

## EXACT SCIENCES CORPORATION

### CODE OF CONDUCT ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

At Exact Sciences Corporation (collectively with its subsidiaries, “Exact” or the “Company”), we are committed to complying with the laws and ethical standards that govern our industry in our interactions with health care professionals. We expect Exact employees to abide by this Code of Conduct on Interactions with Health Care Professionals (this “Code”) and to act in an ethical, honest, and legally compliant manner. Exact employees should become familiar and comply with all applicable legal requirements and Exact compliance policies and procedures. Each Exact employee interacting with health care professionals must electronically sign a certification agreeing to abide by this Code and Company policies and procedures. **Failure to abide by Exact compliance policies and procedures may result in disciplinary action, up to and including termination of employment.**

This Code supplements and is in addition to Exact’s Code of Business Conduct and Ethics. Exact employees are expected to comply fully with the Code of Business Conduct and Ethics as well as this Code.

#### *Core Principles*

- **Professionalism.** Employees are expected to conduct themselves in a professional manner that protects the positive image and reputation of Exact. Any actual or potential conflicts of interest shall be avoided. If an employee has a potential conflict of interest, they shall disclose it to the employee’s supervisor or the Company’s Chief Compliance Officer.
- **Honesty and Integrity.** All communications with health care professionals and the public shall be truthful and not deceptive, false, or misleading. Any claims made shall be based upon reliable data (if applicable, upon scientific evidence) that can be substantiated, and no claims shall imply a certainty of results.
- **Patient-Centered Approach.**
  - **Education.** All interactions with health care professionals shall be primarily for the purpose of educating them on Exact’s products and services with reliable educational and scientific data. The ultimate goal is to benefit patient care.
  - **Patient Privacy.** All communications and conduct shall respect the privacy of patient health or medical information in compliance with applicable law.
- **Compliance.** If an employee has a question as to whether a particular activity is in accordance with this Code and the related Company policies and procedures, the employee shall not engage in such activity without first discussing it with a member of the Company’s

Compliance organization.

- **Arrangements and Relationships with Health Care Professionals.** Remuneration that may be provided to a health care professional shall be in compliance with applicable law and Company policies. Remuneration includes any payment or other benefit made directly, or indirectly, overtly or covertly, in cash or in kind.
- **Reporting Instances of Noncompliance.** If an employee is aware of any instance of noncompliance with the Code or any related Company policies and procedures, or has a good faith belief that such noncompliance has occurred or is occurring, they shall either report such behavior directly to the Chief Compliance Officer, a member of the Compliance team, Human Resources, Legal, or a member of the leadership team. If an employee prefers to remain anonymous, they may contact the Company's Compliance Hotline (unless this requirement is prohibited by employment law applicable to them) (a.k.a. "Integrity Alertline") at 1-800-93-ALERT (25378) or exactsciences.alertline.com. By speaking up, you are helping the Company to follow the law.

Exact will maintain the confidentiality of each report to the extent possible. Exact supervisors and employees are prohibited from engaging in retaliation or any form of harassment against an employee who has reported, or is considering reporting, a compliance concern. Anyone who engages in retaliatory behavior is subject to discipline, up to and including termination of that individual's employment or contract.

### ***Compliance with Industry Codes of Ethics***

- **General.** As described below, the Company abides by, and requires all its officers, employees, and agents to comply with, certain codes of ethics that are common to our industry in regions where the Company conducts business.
- **U.S. Interactions: AdvaMed Code of Ethics on Interactions with Health Care Professionals.** For purposes of the Company's interactions with U.S. health care professionals, whether occurring inside or outside of the United States (such as a conference or other event), Exact abides by the AdvaMed Code of Ethics on Interactions with Health Care Professionals, including all updates adopted by AdvaMed ("AdvaMed Code") and requires all its officers, employees, and agents to comply with the AdvaMed Code. We communicate our compliance with the AdvaMed Code to our business partners and expect them to comply with it as well. The AdvaMed Code should be viewed as part of this Code. **For employees in the U.S. or interacting with U.S. health care professionals, please review the attached AdvaMed Code.**
- **Europe Interactions: MedTech Europe Code of Ethical Business Practice.** For purposes of the Company's (1) interactions with health care professionals or health care entities registered in Europe, or (2) interactions with health care professionals at an event in Europe, Exact abides by the MedTech Europe Code of Ethical Business Practice, including all updates adopted by MedTech ("MedTech Code") and requires all its officers, employees, and agents to comply with the MedTech Code for all European interactions. We communicate our compliance with the MedTech Code to our business partners and expect them to comply with

it as well. The MedTech Code should be viewed as part of this Code. ***For employees in Europe or interacting with European health care professionals, please review the attached MedTech Code.***

- **Both Codes May Apply.** It may be necessary under certain circumstances to apply the requirements of both the AdvaMed Code and the MedTech Code to a single interaction, if, for example, a U.S. health care professional travels to Europe for an event. In this situation, compliance with the more stringent code is required when there is a discrepancy between the AdvaMed Code and the MedTech Code. Please contact the Compliance Team at [compliance@exactsciences.com](mailto:compliance@exactsciences.com) for any questions or to request guidance.
- **Interactions Outside of Europe or U.S.** For interactions with health care professionals where the AdvaMed Code or MedTech Code do not apply, Exact's officers, employees, and agents must comply with Exact's Code of Business Conduct and Ethics, as well as all applicable local laws and regulations. Please contact the Compliance Team at [compliance@exactsciences.com](mailto:compliance@exactsciences.com) for any questions or to request guidance.

Adopted, as revised, effective: October 25, 2023

# MedTech Europe Code of Ethical Business Practice

**March 2024**





# About MedTech Europe

MedTech Europe's mission is to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

MedTech Europe started as an alliance in October 2012 formed by two organisations – EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medical devices industry.

Promoting a balanced policy environment

MedTech Europe engages with EU regulators, politicians and other decision-makers to help shape policies to promote innovation for our growing healthcare needs and expectations.

Demonstrating the value of medical technology

MedTech Europe promotes to its members and the wider industry value-based innovations that support more sustainable healthcare systems.

We use economic research to show the benefits of medical technology and we organise many initiatives to explain the value we bring to healthcare systems in Europe. We bring stakeholders together to discuss trends, issues and opportunities.

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# Scope





## 1. Applicability of the Code

**1.1.** This Code only applies to the Member Companies of MedTech Europe, who are manufacturers of Medical Technology.

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 practising.

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

**1.2.** The Code shall be directly applicable to all activities of Member Companies and their affiliated companies that carry on activities in the Medical Technology sector in the MedTech Europe Geographic Area within the scope applicability defined in Section 1.1. 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 1.1. 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.

**Q1** Is the Code applicable to activities of an affiliate of a Member Company located outside the MedTech Europe Geographic Area?

**A1** With regards to activities of an affiliate of a Member Company located outside of the MedTech Europe Geographic Area the Code is not applicable whenever they:

- support an Event taking place outside the MedTech Europe Geographic Area except if they are supporting participation of Healthcare Professionals registered or practising 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

**Q2** How does the Code apply to members with company platforms that include different business units e.g., medical devices, pharmaceuticals, research only products? How can educational grants be applied in such organizational structures?

**A2** The Code applies to all Member Companies' interactions linked to Medical Technologies. Ensuring compliance with the Code may be more challenging for companies with platforms 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 Technology marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to this Medical Technology 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 or services, the Code shall apply.

## 2. Transposition Obligations

### 2.1 New Member Companies

At the time an applicant becomes a Member, it must begin to take all the necessary steps required to meet all membership obligations, including the obligation to comply with the Code.

MedTech Europe recognizes the complexities involved in this process and the time needed to make changes associated with these new obligations. As a result, Corporate Members have one year from the date of membership ratification by the MedTech Europe Board of Directors to fully comply with the Code. This one-year membership transition period does not include an exemption from the Code's ban on direct sponsorship. From the date of membership ratification by the MedTech Board of Directors direct sponsorship of Healthcare Professionals is prohibited (please see Chapter 2 for more information).

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.

For the avoidance of doubt, this section 2.1 shall also be applicable to membership transition following mergers and acquisitions.

As soon as a Member Company has full control of an acquired company (or part of it) that is not a member of Medtech Europe or any Member Association, or as soon as a Member Company merges with such a company, it shall ensure that no new commitments of direct sponsorship for Healthcare Professionals to attend Third Party Organised Conferences are entered into, and that pre-existing direct sponsorship arrangements are not renewed.

If there are pre-existing commitments all direct sponsorship of Healthcare Professionalsthe Member Company shall terminate all such agreements when contractually viable.

No direct sponsorship of Healthcare Professionals may take place after one year of the formal date of acquisition or merger, including when the commitment pre-dates the acquisition or merger.

### 2.2 New Association Members

Association Members have one year from the date of membership ratification by the MedTech Europe General Assembly to transpose the Code.

For avoidance of doubt, where an Association membership modifies the MedTech Europe Geographic Scope, as provided by the Code, either by changing its own geographic scope or when a new Association becomes a member of MedTech Europe, MedTech Europe Corporate

Members have one year to comply with the Code in these new territories from the date of the date of the change of the geographical scope of an existing Association or the relevant ratification of membership by the MedTech Europe General Assembly..

After the passage of one year from the date of the relevant General Assembly ratification, all Members must fully comply with all obligations under the Code.

# Administering the Code

Part 2 of the Code includes procedures designed to provide an effective and efficient complaint-handling process, at national and MedTech Europe 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 Part 2: Complaint handling and dispute resolution also 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.

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



## 1. The Conference Vetting System

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

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.

The Conference Vetting System approval is required for Members to support Third Party Organised Educational Events which fall within its scope, as provided in Annex I.

Where there is a Conference Vetting System decision in relation to a specific Third Party Organised Educational Event, this decision is binding upon all Member Companies.

## 2. MedTech Europe Code Committee

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 Part 2 of the Code.

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 its dispute resolution principles.

The MedTech Europe Code Committee will be composed of:

- at least one (1) but up to three (3) representatives of the MedTech Europe Legal Affairs Committee, elected in accordance with its own procedures, with a preference for the members of the MedTech Europe Legal Affairs Committee's Steering Committee
- nine (9) representatives of the MedTech Europe Ethics & Compliance Committee, elected in accordance with its own procedures
- the Chair of the MedTech Europe Ethics & Compliance Committee
- at least one (1) but up to three (3) representatives from Member Associations, elected in accordance with its own procedures
- In addition, the Code Committee may co-opt up to four (4) other members from the

MedTech Europe Legal Affairs Committee and the MedTech Europe Ethics & Compliance Committee, where the Code Committee is satisfied that the concerned members will positively enhance the representativeness, operation and objectives of the Code Committee.

- Only one representative from a Member may be a member of the Code Committee at any given time
- The MedTech Europe Compliance Panel and the Conference Vetting System officers shall automatically be non-voting members of the Code Committee
- The Code Committee may invite external lawyers as standing non-voting members, as needed.

The Code Committee will elect its Chair from among the members of the group for renewable periods of two years, or until the Chair ceases to be a member of the Code Committee. The Chairs of other MedTech Europe committees are not eligible to be at the same time Chair of the Code Committee.

### 3. MedTech Europe Compliance Panel

#### 1. Tasks

The MedTech Europe Compliance Panel shall have the following tasks:

- Supervise the MedTech Europe 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 Part 2 of the Code;
- Interact, upon request of the Secretariat, with relevant MedTech Europe groups to further develop the Code and guidance documents;

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

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.

#### 2. Composition

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 conflicts of interest, in particular as regards complaint handling processes.

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 a position on the Board of Directors of a Member Association without any consulting or employment relationship with a Member Company shall not be considered 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 member has given his/her consent.

### **3. MedTech Europe Compliance Panel Internal Procedural Rules**

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 Part 2 of the Code.

## **4. 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.

## Promoting an Ethical Industry



# Introduction



MedTech Europe 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 industry, Member Company and HCP 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.

## 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 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 Technologies and the improvement of existing Medical Technology 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 Medical 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' Medical Technology or related services.

- **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.

**Q3** Must a Member Company require Employer Notification to be given whenever Company personnel meet HCPs at an HCO?

**A3** 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.

# Chapter 1: General Criteria For Event

Member Companies may directly finance the costs of Healthcare Professionals that are Delegates to Company Organised Educational Events and Third Party Organised Procedure Training meetings provided this is in accordance with local professional codes, laws and regulations, and the requirements in Chapters 1, 2 and 3 of the Code.

Member Companies may also support attendance of Healthcare Professionals as Delegates and Faculty to other Third Party Organised Educational Events through Educational Grants in accordance with the rules of Chapters 1, 2 and 4 of the Code. They may also purchase promotional and advertising space at Third Party Organised Educational Events in accordance with the requirements of Chapter 2 of the Code.

Member Companies may also finance the attendance costs of Healthcare Professionals attending as Faculty at satellite symposia at Third Party Organised Educational Events, as well as of Healthcare Professionals providing speaker services at Company Organised Events provided this is in accordance with the rules of Chapter 5: Consulting Agreements.

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.

The detailed programme should be available in sufficient time prior to the Event, present a clear schedule with no gaps during the sessions in the case of in-person Events, including hybrid events, (e.g., the minimum duration for a full day for an in-person Event should be 6 hours or 3 hours for a half day for an in-person Event including refreshment breaks).

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.

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.

**Q4** Do the minimum duration requirements of Section 1 of Chapter 1 apply to Virtual Events?

**A4** No, Virtual Events are not affected by the duration requirements of Section 1, Chapter 1 of the Code.

**Q5** 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?

**A5** 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.

Where an exception is considered, the Event's promotional material should not feature or promote the on-site leisure aspects of the conference venue 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.



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

### 3. Guests

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

- Q6** Under the Code, what is meant by “ease of access” in relation to Event location and venue?
- A6** When the 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.
- Q7** Under the Code, how does the “season” impact evaluation of Event location?
- A7** 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.
- Q8** What does the term “facilitate” mean where used in connection with Guest expenses?
- A8** 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 a Guest of a Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their 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.
- Q9** 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?
- A9** 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 scientific exchange, for a Guest to participate in related hospitality during such Events (for example, lunches, industry booths and coffee breaks) even when the Healthcare Professional pays for the Guest’s expenses.

## 4. Reasonable Hospitality

Member Companies may provide reasonable hospitality to Healthcare Professionals in the context of Company Events and Third Party Organised Educational Events when they are attending the Event in person, but any hospitality offered must be subordinate in time and focus to the Event purpose (no home delivery is permitted, for example through catering or food delivery services to the HCPs' home). 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' Medical Technology or related services.

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, unless when required by travel arrangements in relation to Company Organised Events arranged around Third Party Organised Educational Events (See section 3 of Chapter 2).

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.

**Q10** 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 Professional's travel or accommodation expenses for attendance at the Event?

**A10** 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, unless when required by travel arrangements in relation to Company Organised Events arranged around Third Party Organised Educational Events (See section 3 of Chapter 2).

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.

## 6. Transparency

Member Companies must ensure full compliance with national laws or regulations with regard to the disclosure or approval requirements associated with 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](#)) be made prior to the Event 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 promotional items related to the Healthcare Professional's practice or for the benefit of patients, do not require Employer Notification.

## 7. Virtual Events

Virtual Events must comply with any part of the Code that is by its nature applicable to them. Therefore, Member Companies may provide financial and/or In Kind support (e.g. Member Company Medical Technology) to Virtual Events in accordance with the rules of Chapters 1, 2, 3 and 4 of the Code.

- Q11** 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 notification or approval before the Event is required by local laws or regulations?
- A11** No. Only the compulsory notification before the Event 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 prior to the Event. The transparency provisions of the Code apply only in countries where there is an absence of equivalent national transparency laws and regulations.
- Q12** 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?
- A12** 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.



**Q13** Can a celebration dinner or other type of social Event be supported?

**A13** No. Social events, such as anniversaries, Christmas dinners or other similar events may not be supported by Member Companies, neither as stand-alone events nor as part of Third Party Organised Events. For the avoidance of doubt, Member Companies may also not invite Healthcare Professionals to attend such an event at the Member Company's expense.

# 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 Third Party Organised Educational Conferences (see the [Glossary](#)) with cash and/or In Kind provided these comply with:

- Chapter 1: General Criteria for Events; and
- Where applicable, have approval via the Conference Vetting System (see the [Glossary](#)).<sup>1</sup>

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.

### 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.

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

- Q14** 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”?
- A14** “In Kind support” can be provided to Healthcare Organisations but Member Companies should take care to ensure such In Kind support does not, nor is perceived to, circumvent the prohibition against Member Companies providing direct financial support to identifiable Healthcare Professionals to attend Third Party Organised Educational Conferences. For example, 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.
- Q15** Please provide examples of appropriate booth activities which will be perceived as professional?
- A15** Booth activities at Third Party Organised Educational Conferences should aim primarily at displaying Member Companies’ Medical Technologies and/or related services and related literature. Therefore other activities should be limited and reasonable and in principle only soft drinks and snacks should be served.
- Q16** 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)?
- A16** Please refer to Annex I for a detailed visualisation of the scope of CVS and its impact on commercial activities.
- Q17** 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?
- A17** 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](#))<sup>2</sup>.
- 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
- Should the participants' practical, hands-on portion of a Third Party Organised Procedure Training be cancelled or made virtual, the Event itself would no longer qualify as a Third Party Organised Procedure Training. As such, Member Companies would only be able to support such Event via Educational Grants and registration fee/access to the recording to such Events. Under no circumstances may travel expenses be paid in such a situation.

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

**Q18** What are the main differences between Third Party Organised Educational Conferences and Procedure Trainings?

**A18** Both Third-Party Organised Educational Conferences (see the [Glossary](#)) and Procedure Trainings (see the [Glossary](#)) are a type of Third Party Organised Educational Event. 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 prohibition 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 training, generally involving more than one provider/manufacturer/sponsor
- This must be evident from the programme for 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 Medical 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 with, 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.



**Q19** Do Proctorships and Preceptorships require CVS approval before they can be provided and/ or supported by a Member Company?

**A19** 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.

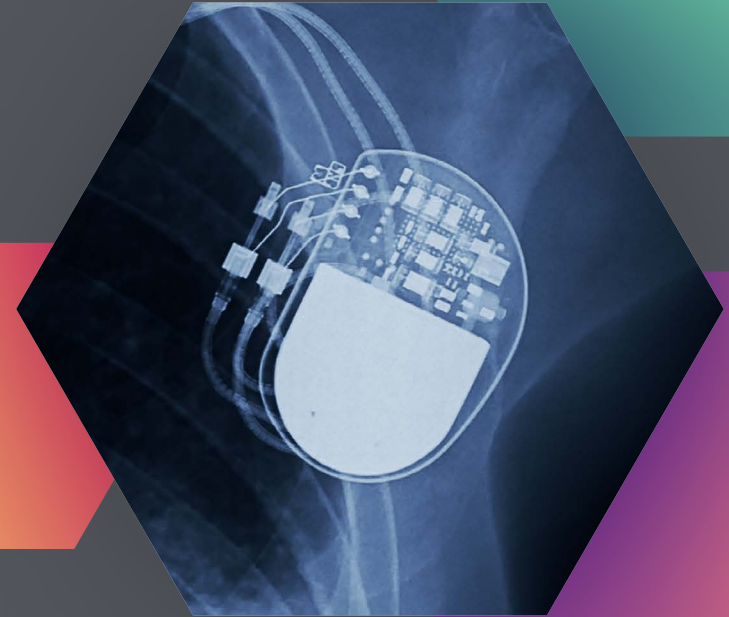
**Q20** Can a Member Company support a Third-Party Organised Educational Event, where the organisers are individual Healthcare Professionals without involvement of a legal entity, such as a Professional Congress Organiser, a Healthcare Organisation or a travel agency?

**A20** In no event can financial support be transferred directly to the bank account of an individual HCP.

In-Kind support may be provided to this kind of Event provided it complies with all the requirements of the Code. Such In Kind support may include the (temporary) loaning of multiple use Medical Technologies, the provision of single-use Demonstration Products, but also the direct payment of catering, venue rental invoices, and/or speakers through Consulting / Speaker Agreements provided that these comply with all requirements of Chapter 5 of the Code.

This type of support carries significant risks for all parties involved, which need to be managed carefully, even where such an Event complies with all other aspects of the Code, including the prohibition of support for attendance of identifiable HCPs at Third Party Organised Educational Events.

# Chapter 3: Company Events



## 1. General Principles

Member Companies may invite and in some cases pay the costs of attendance of Healthcare Professionals at Company Events.

Examples of Company Events are, 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 (including company plant or factory tours) may take place in Member Company's manufacturing plant or Healthcare Organisations used by the Member Company as reference centres, including in countries outside the country of residence of the Healthcare Professional provided the tour complies with the Code in all respects.

## 2. Product and Procedure Training and Educational 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. This may include paying the cost of attendance of Healthcare Professionals if allowed under local laws and regulations.

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

### 2.1 Company Organised Educational Events

Company Organised Educational Events are Company Events, whose objective is genuine and bona fide medical education, and the enhancement of professional skills.

The aim of Educational Events is to directly communicate information 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

**Q21** Are cruise ships or golf clubs appropriate venues for Product and Procedure Training and Educational Events?

**A21** 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.

**Q22** What criteria should a Member Company apply when considering the country location of Product and Procedure Training and Educational Events?

**A22** If the participants are primarily from 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 will be the residence of at least some of the participants of a Product and Procedure Training and Education Event.



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 requirements when organizing such an Event in order to be compliant with the MedTech Europe Code:

The entire Event must comply with the criteria in 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 educational part must fill most of the programme.
- 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 at midday 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.

### 3. Company Events taking place in the context of Third-Party Organised Educational Events

Member Companies cannot directly support travel and/or accommodation or other expenses of individual Healthcare Professionals participating in Company 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 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

#### Q23 Can a Member Company use a meeting venue outside Europe?

**A23** 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) will be the residence of at least some of the participants of the Product and Procedure Training and Education Event.

Healthcare Professionals at that Third-Party Organised Educational Event.

If such an Event overlap occurs, the Member Company may only pay 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).

The Healthcare Professionals must have an active role at such a Company Organized Event, rather than being mere passive attendees. For example, 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 organized at or around a Third Party Organised Educational Event.

#### **a. Specific rules for certain Company Events organized in the context of Third-Party Organised Educational Events**

Satellite symposia or booth speaker engagements 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 applies 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 their attendance to the Event.

#### **b. Hospitality at Company Events organised in the context of Third Party Organised**

## Educational Events

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 clearly subordinate to the purpose of the meeting;
- The invitation to the lunch or dinner should only be made to a small number of participants, in order to ensure effective contribution by way of transfer of knowledge, discussion and exchange amongst the participants in line with the meeting's legitimate business or scientific purpose. Any such invitation should have regard to the rules of Chapter 4, Section 3, subsection a), point 1, "Support for HCP Participation at Third Party Organised Educational Events". In no case may a Member Company issue a blanket invitation to all the participants at the Third Party Organised Educational Event.
- 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, in particular Chapter 1 (General Criteria for Events).

In all cases, Member Companies should pay special attention to instances where Healthcare Professionals may already be benefiting from an Educational Grant which 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.

## 4. 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 Medical Technology and related services features and benefits, conduct contract negotiations, or discuss sales terms.

In addition to the principles laid down in 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.

**Q24** 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?

**A24** 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, Section 2, of the Code ("Product and Procedure Training and Educational Events").

# Chapter 4: Grants and Charitable Donations



## 1. General Principles

- a. While the Code does not cover Grants or Charitable Donations provided to patient organisations, MedTech Europe has published Patient Organisation Guidelines to support Member Companies when interacting with patient organisations. Research Grants are covered in the Code in Chapter 6: Research.
- b. 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. If Grants are provided on more than one occasion to the same recipient, Member Companies should be mindful that perception and contractual risks may arise. Member Companies should therefore establish internal controls and checks to mitigate these risks.
- c. 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.
- d. 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.
- e. In order 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 Member Companies shall implement an independent decision-making/review process with criteria that are not sales and/or commercially oriented. The Member Company's sales and/or commercial function shall not decide upon and/or approve decisions to provide Grants or Charitable Donations.. 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.
- f. 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. It must in all cases be lawful under applicable national laws and regulations for the Grant or Charitable Donation recipient to receive and benefit of the particular type of Grant/Charitable Donation.

**Q25** Under the General Principles in Chapter 4. Grants and Charitable Donations, could you provide an example of an "independent decision-making/review process"?

**A25** 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.

Such an evaluation shall consider all the circumstances including consideration of the legal status and structure of the requesting (and/or 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 on 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.

- g. 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, including, as a minimum a detailed description of the scope and purpose of the programme, activity or other project, which is proposed as 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. No Grant or Charitable Donation shall be provided until a written agreement documenting the terms of this is signed by both parties.
- h. 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 Medical Technology 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 Charitable Donations for charitable or other philanthropic purposes. 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 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.

**Q26** Under the Code, can a Member Company make a Charitable Donation to support the general running of hospital or other Healthcare Organisation?

**A26** No, a Member Company cannot make 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 objects. 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.

Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship (see [Glossary](#)), provided the Charitable Donation benefits patients, is limited to specific needs identified in advance, or is 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.

### Fundraisers

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 organization. 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 shall 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 Educational Grants (see the [Glossary](#)) for the advancement of medical education. 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.

**Q27** 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?

**A27** Member Companies may specify the broad, general purpose for which a Charitable Donation shall be applied, 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 an earthquake in that country). However, Member Companies must take care that such specifications do not amount to control over the specific, final use of the Charitable Donation by the recipient which is not allowed under the Code.

**Q28** 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?

**A28** 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.

**Q29** What are the differences between an Educational Grant and a commercial sponsorship?

**A29** Commercial sponsorships in the context of Third Party Organised Educational Events would involve objective consideration, such as access to the participants for marketing purposes, advertising opportunities or booth space.

On the other hand, an Educational Grant is exclusively provided for the advancement of medical education in situations where the Member Company neither requests, expects nor receives any consideration for the support.

Public notes or mentions thanking the providers of Educational Grants do not amount to consideration for these purposes .

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](#))<sup>3</sup>

##### 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.

For the avoidance of doubt, Educational Grants to support HCP participation at a Third Party Organised Educational Event may, subject to local laws and regulations, cover matters such as travel, accommodation and hospitality, including meals. Member Companies should however be mindful of any specific notification or disclosure requirement linked to support of hospitality.

When providing an Educational Grant to Support Healthcare Professionals' participation at Third Party Organised Educational Events, Member Companies should not proactively seek to receive the names of the Healthcare Professionals benefiting from the 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 and their respective Healthcare Organisation, who have

<sup>3</sup>) For scope of application of CVS please refer to: <http://www.ethicalmedtech.eu>

**Q30** Can a small Healthcare Organisation receive Educational Grants to support Healthcare Professionals participation at Third Party Organised Educational Events?

**A30** 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.

**Q31** 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?

**A31** One of the guiding principles in the Code is that Member Companies should not receive or be able to determine the names of the ultimate HCP beneficiaries. The inclusion of a criterion specifying an individual hospital or hospital department is not prohibited under the Code. However, Member Companies should bear in mind that the smaller the hospital or department the greater will be the risk that Member Companies will be able to identify individual beneficiaries if making use of such criteria inappropriate under the Code. In addition, Member Companies should be mindful of any proximate or ongoing tender proceedings with a specific hospital, as such tenders may raise additional red flags.

**Q32** How can Member Companies in practice ensure that Educational Grants are only made available for Third Party Organised Educational Events which receive a positive review from CVS (where this is required under the Code)?

**A32** 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.



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.

## 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.

## 3) Support for Third Party Organised Events via commercial organisations not involved in the organisation of the Event (or of all of the Events)

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 therefore take all necessary actions to mitigate these risks.

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 sufficient experience and expertise 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.

**Q33** Can Member Companies give criteria for HCOs and/or PCOs to allocate their Educational funds?

**A33** Yes, objective criteria for HCOs and/or PCOs to select HCPs to benefit from Educational funds may be provided 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, or specific hospital, provided the HCP beneficiaries are not identifiable (see Q&As 31 and 32).

**Q34** 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?

**A34** 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.

**Q35** In the event that a commercial organisation, such as a Professional Conference Organiser organises a Third Party Organised Educational Event independently of any Healthcare Organisation, is it appropriate for Member Companies to sponsor such events and what rules shall apply?

**A35** Member Companies may enter into a commercial sponsorship arrangement with a Professional Conference Organiser that is organising a Third Party Organised Educational Event and acting independently of any Healthcare Organisation. However, such arrangements do not fall within the definition of Educational Grant as Professional Conference Organisers 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). 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, the Code provisions governing Educational Grants shall 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.

Member Companies may not provide an Educational Grant or funds for education to a third party travel agency directly. For the avoidance of doubt, a Member Company may provide an Educational Grant to a Healthcare Organisation or funds earmarked for education to a Professional Conference Organizer which has arrangements in place so that payments for travel, accommodation and registration (where applicable) 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.

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 (when applicable) 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. 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 effective monitoring and control of the activity of the third party travel agency.

## b. Scholarships and Fellowships

Member Companies may provide Educational Grants 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.

A Member Company may not additionally pay for, or reimburse, the travel or other participation costs incurred by a Scholar or Fellow attending a Third Party Organised

**Q36** Is it appropriate for a Member Company to provide an Educational Grant to a Healthcare Organisation for the limited purpose of covering, in whole or in part, the cost of some form of peer-to-peer, general public or patient education or training? If so, under what circumstance can such Grants be provided and which criteria would need to be applied?

**A36** As a matter of principle, Member Companies should not cover an HCO's normal overhead or routine costs of operation ("overheads"). These routine costs are to be understood as those costs that would fall under the normal budgeting of a particular HCO. Different types of HCOs may have different kinds of routine costs and whether an activity and its costs are to be understood as "routine" for a particular HCO must be assessed on a case-by-case basis. For the avoidance of doubt, where a particular activity cannot be run due to lack of funding, it does not necessarily mean that such activity is not routine activity and cost for that type of HCO as per the definition of "overheads" above. It may be helpful to consider previous experiences with that HCO or similar HCOs to assess whether such activity would usually be internally funded. If so, the activity would typically be considered a routine activity. As an exception to the above and provided that local laws do not prohibit such setups, Member Companies may support peer-to-peer or public/patient training/education via Educational Grants under the following conditions:

1. If part of a lawful tender, which include internal educational set-ups as "value adds" which would cover, in whole or in part, hospital overheads where these are related to the requirements of that specific tender;
2. Fellowships and Scholarships, in accordance with the provisions of the Code;
3. Support of legitimate educational programs which benefit the delivery of care, and/or provide specific expertise to either an internal or external audience. For such educational support, Member Companies must, however, consider the following to ensure appropriate safeguards against conflicts of interest between the aims of the Member Company and the aims of the HCO, particularly in relation to procurement and competition:
  - the purpose and scope of the support should be transparent and fully disclosed to the hospital administration as well as, where required, any other locally-designated competent authority;
  - such support should be limited in time and not renewed for indeterminate periods;

The supported programme/activity should genuinely aim to improve patient safety and/or clinical outcomes. As such, it must go above and beyond supporting normal hospital capacity and capability, considering the primary purpose of the hospital. It would not be appropriate to support routine or administrative capacity. This support should be brand-agnostic, meaning that it should not promote specific Member Company Medical Technology. Additionally, while respecting the need for transparency, it should not promote the specific HCO.

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.

#### **c. Educational Grants for general medical education topics**

Member Companies may support genuine medical education for Healthcare Professionals on general healthcare-related topics through Educational Grants in accordance with the rules of this Chapter.

The topic must directly relate to the Member Company's area of business, Medical Technologies, therapies or related services. The Event must be conducted in accordance with, and meet the other requirements of Chapter 3 of the Code.

Additionally, Member Companies can also support genuine medical training on general healthcare-related topics through Member Company-organised Product and Procedure Training and Education Events.

#### **d. Grants for Public Awareness Campaigns**

Member Companies may also provide Educational Grants 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.

Additionally, a Member Company may provide an Educational Grant to support the provision of high quality information, promoting awareness and/or educating patients, carers, 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, be designed or used to promote the use of Member Company therapies, products or specific HCOs.

# Chapter 5: Consulting Arrangements



## 1. General Principles

Member Companies may engage Healthcare Professionals and Healthcare Organisations to provide consulting and other services to fulfil a Legitimate Business Need, including research, participation on advisory boards, presentations at Company Events and product development. Member Companies may pay Healthcare Professionals and Healthcare Organisations 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 Organisation is established, or 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 or Healthcare Organisations and Member Companies including where a consultant Healthcare Professional or Healthcare Organisation 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. For example, the decision to engage a specific Healthcare Professional or Healthcare Organisation as a consultant for sales reasons does not constitute a Legitimate Business Need. If it is necessary for a Member Company's sales function to be involved in decisions to engage specific Healthcare Professionals or Healthcare Organisations, the independent decision-making/review process should ensure decision-making is exercised to fulfil Legitimate Business Needs.

## 2. Criteria for genuine Consulting Arrangements with Healthcare Professionals and Healthcare Organisations

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, prior to the selection of the consultant(s).
- b. The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified Legitimate Business 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 Legitimate Business Need. Some examples of these qualifications include the years of experience, geographic location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific Medical Technology. The volume or value of business generated by a prospective consultant is not a relevant criterion.
- d. Consulting Arrangements with Healthcare Professionals or Healthcare Organisations must be documented in a written agreement, signed by the parties in advance of the commencement of the services, which must specify the services to be provided and the basis for compensation for the performance of those services.
- e. When engaging a Healthcare Professional or Healthcare Organisation as a consultant, Member Companies should be mindful of any potential conflict of interest that might arise from the specific project or from the engagement of that specific Healthcare Professional or Healthcare Organisation in particular.
- f. The engaging of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's products or services.
- g. The compensation for the services rendered must be reasonable, comply with local laws and regulations imposing limits on it and reflect the Fair Market Value of the services provided.

- h. Member Companies must maintain records and documentation of the services, and associated work products, provided by the consultant and of the use made of those services by the Member Company. Examples of the documentation include the presentation, invitation letter, agenda, attendance list, minutes, etc.
- i. 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. Compensation and Fair Market Value

The compensation paid to Healthcare Professionals and Healthcare Organisations engaged as consultants by Member Companies shall reflect Fair Market Value for the services provided and shall be determined by Member Companies based on a documented internal method to determine FMV. 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. 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 and/or business operations.

All payments made for services must comply with all applicable tax and other legal requirements. Member Companies may pay for documented and actual 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. Such expenses must comply with local laws and regulations. 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.

### 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 prior to commencement of the services, 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 impose appropriate obligations on the consultant to ensure that the consultant's status as a consultant for the Member Company and their 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



## Introduction

Member Companies may engage Healthcare Professionals to conduct Member Company-initiated research, support investigator-initiated research through Research Grants, or through collaborative research in accordance with the specific rules of this chapter and any general rule applicable to the interactions with Healthcare Professionals and having regard to the general principles of the Code.

### 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 or performance follow up (PMCF/PMPP), 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); to provide advice as an advisory committee member or adverse event committee member – 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

**Q37** What is an example of an external public register for clinical trial transparency?

**A37** Examples of an external public register for clinical trial transparency are [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.who.org](http://www.who.org)

about Member Companies' clinical trials, for example in external public registries and peer-reviewed journals, and having regard to local transparency laws and regulations.

Where Member Companies engage third party intermediaries for research (e.g. contract research organisations (CROs)), they shall ensure that the contractual arrangements impose obligations on the third party intermediaries to 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.

## 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 Medical Technology, therapies and/or related services and may therefore provide Evaluation Products under a written contract 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 that should be reasonable in the context. 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 or leased 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 related 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 and ethical requirements.

### 3. Third Party-Initiated Research: Research Grants

Where permitted by national laws, regulations, national guidelines and professional codes of conduct, Member Companies may provide 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 unduly influence the research. However, Member Companies shall clearly specify 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. Bearing in mind that the investigator is at all times responsible with regards to compliance with local laws and regulations a Member Company may give consideration to a request for a Research Grant prior to ethics committee approval for the specific research project.

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.

### 4. Collaborative Research

Where there is a need to do so, and provided it is allowed by local laws and regulations, Member Companies and non-industry partners may collaborate to develop and/or conduct scientific research, provided this has a legitimate purpose. Collaborative research may be conducted before, during or after regulatory approval of a drug, Medical Technology, therapy or related service.

**Q38** Can Member Companies support the participation of Poster or Abstract Presenters in Third Party Organised Educational Conferences?

**A38** Poster or Abstract Presenters at Third Party Organised Educational Conferences are not to be considered as Faculty, as defined in the Code ("Glossary"). As such, if Member Companies want to support their participation in the Third Party Organised Educational 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 Member Company initiated or third party initiated research.

However, if the support is included in a research agreement, Member 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 Member 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). Member 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.

**Q39** What is the difference between Member Company-initiated research, ythird party-initiated research (Research Grant) and collaborative research?

**A39** Member Company-initiated research is sponsored by the Member Company, it is the Member Company who is responsible for all aspects of the research and who owns the data (e.g. used for regulatory purposes). Member companies may contract researchers to conduct the research on their behalf (i.e a fee-for-service agreement).

Third party-initiated research (investigator-initiated) is sponsored by the third party and it is the third party who is responsible for independently managing all aspects of the research. Member Companies may support the research e.g. financially (Research Grant).

Collaborative research is usually sponsored by a third party investigator, but may also be sponsored by a Member Company, so that there is a pooling of skills, experience and/or resources from all the parties that jointly complement the objectives of the collaborative research project as a shared commitment.

The scope of the collaboration must be agreed in advance by the Member Company and third party or parties (collaborative research agreement).

Each collaborator must actively contribute significant skills, experience and/or resource complementary to the collaboration, for example study objectives and design, methodology, protocol development, study conduct, statistical analysis plan, clinical study report and publication. Before engaging in research collaborations, it is critical for Member Companies to take into account key considerations such as the review and approval/authorisation process; due diligence criteria; budgeting and contracting processes; permissible interactions during the execution of the research and other relevant considerations. Items within scope and out of scope of the collaborative research should be clearly defined to justify the treatment of a research project as collaborative research as opposed to Member Company-initiated research or third-party-initiated research (for which a Research Grant is appropriate).

In accordance with the Documentation Principle, any arrangements made by a Member company to conduct collaborative research shall be set out in a written agreement to define roles and responsibilities transparently and in accordance with the study protocol. Examples include identification of the study [initiator and] sponsor; intellectual property ownership; financial support; transparency of involvement; reporting; rights to data; registration of publications; adverse event reporting procedures and dispute resolution.

Member Companies shall ensure that the pooling of all collaborators' skills, experience and/or resources is clear expressed in a collaborative research agreement and all activities falling within the scope of the Member Company's responsibility are performed in accordance with all applicable national laws and regulations, professional codes of conduct and ethical requirements as well as with applicable good practice guidelines.

**Q40** What is meant by “legitimate purpose” in the context of collaborative research?

**A40** A collaborative research project must enhance patient care or be for the benefit of patients, or alternatively benefit the HCO and, as a minimum, maintain patient care. It must, therefore, always be ensured that none of the benefits of any collaborative research project go to individual HCPs or their practices. If there are benefits which are due to the HCO in the collaborative research project, these must go to the HCO or similar organization.

A collaborative research project shall not constitute an inducement to HCPs or other relevant decision makers to prescribe, supply, recommend, buy or sell a Member Company's Medical Technology or any related service. It shall be legitimate from a scientific and ethical viewpoint and ethical approval must be obtained where required by national laws and regulations, professional codes of conduct and ethical requirements as well as with applicable good practice guidelines and it shall be carried out in an open and transparent manner.

# 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 Promotional Items





It is generally prohibited to provide gifts to Healthcare Professionals and Healthcare Organisations. Member Companies may exceptionally provide inexpensive educational items and/or promotional items, 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 promotional items in accordance with the following principles:

- a. Educational items and/or promotional items 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 promotional items should be provided in response to requests made by Healthcare Professionals.
- c. Educational items and/or promotional items must not be given in the form of cash or cash equivalents.
- d. Educational items and/or promotional items must be modest in value, and can be branded or non-branded items.
- e. Educational items and/or promotional items must not be given to mark significant life events (e.g., birthday, birth, wedding, etc.).
- f. 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 purely 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.
- g. Provision of educational items and/or promotional items must not improperly reward, incentivise and/or encourage Healthcare Professionals to purchase, lease, recommend, prescribe, use, supply or procure the Member Company's Medical Technology or related services.
- h. The educational items and/or promotional items shall not be intended mainly for personal use.

Member Associations shall provide guidelines on appropriate limits for educational and/or promotional items, 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 Promotional Items. In addition, it must comply with national laws, regulations and industry and professional codes of conduct.

- Q41** 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”.
- A41** 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 promotional items 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.
- Q42** 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?
- A42** 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 Promotional Items as they neither relate to a Healthcare Professional's practice nor serve an educational function.
- Q43** Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?
- A43** 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.



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.

# Chapter 9: Demonstration Products and Samples



## 1. General Principles

Member Companies may provide their own Medical Technologies 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 Medical Technology and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the Medical Technology 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. It is also not intended to cover the placement of capital equipment at a Healthcare Organisation's premises<sup>4</sup>.

4) Please note MedTech Europe has issued the "MedTech Europe Guidance on Placement of Capital Equipment". It can be found in the Members Area or upon request to the Secretariat (only available to Members).

## 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 himself 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.

# Chapter 10: Third Party Intermediaries



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 and/or services.

Accordingly, where such arrangements are entered into, and provided local laws and regulations allow it, Member Companies shall ensure that the relevant contractual documentation imposes obligations upon the Third Party Intermediary to comply with provisions set out in the Code and other applicable guidelines, as well as appropriate oversight to ensure this is duly implemented.

### **Risk Assessment**

Member Companies should evaluate the risk profile for proposed and utilised Third Party Intermediary arrangements, including, for example, assessing:

- Risk in the relevant country, as well as specific risk profiles of planned or utilised Third Party Intermediaries;
- Information concerning local market legal and ethics requirements;
- Information from the Third Party Intermediaries for potentially unusual arrangements ; and
- Information available from public sources or employees for potential risks associated with the Third Party Intermediaries.

### **Due diligence**

Before engaging with a Third Party Intermediary, Member Companies should perform a robust due diligence process by establishing a risk-based pre-engagement and renewal due diligence programme to identify, prevent and mitigate risks relating to the market in which the Third Party Intermediary is engaged to operate, as well as any specific activities the Third Party Intermediary may deploy on behalf of the Member Company. Member Companies should also consider performing due diligence checks during the execution of the engagement to continuously update any relevant information regarding the Third Party Intermediary, and in any case whenever required by local laws and regulations.

### **Training**

Member Companies should be mindful of current standards regarding onboarding and training of Third Party Intermediaries, and maintain and update their training materials accordingly.

It is therefore recommended Member Companies maintain an up-to-date assessment of the training needs of all individual Third Party Intermediaries with which a Member Company engages and to ensure that they are trained on a regular basis on new rules, requirements and standards applicable to the activity they perform for or on behalf of the Member Company. For example, Member Companies may consider providing access to relevant training materials (including internal Member Company) to small and medium sized enterprises or in general to Third Party Intermediaries that might have difficulties creating or accessing adequate training materials. Where practical, training should be done in local languages.

### **Written Contract**

Member companies should encourage contract terms that require adequate controls and implementation of the Company's anti-corruption policy, such as the following:

- Compliance with applicable laws, industry or professional codes, best practice principles and Member Company policies;
- Right to conduct independent audits, including where possible access to relevant books and records;
- Rights for early termination for failure to comply with applicable laws, industry or professional codes, best practice principles and/or Member Company policies.

### **Oversight**

Member Companies should, where applicable applicable, exercise reasonable efforts to perform risk-based, routine monitoring, auditing or other assessment of Third Party Intermediaries for compliance with applicable laws, industry and professional codes, best practice principles and Member Company policies and relevant contractual terms; and should request regular confirmation of Third Party Intermediaries' compliance with applicable laws, industry and professional codes, best practice principles and Member Company policies and relevant contractual terms.

### **Appropriate Corrective Action**

Member Companies are encouraged to implement necessary and appropriate corrective measures, consistent with applicable local laws if a Third Party Intermediary fails to comply with applicable laws, industry or professional codes, best practice principles, Member Company policies and/or applicable contractual terms or engages in other impermissible conduct.



## MedTech Europe Code of Ethical Business Practice Part 2:

# Complaint handling and dispute resolution



## 1. General Principles

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.

- The general principles 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 section 2.4.

## 2. Complaint handling procedure

### 2.1 Who can complain?

- A complaint concerning an alleged breach by a MedTech Europe Member Company (together “Member Companies” or individually “Member Company”) of the Code, can be lodged by any organisation or individual directly affected by the activities of MedTech Europe Member Companies, such as sickness funds, individual Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) or patients and Patient Organisations (“Complainants”).
- In the event that the MedTech Europe Secretariat becomes aware of information or facts which could involve a breach of the Code by a MedTech Europe Member Company, the MedTech Europe Secretariat may itself file a complaint with the MedTech Europe Compliance Panel<sup>5</sup>.

### 2.2 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 section 2.4.

### 2.3. Processing of complaints

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 section 2.4.
- 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

<sup>5</sup>) Please refer to the Code’s “Administering the Code” Chapter

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 in this section as well as in the Internal Rules of Procedure.
- v Complaints shall be handled confidentially by all parties involved in the procedure.

**2.4. Notwithstanding any provisions of this Code 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 following cases:**

- i there is no dispute resolution process in the territory concerned; or
- ii a Member Company is not a member of a Member Association; or
- iii more than one national compliance panel has or may have jurisdiction, but the parties to the dispute cannot agree on which one does. Referral may be made either by one of the parties or by a Member Association Secretariat or by the MedTech Europe Secretariat; or
- iv the national panel having jurisdiction cannot take the case based on provisions of its national code or any other legitimate reason; or
- v 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
- vi 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 the General Principles of this Part 2 or
- vii a dispute concerns an alleged violation of the MedTech Europe 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.

When deciding on such matters, the MedTech Europe Compliance Panel will act in conformity with the dispute resolution principles set out below and in the Internal Procedural Rules and will have the right to impose sanctions in line with the ones enumerated in section 4 below.

## 3. Dispute resolution principles and procedures

### 3.1 Principles for complaint handling and sanctions

Processing of complaints and sanctions by Member Associations as well as the MedTech Europe Compliance Panel shall follow the principles set out below:

- i 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. National panels and the MedTech Europe Compliance Panel shall not receive or process anonymous complaints.
- ii Member Associations and the MedTech Europe Compliance Panel may request any company, which is not a member of the Association and making a complaint under their codes, to undertake to abide by the provisions of their codes of conduct and their complaint handling principles as a pre-condition before processing the complaint.
- iii For complaints and other matters that are handled by the MedTech Europe Compliance Panel, it 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
- iv 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.

- v 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. It is the responsibility of the parties to notify the national panels and the MedTech Europe Compliance Panel of such proceedings.

### 3.2 Procedural steps for dispute resolution

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. Where a national panel or, where applicable, the MedTech Europe Panel considers a complaint fails to establish a prima facie case of violation of the Code or a national code, such complaint shall be dismissed with respect to that code.
- ii The second stage of the dispute resolution procedure shall be based on the principle provided in section 1 above. 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, by the MedTech Europe Secretariat, if considered appropriate, a 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.
  - 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.
- 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 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.
- v Decisions by the MedTech Europe Compliance Panel are final and no appeal is available.

## 4. Sanctions

### 4.1 The potential sanctions available to the MedTech Europe Compliance Panel and Member Associations' national panels must be proportionate to the infringement, act as a deterrent, and be commensurate with the seriousness and/or persistence of the breach.

Such sanctions may range from/to:

- 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; suspension – with specific time limit and detail on conditions of 're-entry' - of membership of the Member Association and/or MedTech Europe; expulsion from membership of the Member Association and/or MedTech Europe;

- Publication of any decisions or sanctions imposed upon the offender.

**4.2 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.**

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.

**MedTech Europe Code of Ethical  
Business Practice Part 3:**

Glossary and  
Definitions



- **Charitable Donations:** means provision of cash, equipment, Member 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 to bona fide charities or other non-profit entities or bodies whose main objects are genuine charitable or philanthropic purposes.
- **Clinical Research:** a type of research that studies tests and treatments and evaluates their effects on human health outcomes. This includes clinical investigations or interventional and non-interventional clinical performance studies where people volunteer to take part in order to test medical interventions including drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments and preventive care.
- **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, and Part 2: Dispute Resolution Principles.
- **Consulting Arrangement:** means any provision of service by a Healthcare Professional or Healthcare Organisation for or on behalf of a Member Company. Consulting arrangements include, but are not limited to marketing and Clinical Research activities, providing technical expertise for the development, testing, etc. of Medical Technology, providing feedback in post-market evaluations and market research, providing speaking services at Events, teaching other Healthcare Professionals, providing training on how to use the Member Company's Medical Technology, participating in research-related meetings, etc.
- **Delegate:** means Healthcare Professionals that attend an Event neither as Faculty, nor as Healthcare Professionals providing services to Member Companies for the specific Event.
- **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 solely for the support and 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 and where such support is provided solely for a specified intended purpose within this category.

- **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 an Event. Poster- and abstract-presenters are not considered to be Faculty.
- **Fair Market Value (FMV):** means the value of the specified services (or products, if applicable) which would be paid by the Member Company to the other party (for example a Healthcare Professional or a Healthcare Organisation), 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.
- **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. This definition does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of Member Companies' Medical Technologies or related services for or on behalf of medical or clinical personnel. For example, if a Member Company's Medical Technologies or related services are sold as part of the common merchandise of the retail outlet, interactions between the Member Company and the purchasing professional do not fall within the Code. However, where the Member Company's Medical Technologies or related services 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 within the Code.
- **In kind:** means the provision of Grants, Charitable Donations and other types of support in the form of goods or services other than money, including the provision of labour, lent or donated goods, or lent or donated services (e.g. catering services for Events, provision of venue space, company products and other services).
- **Legitimate Business Need:** means a current and actual business objective pursued by a Member Company such as the advancement of medical education, Clinical Research and/or the safe and effective use of the Member Company's Medical Technology . Engaging a Healthcare Professional or a Healthcare Organisation for the purpose of influencing the prescription, recommendation, purchase, order, supply, utilisation, sale or lease of Medical Technologies or related services directly or indirectly by a Healthcare Professional or Healthcare Organisation is never deemed a Legitimate Business Need.
- **Medical Technology or Medical Technologies:** Within the framework of the Code, Medical Technology refers to 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.
- **Members:** means all full and associate corporate members ("Member Companies") of MedTech Europe as well as full and associate national association members of MedTech Europe ("Member Associations"), as defined in the MedTech Europe statutes and as applicable and amended from time to time.
- **Preceptorship:** means a type of clinician-to-clinician training funded by a Member Company 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.
- **Proctorship:** means a type of clinician-to-clinician training funded by a Member Company 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.
- **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 purpose of supporting the development or furtherance of clearly specified 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 Intermediary:** means any legal entity or person that markets, sells, promotes or otherwise brings to end-users Member Companies' products or related services, and may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives.
- **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 is 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.
- **Virtual Event:** A Virtual Event is a Third-Party Organised or Company Organised Event that is characterised by the participation of Healthcare Professionals Delegates who attend exclusively remotely. As a result, a Virtual Event is not connected in any way with a physical Third Party Organised Educational Event. For example, the filming of presentations, discussions, etc. taking place during a Third Party Organised Educational Event ("hybrid" events), and their broadcasting to audiences not present at the physically attended Event—whether contemporaneously or after the Event—do not qualify as a Virtual Event, and therefore need to comply with all requirements of (in person) Third Party Organised Events.

## ANNEX I

### 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?		<b>NATIONAL</b> Third Party Organised Educational Events attended by delegates which are local HCPs only)	<b>INTERNATIONAL</b> (Third Party Organised Educational Events attended by delegates coming from at least two countries of the MedTech Europe Geographic Area <sup>1,2</sup> )	<b>INTERNATIONAL</b> (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practising in the MedTech Europe Geographic Area <sup>3</sup> )	<b>INTERNATIONAL</b> (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 <sup>4</sup> PROVIDED TO SUPPORT A THIRD PARTY ORGANISED CONFERENCE	Educational Grant to support the general running of a conference	Allowed <sup>5</sup> .	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code <sup>6</sup>
	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	Not allowed	Not allowed	N/A
	Direct sponsorship of HCPs as Faculty (active participation)	Not allowed	Not allowed	Not allowed	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 the avoidance of doubt, in 2018, this category of "Third Party Organised Educational Events attended by Delegates who are Healthcare Professionals registered and practising 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 solely for the support and 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 and where such support is provided solely for a specified intended purpose within this category

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 the situation involves neither a Member Company interacting with an HCP or HCO registered, practising and/or operating in the MedTech Europe Geographic Area nor does the activity take place in the MedTech Europe Geographic Area.

## ANNEX II Calculating the value of In Kind Educational Grants

### What is an In-Kind Educational Grant?

Please note that the [Glossary](#) includes a definition of Educational Grant, and Chapter 4 provides guidance as to how Member Companies can use them to support Third Party Organised Events or educational programs. The definition outlines two types of Educational Grants:

- Monetary grants which involve a transfer of funds to the organization
- In Kind grants which is a contribution that includes any other type of support

An In Kind Educational Grant is a non-monetary (i.e non-cash) contribution to an HCO to support an Event or educational program. Both Member Company and HCO should understand what constitutes an In Kind contribution as well as how to value this and this should be clearly documented.

### Types of In-Kind Educational Grant

An In Kind Educational Grant includes goods or services other than cash transfers, including where the In Kind support is provided by a third party and the payment is made directly by the Member Company to the third party (i.e. no funds are transferred to the Educational Grant beneficiary). Any In Kind Educational Grant must always strictly comply with the general requirements for Educational Grants set out in the Code and shall have the purpose of advancement of genuine medical education.

For example:

- **Goods** such as computers, furniture, electronic equipment, Xray protection clothing, masks, office equipment, etc.
- **Services** such as meeting space, transportation, copy services, administrative services, the supply of access to digital platforms (Zoom, Teams...) etc
- **Expertise:** Members could provide skills, expertise and/or resource to an HCO, such as providing technical support/analysis/work (hours spent by Members’ employees), which shall, if so, be provided solely for the purpose of supporting educational activities.
- **Member Company’s products** including commercially available / saleable products, re-usable training products and equipment, which may be returned to the Member Company after use

### Value of In Kind Contributions

The Member Company should, whenever possible and practicable, determine the amount of the In Kind contribution and quantify the value in the Educational Grant agreement. The basic principle for valuation of In Kind contributions should be the cost to the Member Company, which should, whenever possible and applicable include logistics, documentation and training costs. For specific recommendations on how to value In Kind Educational Grants please refer to the table below.

IN-KIND CATEGORY	EXAMPLES OF VALUES THAT CAN BE CONSIDERED, VAT EXCLUSIVE WHEN RELEVANT
Third Party Services	Contractual value or Fair Market Value
Services provided by Member Company Staff	The salary (inclusive social contributions), or a portion of the salary, for technical support provided by personnel employed by the Member Company (based on time spent and salary)
Goods (whether third party or Member Company-produced)	<ul style="list-style-type: none"> <li>• Provision of used goods                             <ul style="list-style-type: none"> <li>• Fair Market Value</li> <li>• Company book value</li> </ul> </li> <li>• Provision of new goods                             <ul style="list-style-type: none"> <li>• For third party goods, the listing price.</li> <li>• Contractual value or Fair Market Value</li> <li>• Internal costs, whether relating to cost of manufacture or transfer price</li> </ul> </li> <li>• Loaned goods                             <ul style="list-style-type: none"> <li>• Rental equivalent based on depreciation</li> <li>• Rental equivalent to highest-volume rate – NOTE: Rent cannot exceed accepted values if the equipment were to be donated or sold                                     <ul style="list-style-type: none"> <li>• Exception: if single used products are bundled, they should be separated and valued as a donation of equipment</li> </ul> </li> </ul> </li> </ul>

Materials, technological infrastructure, components	<ul style="list-style-type: none"> <li>• Fair Market Value</li> </ul>
Licenses	<ul style="list-style-type: none"> <li>• FMV for Member Company-owned licences</li> <li>• For licences acquired from third parties for HCO's use in the educational project, the cost.</li> </ul>
Software	<ul style="list-style-type: none"> <li>• Copying costs</li> <li>• Licensing costs</li> <li>• Software technical support costs</li> </ul>
Use of Facilities	<ul style="list-style-type: none"> <li>• Internal costs for use of facilities with specialised equipment</li> </ul>

In-Kind Educational Grant do not include the following:

- Samples and Demonstration Products
- Products or services provided as part of a commercial deal (e.g. samples required to be provided pursuant to a public procurement procedure)
- Products and services that could be used for non-educational clinical activities
- Any Products or services that are for research purposes (see Chapter 6: Research).

## Annex III

### 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
- Israel
- Italy
- Latvia
- Lithuania
- The Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- The United Kingdom
- Countries covered by Mecomed\*

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

		Direct Support for HCP attendance		
Event	Setting	Faculty /Speaker	Delegates	
Third Party Organised Educational Conference	Main Event / Independent Scientific Program	Not allowed	Not allowed	
	Satellite Symposium	Allowed (consulting agreement required)	Not allowed	
	Booth	Allowed (consulting agreement required)	Not allowed	
Third Party Organised Procedure Training meeting* *The criteria for a Third Party Organised Procedure Training meeting can be found in Q&A 18		Allowed	Allowed	
Company Events	Product and Procedure Training and Education Event	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed	
		Taking place at or about the same time as a Third Party Organised Educational Event	Not allowed	
	Sales, Promotional and Other Business Meeting	NOT taking place at or about the same time as a Third Party Organised Educational Event	Allowed (consulting agreement required)	Not allowed (except for demonstration of non-portable equipment)
		Taking place at or about 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 programme (i.e. not focused on marketing of 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 a speaker at an Event, for example someone who gives a presentation whether at a Company Event or a TPOE; someone who moderates/chairs a session and therefore needs to prepare ahead of the presentation/moderation.

### Guidance:

In order to determine whether an event is a TPOE or a Company Event, the following aspects should be taken into account:

- Open events (not only Company’s customers) are typical of a TPOE, and in this case, it is a third party chooses which HCPs attend or HCPs self-select;
- Who is the primary initiator of the Event: To what extent is the third party vs. the Member Company involved and who is determining the agenda?
- CME accreditation is an indication of a TPOE;
- TPOE generally have a broader focus than one or only a few products;
- 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.

### 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 rendering 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.