became effective. The MedTech Europe Secretariat shall appropriately document and maintain records of all such notifications for statistical purposes.

**2.2.** Member Associations shall transpose the Code at the national level by 1 January 2020. This means that Member Associations shall either:

a) Transpose the Code in its entirety,

b) Transpose the Code with some adjustments to the local situation,

c) If transposition of the Code is not feasible for objective reasons, the Member Association shall promote the Code as a best practice and actively engage national, and if applicable local government/authorities and/or other stakeholders, to change practice in their country through legal or self-regulatory measures.

In particular on 1 January 2017 at the latest each Member Association shall submit, in a timely manner, to the MedTech Europe Board its strategy and action plan on how the Member Association plans to transpose the Code in its country, timelines, and main milestones as well as how enforcement of the Code will be addressed during the transition period as well as after 2020. After 1 January 2018, Member Associations shall provide annual progress updates to the MedTech Europe Board.

The MedTech Europe Secretariat shall support the Member Associations in their transposition of the Code at the national level. Upon the request of the MedTech Secretariat, Member Associations shall provide, in a timely manner, a copy of its national code of conduct including its dispute resolution process.

# 3. Applicability of codes

**3.1.** This Code only applies to the Member Companies of MedTech Europe, who are manufacturers of medical technologies, in particular Medical Devices and In Vitro Diagnostics.
As provided by the Statutes of MedTech Europe, Member Companies must comply with the Code, as amended from time to time, as a minimum standard when:

- Member Companies interact with Healthcare Professionals and Healthcare Organisations registered and practising in MedTech Europe Geographic Area irrespective of where the activity takes place; and/or
- Activities take place in MedTech Europe Geographic Area, irrespective of where Healthcare Professionals and Healthcare Organisations are registered and practicing.

The MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where Member Associations are located.

***Q1** What is the definition and scope of medical technologies? (Amended in July 2018)*

***A1** Medical Technology refers to, within the framework of the Code, Medical Devices and In Vitro Diagnostics medical devices as defined in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as amended from time to time.*

**3.2.** The Code shall be directly applicable to all activities of Member Companies and their affiliated companies in the MedTech Europe Geographic Area within the scope applicability defined in Section 3.1. above. If such affiliated company of a Member Company is also in its own name a member of a Member Association, the respective code of such Member Association shall apply to activities of such affiliated company in addition to the Code, which sets out the minimum standards appropriate to the various types of activities carried out by the Members.

Any activity or interaction described in Section 3.1. above and conducted by an affiliated company of a Member Company located outside the MedTech Europe Geographic Area will be deemed attributable to said Member Company.

**3.3.** In the event of a conflict between the provisions of a national code and the MedTech Europe Code, national panels shall apply their own national codes when rendering decisions on complaints, except when there is a contradiction with the MedTech Europe Code and the national code is less stringent, in which case the provisions of the MedTech Europe Code should be applied.

**3.4.** For complaints and other matters that are handled by the MedTech Europe Compliance Panel, the latter shall apply the MedTech Europe Code and, at its sole discretion and as it deems appropriate, Member Association codes in the event that both parties are also bound by them.

## 4. Dispute Resolution Principles

**4.1.** Each Member Association shall adopt a national dispute resolution framework which complies with the principles of this Procedural Framework. To that effect, each Member Association is also required to establish a panel (i.e. a national body) that is designated to handle complaints relating to their code. MedTech Europe strongly recommends that this panel is headed by a non-active industry chairman and for obvious reasons of independence, transparency and expertise, is composed not only of persons having industry experience. MedTech Europe recommends that at least one of the members of a national panel should have a professional legal background. In the composition of the panel, Member Associations should balance the need for independence, legal background, expertise and knowledge of the industry and industry practices.

**4.2.** The dispute resolution principles set out in this Procedural Framework do not preclude complainants from having recourse to the regular courts or other tribunals to seek resolution of complaints based upon applicable laws and regulations. The Code, including this Procedural Framework, shall not be interpreted so as to provide a legal basis for such recourse to regular courts or other tribunals.

**4.3.** In all territories where there is no dispute resolution process which complies with these MedTech Europe dispute resolution principles or in cases provided under sections 3.4 and 6.1.5, the MedTech Europe Compliance Panel (as defined below) shall handle complaints as a first and last instance decision-maker.

**4.4.** Member Associations shall take due account of the interpretation issued by the MedTech Europe Compliance Panel in accordance with sections 7.4.6 (iv) & (v).

## 5. MedTech Europe Code Committee

**5.1.** The MedTech Europe Code Committee shall assist Member Associations and Member Companies to comply with their obligations under the Code, including the dispute resolution principles set out in this Procedural Framework.

**5.2.** As a key part of its role, the MedTech Europe Code Committee shall promote the Code, monitor the adoption of compliant national codes, including preparation of updates to the MedTech Europe Board and assist Member Companies and Member Associations to share best practice and harmonised interpretation of the Code and the dispute resolution principles set out in this Procedural Framework.

**5.3.** The MedTech Europe Code Committee will be composed of five (5) representatives of the MedTech Europe Legal Affairs Committee and five (5) representatives of the MedTech Europe Compliance Network, at least one representative from Member Associations, and a chair appointed by the Legal Affairs Committee. In addition, the Code Committee may co-opt up to five (5) other members, where Code Committee is satisfied that, the concerned Members will positively enhance the representativeness, operation and objectives of the Code Committee.

## 6. MedTech Europe Compliance Panel

**6.1.** The MedTech Europe Compliance Panel shall have the following tasks:

- Supervise the Conference Vetting System.
- Review consistency with the Code of interpretations of national panels of nationally applicable codes of conduct, upon request of the MedTech Europe Code Committee;
- Provide guidance to Member Associations on the dispute resolution principles set out in this Procedural Framework;
- Interact, upon request of the Secretariat, with relevant MedTech Europe groups to further develop the Code and guidance documents;
- Render decisions directly on complaints or procedural matters, as a first and last instance in the following cases:

**i.** there is no dispute resolution process which complies with the dispute resolution principles set out in this Procedural Framework in the territory concerned; or

**ii.** a Member Company is not a direct member of a Member Association; or

**iii.** a dispute concerns an alleged abuse or violation of the MedTech Europe Ethical Business Logo System; or

**iv.** more than one national compliance panel has or may have jurisdiction, but the parties to the dispute cannot agree on which one does. In such case, the matter shall be referred to the MedTech Europe Compliance Panel for a determination. The referral may be made either by one of the parties or by a Member Association Secretariat or by the MedTech Europe Secretariat. Following such referral, the MedTech Europe Compliance Panel may decide that a specific panel has jurisdiction and refer the complaint to that panel or that more than one national panel has jurisdiction, in which case the matter shall be resolved by the MedTech Europe Compliance Panel in the first and last instance; or

**v.** the national panel having jurisdiction refuses to hear a complaint for any reason or cannot take the case based on provisions of its national code; or

**vi.** a complainant refuses the jurisdiction of a national panel for what it considers to be a "legitimate reason". In such case, the matter shall be referred to the MedTech Europe Compliance Panel to determine, at its sole discretion, whether or not the reason is legitimate. If the MedTech Europe Compliance Panel determines that it is, then it shall resolve the complaint in the first and last instance; or

**i**.a party to a dispute believes that conciliation, mediation or mutual settlement is inappropriate due to the serious or repeated nature of the alleged infringement, and petitions the MedTech Europe Compliance Panel to waive the requirements as set out in sections 7.1.(a) and 7.3.2. (iv) of this Procedural Framework; or

**ii.** a dispute concerns an alleged abuse or violation of the Conference Vetting System or an alleged violation of the Code relating to a third party medical education conference which was eligible for assessment under the Conference Vetting System, whether or not it was actually assessed.

The MedTech Europe Board may allocate additional tasks to the MedTech Europe Compliance Panel as deemed appropriate.

**6.2.** As an independent body, the MedTech Europe Compliance Panel shall be entitled to report to the MedTech Europe Code Committee any concerns that it might encounter in the exercise of its functions.

**6.3.** The MedTech Europe Compliance Panel will be composed of at least three individuals. These shall include not only persons having industry experience but also for obvious reasons of independence, transparency and expertise, persons whose knowledge will contribute to the proper functioning of the MedTech Europe Compliance Panel, such as other relevant stakeholders and whose position may not raise potential conflict of interest situations, in particular as regards complaint handling process. The chair of the MedTech Europe Compliance Panel must have a legal background. Neither the chair nor any member of the Compliance Panel can be employed by or be contracted as a consultant for a Member Company or an entity affiliated to a Member Company or by a Member Association or a company member of such Member Association. For avoidance of doubt, holding position in the Board of Directors of a Member Association without any consulting or employment relationship with a Member Company will not be considered as a consultant or employee relationship with the concerned Member. If for any reason a potential conflict of interest of a member of the MedTech Europe Compliance Panel occurs, then the concerned member shall refrain from participating in the specific complaint handling and decision process. The term of office of the MedTech Europe Compliance Panel members will be three years, renewable twice. The chair shall appoint two other individuals for the MedTech Europe Compliance Panel, after consultation with and consent of the MedTech Europe Code Committee and the MedTech Europe Secretariat.

The term of office of the two other MedTech Europe Compliance Panel members will also be three years and may be renewed twice by the chair, after consultation with and consent of the MedTech Europe Code Committee and the MedTech Europe Secretariat. Notwithstanding the foregoing, the MedTech Europe Board may decide on different terms of office in order to ensure a staggered rotation of the three MedTech Europe Compliance Panel members, provided, however, that the MedTech Europe Compliance Panel gave his/her consent.

# 7. Procedural principles

**7.1.** The general principles underlying the dispute resolution principles set out in this Procedural Framework, are that:

a) Disputes are best resolved amicably and efficiently by conciliation, mediation or mutual settlement; and

b) Disputes are generally best handled by national panels subject to exceptions laid down in sections 3.4. and 6.1.5.

**7.2.** The MedTech Europe Compliance Panel may develop, after consultation with and consent of the MedTech Europe Code Committee, Internal Procedural Rules to hear and decide on disputes or questions of interpretation. These Internal Procedural Rules shall be based on the principles of article 7 of this Procedural Framework.

**7.3.** Reception of Complaints

- Complaints may be lodged either with a Member Association or with the MedTech Europe Secretariat. Adjudication of complaints shall be a matter solely for Member Associations at a national level subject to exceptions laid down in sections 3.4. and 6.1.5.
- Complaints received by the MedTech Europe Secretariat shall be processed as follows:

  **i.** The MedTech Europe Secretariat will forward any complaints it receives (without commenting upon them) to the relevant Member Association(s), subject to the exceptions laid down in sections 3.4. and 6.1.5.

  **ii.** The MedTech Europe Secretariat will send an acknowledgement of receipt to the complainant, indicating the relevant Member Association(s) to which the complaint has been sent for processing and decision.

  **iii.** In addition, upon receipt by the MedTech Europe Secretariat of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), the MedTech Europe Secretariat will communicate these complaints to the Member Association either of the parent company or of the European subsidiary designated by the parent company.

  **iv.** For complaints for which the MedTech Europe Compliance Panel has jurisdiction, the rules of procedure are laid down in the Internal Rules of Procedure.

  **v.** Complaints shall be handled confidentially by all parties involved in the procedure.

- Notwithstanding any provisions of this Procedural Framework to the contrary, the MedTech Europe Secretariat shall refer the complaint to the MedTech Europe Compliance Panel that will render a decision in the first and last instance in the cases set out in sections 3.4. and 6.1.5.
- When deciding on such matters, the MedTech Europe Compliance Panel will act in conformity with the dispute resolution principles set out below and the Internal Procedural Rules, if any, and will have the right to impose sanctions in line with the ones enumerated below in article 8.

**7.4.** Processing of complaints and sanctions by Member Associations shall follow the following principles:

- Member Associations and the MedTech Europe Compliance Panel shall ensure that industry and non-industry complaints are processed according to the same principles, without regard to who has made the complaint. As a minimum, the national panel and the MedTech Europe Compliance Panel should know the identity of the complainant.
- Member Associations may request any company which is not a member of the Association and making a complaint under their code to undertake to abide by the provisions of the national code of conduct and of its complaint handling principles in force in its country, and/or the MedTech Europe Code, as a pre-condition before processing the complaint.
- Each Member Association's national panel and the MedTech Europe Compliance Panel shall respect fair procedure rules allowing all parties to be heard fairly.
- Each Member Association's national panel and the MedTech Europe Compliance Panel shall take decisions and pronounce any sanctions to be applied on the basis of the national code of conduct in force in its country.
- A complaint handling procedure should not be initiated or should be suspended in case of a formal investigation by criminal law enforcement authorities or commencement of criminal proceedings or a proceeding at ordinary courts with respect to the same or a substantially similar subject matter.

• The procedural steps for dispute resolution should be as follows:

**i.** The first stage of any dispute resolution procedure shall be the filing of a written complaint with the Member Association or the referral of such a complaint to a Member Association by the MedTech Europe Secretariat. Where a national panel or where applicable the MedTech Europe Panel consider a complaint fails to establish a prima facie case of violation of its national code, such complaint shall be dismissed with respect to that code. A national panel or, where applicable, the MedTech Europe Panel may also provide that any complaint, which a national panel considers to be in pursuit of an entirely or predominantly commercial interest, shall be dismissed.

**ii.** The second stage of the complaints handling procedure shall be based on the principle provided in section 7.1. To that end the following steps shall be considered by the Member Association and the MedTech Europe Compliance Panel:

- Within a reasonably short time frame of receipt of a written complaint by a Member Association or where applicable the MedTech Europe Secretariat, if considered appropriate, a genuine mediation should be attempted, involving an independent third-party or mediator or depending on the nature of the complainant an attempt to reach an amicable solution.
  For complaints between companies, mediation should be considered seriously before further pursuit of the matter directly via any complaints handling process based on the dispute resolution principles set out in this Procedural Framework.
- In cases of a serious or repeated breach, the Member Association Secretariat, the MedTech Europe Secretariat or the mediator may decide to direct complainant(s) to further pursue the matter directly via the relevant complaints handling process.
- If no amicable resolution of the complaint can be reached within a time frame set by the Member Association Secretariat, the MedTech Europe Secretariat or the mediator, the mediator shall direct complainant(s) to further pursue the complaint via the relevant complaints handling process, pursuant to which the national panel or where applicable the MedTech Europe Compliance Panel shall ensure that a final decision is taken promptly in relation to each case thus referred to it for consideration.
- When it appears to a Member Association or to the MedTech Europe Secretariat that a company may have breached the code, it may direct matter as a complaint to the relevant panel.

**iii.** Member Associations may establish a national appeal procedure, pursuant to which either party may appeal in writing against a decision of the national panel.

**iv.** During a national dispute resolution process,

- The national panel may, at any time, or
- Any of the parties (with the permission of the national panel) may, at any time, or
- Any of the parties may within 15 days following a decision by the national panel (without permission of the national panel) refer questions of interpretation of the Code in writing to the MedTech Europe Compliance Panel. The MedTech Europe Compliance Panel may at its discretion either:
- Decline to entertain the matter if it determines that no question of principle is at issue, or
- Accept the interpretation referral, review and provide guidance on the interpretation of the MedTech Europe Code (i.e. but not rule on merits/facts) with a view to ensuring harmonised interpretation and enforcement of the principles of the Code and these dispute resolution principles.

The MedTech Europe Compliance Panel shall promptly issue guidance on the interpretation and no later than 90 days from receipt of a request for interpretation.

**v.** Where an interpretation referral is made to the MedTech Europe Compliance Panel during a national dispute resolution process, in accordance with the procedure described above, the national panel shall suspend the proceedings pending the issuance of guidance by the MedTech Europe Compliance Panel and shall take such guidance into consideration when making its final decision. In the event that one of the parties to a national dispute resolution process refers a question of interpretation to the MedTech Europe Compliance Panel within 15 days following a decision by a national panel, that decision shall be suspended pending the issuance of guidance by the MedTech Europe Compliance Panel and the national panel shall take such guidance into consideration prior to rendering its final decision.

**vi.** National panels as well as the MedTech Europe Compliance Panel shall notify their decisions in writing to the parties by registered or certified mail with return receipt or other equivalent means of delivery. The 15 day period referred to above shall commence for each party upon the date of receipt of the decision by that party. If a party makes an interpretation referral to the MedTech Europe Compliance Panel, it shall copy the other party or parties and such other party or parties shall have an additional 15 days after such referral to submit written observations to the MedTech Europe Compliance Panel. All national panel notices of decisions shall inform the parties to a national proceeding of their right to make an interpretation referral to the MedTech Europe Compliance Panel within 15 days of the decision and to submit written observations on the other parties' referral in accordance with the procedures described above.

# 8. Sanctions

**8.1.** The potential sanctions available to the MedTech Europe Compliance Panel and Member Associations' national panels must be proportionate to the infringement, predictable and act as a deterrent. Commensurate with the seriousness and/or persistence of the breach, such sanctions may range from:

- A written reprimand;
- The requirement that the offender takes steps to conform with the national and/or the MedTech Europe code(s) (specific steps may be specified in whole or in part, and may be subject to time limits);
- The inspection and audit by a third party (at the offender's cost and expense) of the offender's relevant compliance systems ;
- The requirement that the offender recovers items given in connection with the promotion of products and/or to issue a customer communication regarding future corrective practice;
- The requirement that the offender publishes or otherwise disseminates corrective or clarificatory information or statements;
- The prohibition against offending company representative(s) standing for elected office within the institutions of Member Association and/or MedTech Europe;
- Recommendation to suspend the offending company – with specific time limit and detail on conditions of 're-entry' - of membership of the Member Association and/or MedTech Europe;
- Recommendation to expel the offending company from membership of the Member Association and/or MedTech Europe;
- Up to publication of any decisions or sanctions imposed upon the offender.

**8.2.** Notwithstanding the foregoing, Member Associations and MedTech Europe Compliance Panel shall ensure that any final decision (including any appeal decision) taken in an individual case shall be rendered in writing, detailing the reasons for reaching this decision and signed by the members of the respective panel. At the minimum, copies of such decisions shall be made available to the parties of a proceeding.

**8.3.** Member Associations shall make available to both MedTech Europe Compliance Panel and the Code Committee summaries in English of the main facts and conclusions of the national decisions that have precedent or interpretative value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest). Member Associations are encouraged to publish in English the full decision.

# PART 4
# Glossary

# Glossary and Definitions

- **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 Research or Educational Grant; or
    - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

- **Educational Grants**: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.

- **Employer Notification**: means the prior written notification provided to a Healthcare Organisation (e.g. hospital administration), a Healthcare Professional's superior or other locally-designated competent authority of any interaction, collaboration or other matter concerning any Member Company and any Healthcare Professional, the purpose and/or scope of which requires notification under this Code.

- **Entertainment**: Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment.

- **Evaluation Products**: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a Member Company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose, as per the authorisation in the country where the supply occurs. Evaluation Products do not include the following:
    - Demos;
    - Samples;
    - Products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

- **Event**: means either a Company Event or Third Party Organised Educational Event.

- **Faculty**: means a podium speaker, moderator and/or chair, who presents during a Third Party Organised Educational Event. Poster- and abstract-presenters are not considered to be Faculty.

- **Financial Hardship**: means in relation to a Healthcare Organisation extreme and unavoidable financial distress resulting from matters outside the Healthcare Organisation's control where the Healthcare Organisation is unable to operate and where patient care is consequently jeopardised. Financial distress resulting in whole or in part from mismanagement of the Healthcare Organisation's funds or other matters within its control is not considered to be financial hardship. Financial Hardship must be documented and objectively substantiated.

- **Grants**: means either an Educational Grant or a Research Grant, or both.

- **Guests**: means spouses, partners, family or guests of Healthcare Professionals, or any other person who does not have a bona fide professional interest in the information being shared at an Event.

- **Healthcare Organisation (HCO)**: means any legal entity or body (irrespective of its legal or organisational form) that is a healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching institution or learned or professional society (except for patient organisations); or through which one or more Healthcare Professionals provide services.

- **Healthcare Professional (HCP)**: means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.

- **Members**: means all full and associate corporate members ("Member Companies") of Eucomed and/or EDMA (or as applicable MedTech Europe) as well as full and associate national association members of Eucomed and/or EDMA (or as applicable MedTech Europe) ("Member Associations"), as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.

- **Professional Conference Organiser (PCO)**: a for-profit company or organisation which specialises in the management of congresses, conferences, seminars and similar events.

- **Product and Procedure Training and Education Event**: means a type of Company Event that is primarily intended to provide Healthcare Professionals with genuine education, including information and/or training on:
    - The safe and effective use of medical technologies, therapies and/or related services, and/or
    - The 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.

- **Research Grants**: means the provision by or on behalf of a Member Company of funding, products/equipment and/or in kind services to any organisation that conducts research which is made for the sole, restrictive purpose of supporting the development or furtherance of bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve patient outcomes.

- **Sales, Promotional and Other Business Meetings**: means any type of Company Event the objective of which is 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.

- **Samples**: means 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 in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:
    - Demos;
    - Evaluation Products;
    - products provided at no charge as part of a Charitable Donation or as part of a Research or Educational Grant; or
    - products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

- **Scholarships and Fellowships**: means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). "Scholars" and "Fellows" shall be understood accordingly.

- **Third Party Organised Educational Events**: means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.

- **Third Party Organised Educational Conferences**: means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include 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**: means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals 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.

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- **Transition Period**: means the period from 1 January 2016 up to and including 31 December 2017, following which Member Companies shall no longer provide financial or in kind support direct to Healthcare Professionals to cover costs of their attendance at Third Party Organised Educational Events with the exception of Third Party Organised Procedure Training meetings or pursuant to a consulting agreement with a Healthcare Professional speaker engaged by a Member Company to speak at a satellite symposium.

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# Annexes

# ANNEX I (added in October 2016, removed references to 2017 in January 2018)

## CVS scope: When are CVS assessments required?

| | | PRIOR CVS SUBMISSION | | | |
|---|---|---|---|---|---|
| | | IN MEDTECH EUROPE GEOGRAPHIC AREA | | OUTSIDE MEDTECH EUROPE GEOGRAPHIC AREA | |
| **WHICH TYPE OF SUPPORT CAN MEMBER COMPANIES PROVIDE TO WHICH THIRD PARTY ORGANISED EDUCATIONAL EVENTS?** | | **NATIONAL** Third Party Organised Educational Events attended by delegates which are local HCPs only) | **INTERNATIONAL** (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area[1],[2]) | **INTERNATIONAL** (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area[3]) | **INTERNATIONAL** (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area attend, neither as speakers or delegates) |
| EDUCATIONAL GRANTS[4] PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE | Educational Grant to support the general running of a conference | Allowed. | Subject to CVS decision | Allowed. Not subject to CVS decision | Out of scope of the application of the Code[6] |
| | Educational Grants that includes funds to support HCP attendance to the conference | Allowed. | Subject to CVS decision | Subject to CVS decision | N/A |
| | Educational Grants that includes funds to support Faculty | Allowed. | Subject to CVS decision | Allowed. Not subject to CVS decision | N/A |
| COMMERCIAL ACTIVITIES | Consultancy agreement for speakers in satellite symposia | Allowed. | Subject to CVS decision | Allowed. Not subject to CVS decision | N/A |
| | Booths/advertising | Allowed. | Subject to CVS decision | Allowed. Not subject to CVS decision | Out of scope of the application of the Code |
| DIRECT SPONSORSHIP OF HCPs REGISTERED AND PRACTISING IN THE MEDTECH EUROPE GEOGRAPHIC AREA | Direct sponsorship of HCPs as delegates (passive participation) | Not allowed[7]. | Not allowed[7] | Not allowed[7] | N/A |
| | Direct sponsorship of HCPs as Faculty (active participation) | Not allowed[7]. | Not allowed[7] | Not allowed[7] | N/A |

[1] *MedTech Europe Geographic Area includes the countries in the European Economic Area (EEA), as well as those other countries where Member Associations are located.*

[2] *Formerly referred to as "Cross-border Events".*

[3] *For avoidance of doubt, this category of "Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area" has to be understood as covering only Healthcare Professionals from the MedTech Europe Geographic Area benefiting from an Educational Grant.*

[4] *Educational Grants: means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.*

[5] *Allowed means no CVS decision is required but the provisions of the MedTech Europe Code of Ethical Business Practice and national laws and regulations still apply.*

[6] *Out of scope: Means the Code does not apply given that the situation does neither involve a Member Company interacting with an HCP or HCO registered and practicing in the MedTech Europe Geographic Area nor does the activity take place in the MedTech Europe Geographic Area.*

[7] *Please note direct support for attendance of HCPs to Third Party Organised Procedure Training meetings is allowed provided it complies with the requirements of the Code.*

# ANNEX II (added in October 2016)

## Disclosure Guidelines Template Example*

| COMPANY_ID | RECIPIENT_NAME | RECIPIENT_CITY | RECIPIENT_COUNTRY_CODE | RECIPIENT_POSTAL_CODE | RECIPIENT_ADDRESS | RECIPIENT_VAT_OR_UNIQUE_IDENTIFIER | DECLARATION_DATE | EEDUCATIONAL_GRANT_TYPE | AMOUNT | CURRENCY_CODE | OBJECT |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NOVQZCLM | Test | Testville | [FR] | 123456 | Rue du Test 123 | FR123456789 | 12/12/16 | [B] | 5000 | EUR | Test object |

Export to csv

*The version of the Template to be used in Transparent MedTech can be found in the website's Members Area.

***Q**: What is a "unique country local identifier"?*

***A**: It refers to a specific , unique and sustainable reference to identify Healthcare Organisations. Reporting companies will use the Healthcare Organisation's VAT as unique country local identifier by default. In those countries where Healthcare Organisations do not necessarily have a VAT number, another identifier, unique for this Healthcare Organisations and common for all reporting companies will be provided.*

## ANNEX III (added in November 2016)

## The Geographical Area where the Code applies as the minimum standard

The MedTech Europe Geographic Area currently includes

Countries with National Associations:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom
- The Mecomed countries (Middle East and Africa except for South Africa, Lesotho and Eswatini)

Countries party to the European Economic Area agreement without a MedTech Europe National Association:

- Iceland
- Liechtenstein
- Luxembourg
- Malta

Countries covered by Mecomed, the Middle East Medical Devices and Diagnostics association, are not currently under the scope of the Disclosure Guidelines.

# ANNEX IV
# Verification Of The Use Of Funds

**How can a Member Company verify that the Educational Grant is in fact used for the intended purpose as agreed in the Educational Grant agreement?**

A Member Company should set up an internal verification process for the purpose of ensuring that the funds provided through an Educational Grant are used for the agreed intended purpose. For example, such a process could include verification of every single Grant provided by a Member Company or periodic verification of a selected sample of Grants, after the Event takes place or before any subsequent application for an Educational Grant.

Examples of the documents requested by Member Company for verification purposes could include, but are not limited to, the following:

Grant to support Healthcare Professionals' attendance at the Third Party Organised Educational Event:

- Attendance proof (e.g. hotel check out form, signed attendance list, a digital certificate issued by the Event organiser etc.)
- Travel proof (e.g. flight/train tickets)
- Copy of the receipts of taxi fares, meals, etc.
- Where allowed, pictures of the Event.

Grant to support the costs related to organisation of the Third Party Organised Educational Event:

- Budget breakdown listing the general expenses of the Event
- Accounting records, copies of invoices, receipts
- Verifications performed by company staff on-site during the Event
- Written confirmation from the Event Organiser that the funds were spent as intended
- Documentation of the speaker's presentation (e.g. slides)

Grant provided in a form of a Scholarship or Fellowship:

- Activity records of the educational programme
- Certification of enrollment from the institution or professor in charge
- Progress report by or of the beneficiary

If a Grant recipient fails to provide the requesting Member Company with the documents or if a Member Company determines that the Grant funds were not used as provided in the Grant agreement, the Member Company:

- Should take this into account when assessing any future funding request from the same Healthcare Organisation.
- May consider requesting MTE to withdraw the right to use the Logo, if the HCO/PCOs is a MTE "Chartered Organisation" under the Ethical Charter.

# ANNEX V
# Methodology Note Example

## Structure

- Introduction
- Executive summary of the methodologies used for disclosure purposes and countries specificities
- Definitions
    - Recipients
    - Types of Educational Grants
- Disclosure scope and timelines
- Disclosures in case of partial performance or cancellation
- Cross-border activities
- Specific considerations:
    - Multi-year agreements
    - Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
        - Consent collection
        - Management of recipient consent withdrawal
        - Management of recipient's request
        - Partial consent
- Disclosure Form
    - Date of submission
    - Currency in case of aggregated payments made in different currencies
    - VAT included or excluded and any other tax aspects
- Disclosure financial data and amount of Educational Grants provided
- Calculation rules

**Disclaimer**: This Methodology note is provided as a template to support Member Companies in the implementation of these Disclosure Guidelines. Any other template may be equally valid provided they comply with the general requirements set out in *Section 2.4 Methodology*.

# ANNEX VI

## Direct support to HCP participation in Events as of 1 January 2018

| | | | Direct Support for HCP attendance(*) | |
|---|---|---|---|---|
| **Event** | **Setting** | | **Faculty/speaker(s)** | **Delegates** |
| **Third Party Organised Educational Conference** | **Main Event / Independent Scientific Program** | | Not allowed | Not allowed |
| | **Satellite Symposium** | | Allowed (through a consulting agreement) | Not allowed |
| | **Booth** | | Allowed (through a consulting agreement) | Not allowed |
| **Third Party Organised Procedure Training meeting*** *Criteria to distinguish a Third Party Organised Procedure Training meeting can be found in Q&A 20 | | | Allowed | Allowed |
| **Company Events** | **Product and Procedure Training and Education Event** | **NOT** taking place around or at the same time as a **Third Party Organised Educational Event** | Allowed | Allowed |
| | | Taking place around or at the same time as a **Third Party Organised Educational Event** | Allowed | Not allowed |
| | **Sales, Promotional and Other Business Meeting** | **NOT** taking place around or at the same time as a **Third Party Organised Educational Event** | Allowed (through a consulting agreement) | Not allowed (except for the demonstration of non-portable equipment) |
| | | Taking place around or at the same time as a **Third Party Organised Educational Event** | Allowed | Not allowed |

### Description

**Delegate:** "Delegate" is any Healthcare Professional who is attending passively a Company Event or a TPOE and cannot be considered as "Faculty". For avoidance of doubt, poster- and abstract-presenters are considered to be Delegates.

**Satellite Symposium:** Common elements of Satellite Symposia are:
- It takes place at a Third Party Organised Event (TPOE) and it is part of the TPOE official program (i.e. not focused on marketing specific products);
- The Company is responsible for the content subject to review by the Organiser where required;
- It's open to any delegate, not only to selected individuals;
- It has Company branding and the Company can promote the Satellite Symposia to customers.

**Speaker/Faculty:** "Faculty/speaker" in this chart is someone who is considered as speaker, for example someone who gives a presentation whether in a Company Event or a TPOE; is moderating/chairing a session and therefore needs to prepare ahead of the presentation/moderation.

### Guidance

**Speaker/Faculty:** In order to determine whether an event is a TPOE or a Company Event, the following aspects should be taken into account:
o Open events (not only Company's customers) are typical of TPOE, and in this case, it is a Third-Party chooses HCPs attending;
o Who is primary initiator of the Event: How much is the Third-Party vs. the Company involved, who is driving the agenda?
o CME accreditation is an TPOE indication;
o TPOE are generally broader than one or few products;
o Single-sponsored events are often Company Events.

# ANNEX VII

# The Criteria Applicable to Third Party Organised Procedure Trainings (Effective as of 3rd September 2018)

Third Party Organised Procedure Training, as defined in the Glossary of the MedTech Europe Code of Ethical Business Practice ("the Code") means a type of Third Party Organised Educational Event that is 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.

Chapter 2 of the Code provides that Member Companies may support Third Party Organised Procedure Trainings ("TPPT") either:

- via Educational Grants (in accordance with Chapter 4: Charitable Donations and Grants); OR
- by providing financial support directly to individual Healthcare Professionals ("HCP") to cover the cost of attendance at Third Party Organised Procedure Training sessions.

This exception is to be narrowly interpreted.

For cross-border and international Third Party Organised Events, it is the CVS Compliance Officers whose responsibility it is to determine whether or not a conference meets the criteria to be qualified as a Third Party Organised Procedure Training. In case the Event does not meet the TPPT criteria, it will be re-qualified as a Third Party Organised Educational Conference.

## CRITERIA FOR TPPT DETERMINATION

1. Programme:
Practical and hands-on activities must comprise the majority of the programme of TPPTs (unlike Third-Party Organised Educational Conferences which are theoretical in nature). TPPTs are often referred to as "courses", rather than "conferences" or "seminars". Examples may include courses aimed at acquiring or improving the HCP's skills in minimally invasive surgery, orthopaedic trauma surgery, or the implantation of cardiac rhythm devices, etc.
The programme must be focused on acquiring specific medical skills relevant to certain medical procedures as opposed to products, or medical technologies. The programme must include practical sessions.
In order to be considered a TPPT, the practical sessions must in all cases represent more than 50% of the full programme and hands-on sessions must represent at least one-third of the full programme. These requirements must be clearly indicated in the TPPT programme.
The following will be considered as examples of practical sessions:

- Hands-on sessions in which all attendees to the TPPT participate actively. In these sessions, attendees perform specific procedures on settings and environments appropriate for the practice of the relevant procedure. Examples of hands-on sessions may include surgery simulations where the technologies relevant to the specialty are practiced on cadavers, skin models, synthetic bones, cath labs; etc. To ensure that attendants are able to fully benefit from the active aspects of hands-on sessions, no "station" (model, cadaver, table, etc.) can in principle have more than four participants. For ethical considerations, when human cadavers are used, up to eight participants may share a "station".
- Streaming (e.g. video, 3D-rendering software, augmented reality) or demonstrations of live surgeries.
- Case study sessions when the trainees learn about procedure preparations and best practices from specialty expert(s). These sessions must be interactive and based on pictures, videos, animations, 3D rending software, augmented reality, etc.

2. Venue: TPPTs' hands-on sessions are typically organised in either a clinical environment or in places suitable for medical procedures. Examples of a clinical environment include hospitals or clinics, where medical treatment on real patients is given (f.ex. operating room, cath lab). Examples of simulation settings include conference or meeting rooms which are appropriately equipped with relevant simulation devices/systems, or experimental laboratories suitable for training on cadavers, skin models, synthetic bones, live animals in accordance to applicable regulations and ethical rules, etc.

3. Stand-alone event: TPPTs must be stand-alone. Where the majority of the training is not given in a clinical environment, for example where the training is organised in connection with, adjacent to, or at the same time as a larger Third-Party Organised Educational Conference, that training will not qualify as a TPPT as defined in the Code.

4. Size: Given the essential practical and hands-on element of a TPPT and given the fact that Member Companies would know the identity of the HCPs participating in the course, the size of such training is usually relatively small. However, provided that the above criteria are met, size may not be a determining factor.

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