Irish Medtech
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Irish Medtech Code of Ethical Business Practice 2026

Guidelines on Interactions with Healthcare Professionals and Healthcare Organisations

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Harmonised with

MedTech Europe
from diagnosis to cure

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Introduction

1.1 Promoting an Ethical Industry

Irish Medtech is the business association within Ibec representing the Medical Technology sector in Ireland. Irish Medtech's broad focus is to promote and support an environment that encourages the sustainable development and profitable growth of our multinational and small to medium size Medical Technology companies in Ireland.

We are fortunate to work in an industry whose main aim is to bring hope to patients and it's important that we do so in an ethical manner to ensure quality of care but also good business practice. We as an industry have responsibility both to patients and to the healthcare providers and system. The long collaborative tradition between the Medical Technology industry and the healthcare profession has produced groundbreaking treatments which have transformed healthcare and patient quality of life. However, it is widely recognised that Medical Technology companies and the healthcare profession are entering a new era in terms of how they deal with each other. MedTech Europe (the European organisation representing the Medical Technology industry) published the new MedTech Europe Code of Ethical Business Practice in March 2022 (the "**2022 Code**"). Irish Medtech as a member association of MedTech Europe has adopted the 2022 Code and over the past number of years we have been busy providing guidance and information to Members about the 2022 Code. The 2022 Code is mandatory for all Members of Irish Medtech. It is not meant to restrict or in any way hamper how companies do business with healthcare systems but instead sets expectations and norms concerning the conduct of business and our interaction with healthcare professionals.

The Irish Medtech Code of Ethical Business Practice (the "**Code**") is comprehensive in its commitment to high ethical standards. It governs all interactions between Medical Technology companies and healthcare professionals, and it is supplemented by detailed guidelines which clarify and distinguish between appropriate and inappropriate activity in areas such as:

- Appropriate support of scientific and educational conferences
- Legitimate consulting agreements with Healthcare Professionals
- Provision of Educational Grants and Charitable Donations
- Provision of modest hospitality and promotional items

Irish Medtech is committed to this Code, and we look forward to working with our Members and other stakeholders to oversee its continued implementation. Irish Medtech recognises that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the Medical Technology industry. The Code sets out the minimum standards appropriate to the various types of activities carried out by the Members. The Code is not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon Members and all Members should independently ascertain that their activities comply with all current national and local laws, regulations and professional codes. Furthermore, Members must be mindful of the fact that they may be liable for the activities of third-party intermediaries who interact with Healthcare Professionals (HCPs) or Healthcare Organisations (HCOs) in connection with the sale, promotion or other activity involving Member companies' products

Key Legislation

The Medical Technology industry in Ireland, in common with other industries, is subject to national and supranational laws which govern many aspects of their business operations. Irish Medtech underlines compliance with the following laws and regulations as having particular relevance to the Medical Technology industry:

- Medical device and in-vitro device laws;
- Product liability laws;
- Safety, quality and performance laws;

- Advertising and promotion laws;
- Data protection laws;
- Anti-corruption and anti-bribery 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 Irish Medtech, each of the association'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, in addition to other applicable laws and rules.

1.2 Aims and Principles of the Code

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

(a) 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.

(b) 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.

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

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

(d) The Principle of Image 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.

(e) 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.

(f) 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.

(g) 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 compensation paid by the Member Company must be commensurate with, and represent a Fair Market Value for, the services performed by the Healthcare Professional.

(h) 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 compensation 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 compensation paid.

1.3 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.

1.4 Administering the Code

Compliance with the Code and with this Complaints Procedure and Panel Constitution is mandatory for members of Irish Medtech. The Code is administered by a Panel Administrator and by a panel of independent representatives. The independent panel is chaired by an independent solicitor / barrister. The panel may comprise of up to five, but not less than four independent experts. In the event that there are five, the areas of expertise should be categorised as follows: Legal, Company/Commercial, Clinical, Patient/Research, Public/ Patient interest.

A full overview of complaints procedure and sanctions are available on https://www.ibec.ie/irishmedtech_ethics

The introduction of more stringent rules on Educational Grants means that member companies are obliged to disclose financial contributions to HCPs. Ethical MedTech (https://www.ethicalmedtech.eu) is a platform, supported by MedTech Europe, dedicated to ethics and compliance projects in the Medtech industry. MedTech Europe have provided Irish Medtech members (whether MedTech Europe members or not) access to this portal for disclosure of financial contributions.

If an Irish Medtech member company is funding third party educational events, i.e., Educational Grants, promotional activity (e.g. booths) and satellite symposia), – they must ensure that the conference has been vetted under the Conference Vetting System (CVS).

1.5 Implementation

This edition of the Code is effective from 3 March 2026.

1.6 Complaint Handling

For complaints between Member Companies, inter-company dialogue should be considered seriously before further pursuit of the matter via any formal complaint handling process, either at national or MedTech Europe level *(Please see Part 2: Complaint Handling and Panel Constitution)*.

1.7 Company 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 *(Please see Chapter 3: Company Events)*.

Under no circumstances may a Member Company pay for additional costs (no costs beyond the company event or beyond the event duration) relating to the Healthcare Professional's attendance at the Third Party Organised Educational Event, such as registration costs, hospitality, additional travel or accommodation.

1.8 Q&As

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

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.

(b) ***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?***

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 organisational set up.

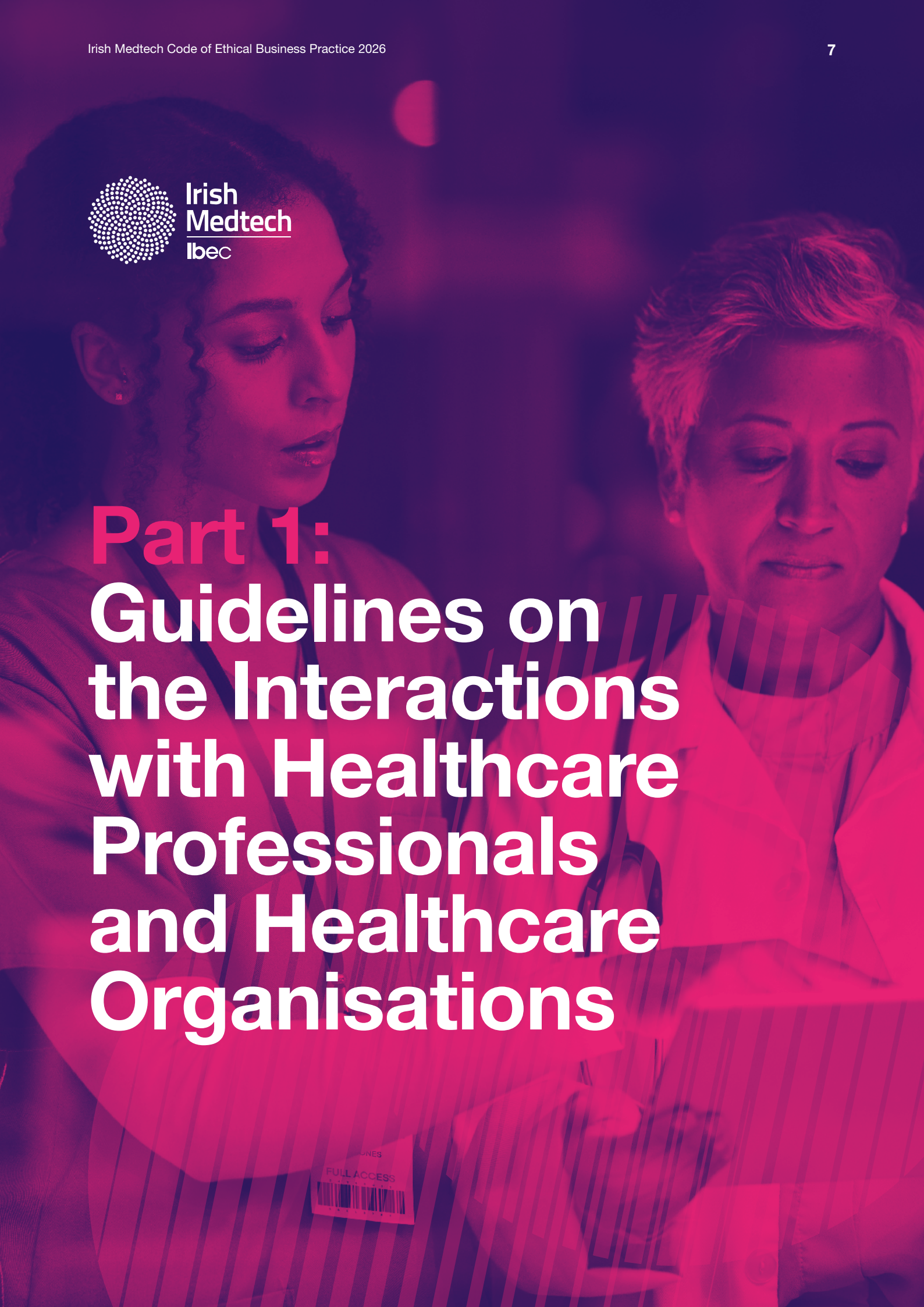
For example, if a Member were to have Medical Technology marketed under or linked to their pharmaceutical business unit, the interactions with Healthcare Professionals and Healthcare Organisations in relation to this Medical Technology would be governed by the Code irrespective of the business unit that 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.

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

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.



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Part 1: Guidelines on the Interactions with Healthcare Professionals and Healthcare Organisations

2. Chapter 1 General Criteria for Events

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.

2.1 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.

2.2 Event Location and Time

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

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

2.3 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.

2.4 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 [4.3] of Chapter 2)*.

2.5 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 [4.3] 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.

2.6 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.

2.7 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.

2.8 Q&As

(a) Q4 Do the minimum duration requirements of Section [2.1] of Chapter 1 apply to Virtual Events?

No, Virtual Events are not affected by the duration requirements of Section [2.1], Chapter 1 of the Code.

(b) 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?

No, it would not be appropriate for Member Companies to organise or support Events at hotels centred around leisure facilities such as golf, casinos or ski/water sports. An important factor in evaluating a hotel is its suitability for business meetings, including the availability of conference facilities. For hotels which include minor leisure and sporting facilities, such as a spa, while it would not be reasonable to exclude these venues if otherwise appropriate, Member Companies must exercise caution. The Event agenda should be arranged in such a way that Healthcare Professionals attending the Event 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 enable Guests to use the leisure and sporting facilities, Member Companies may not make such payments on behalf of the Healthcare Professionals.

(c) Q6 Under the Code, what is meant by "ease of access" in relation to Event location and venue?

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.

(d) Q7 Under the Code, how does the "season" impact evaluation of Event location?

For European and international Events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. Member Companies must not support or organise Events at these locations during those seasons.

(e) Q8 What does the term "facilitate" mean where used in connection with Guest expenses?

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.

(f) ***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?***

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.

(g) ***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?***

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.

(h) ***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?***

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.

(i) ***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?***

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 compensation 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.

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

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.

3. 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.

3.1 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)*.[1]

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.

3.2 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:

1. For scope of application of CVS please refer to: www.ethicalmedtech.eu

- 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)*.[2]
- 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.

3.3 Q&As

(a) ***Q14 What is meant by "In-Kind support" as used in Chapter 2, Section [3.1] of the Code in connection with "Third Party Organised Educational Conferences"?***

"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.

(b) ***Q15 Please provide examples of appropriate booth activities which will be perceived as professional?***

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.

(c) ***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)?***

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

(d) ***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?***

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.

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

Both Third-Party Organised Educational Conferences *(see the Glossary)* and Procedure Trainings *(see the Glossary)* are a type of Third Party Organised Educational

2. For scope of application of CVS please refer to: www.ethicalmedtech.eu

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.

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

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.

(g) 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?

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.

4. Chapter 3 Company Events

4.1 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 Need, 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.

4.2 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.

(a) 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 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 organising such an Event in order to be compliant with the Irish Medtech Code:

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

- 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.
- 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.
- 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.

- 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.

4.3 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 Healthcare Professionals at that Third-Party Organised Educational Event.

If such an Event overlap occurs, the Member Company may only pay the contractual compensation 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 organised 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 [5.3], subsection [(a)]), point [(i)], "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 Irish Medtech 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.

4.4 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 [4.4], 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.

4.5 Q&As

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

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.

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

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.

(c) ***Q23 Can a Member Company use a meeting venue outside Europe?***

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.

(d) ***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?***

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 [4.2], of the Code ("Product and Procedure Training and Educational Events").

5. Chapter 4 Grants and Charitable Donations

5.1 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. 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.

5.2 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.

Charitable Donations to non-profit hospitals may be permissible in case of demonstrated Financial Hardship *(see the 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.

(a) 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 organisation. The Member Company may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring charitable or non-profit philanthropic organisation for use as the sponsoring organisation sees fit. However, the Member Company 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.

5.3 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.

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)*[3]

(i) ***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 benefited from the Educational

3. For scope of application of CVS please refer to: www.ethicalmedtech.eu

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.

(ii) ***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 compensation 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 the 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.

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

Member Companies must bear in mind that certain compliance risks may arise 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.

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 Organiser 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/Processional Conference Organizer (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) Scholarship and Fellowship
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 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.

5.4 Q&As

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

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.

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

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.

(c) ***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?***

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.

(d) ***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?***

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.

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

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.

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

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.

(g) ***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?***

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.

(h) ***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)?***

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.

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

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)*.

(j) ***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?***

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.

(k) ***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?***

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, all 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.

(l) ***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?***

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:

(i) 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;

(ii) Fellowships and Scholarships, in accordance with the provisions of the Code;

(iii) 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.

6. Chapter 5 Consulting Arrangements

6.1 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 compensation 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.

6.2 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.

6.3 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 Fair Market Value (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.

6.4 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.

7. Chapter 6 Research

7.1 General Principles

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.

7.2 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/PMPF), 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 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.

7.3 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.

7.4 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.

7.5 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.

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.

7.6 Q&As

(a) Q37 What is an example of an external public register for clinical trial transparency?

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

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

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.

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

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).

(d) Q40 What is meant by "legitimate purpose" in the context of collaborative research?

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.

8. 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 compensation 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.

9. 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.

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.

9.1 Q&As

(a) ***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"?***

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.

(b) ***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?***

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.

(c) ***Q43 Please provide examples of educational items of greater value that can be provided to Healthcare Organisations under the Code?***

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.

10. Chapter 9 Demonstration Products and Samples

10.1 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.[4]

10.2 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

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).

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.

10.3 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 themself 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.

11. 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.

(a) 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.

(b) 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.

(c) 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.

(d) 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;

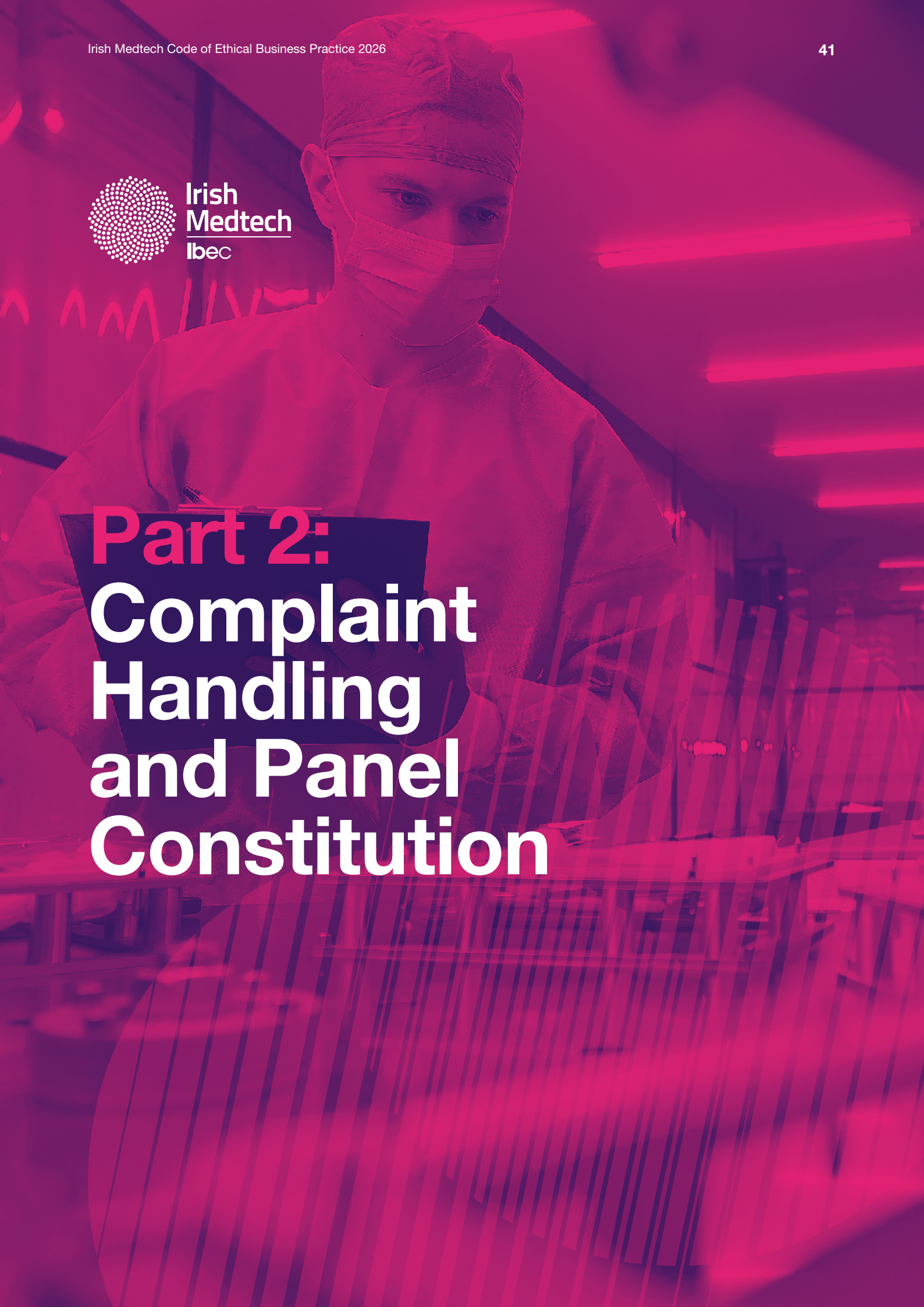
- Right to conduct independent audits, including where possible access to relevant books and records;
- Rights for early termination for failure to comply with applicable laws, industry or professional codes, best practice principles and/or Member Company policies.

(e) Oversight

Member Companies should, where 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.

(f) 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.



Irish Medtech
Ibec

Part 2: Complaint Handling and Panel Constitution

12. Complaint Handling and Panel Constitution

12.1 Introduction

A Code of Ethical Business Practice has been adopted by Irish Medtech. Compliance with the Code and with this Complaints Procedure and Panel Constitution ("the Procedure") is mandatory for members of Irish Medtech. Anyone (individuals and non-member companies) can submit a complaint against a member company of Irish Medtech, however, complaints made in relation to non-member companies do not fall within the scope of this Procedure and as such, will not be investigated.

The Code is administered by a Panel Administrator and by a panel of independent individuals ("the Panel") and the Panel is chaired by an independent solicitor/ barrister ("the Chairman"). The Panel or the Panel Administrator may ask the member company whose activities are the subject of a complaint ("the Respondent") for a complete response and may ask the parties to a case for further information in order to clarify the issues.

The company or individual making the complaint ("the Complainant") has the burden of proving their complaint on the balance of probabilities. Any Complainant wishing to use the Procedure must initially attempt to resolve any dispute with the Respondent through the dispute mechanism set out in Section [12.3] hereunder. Where the Complainant is an individual, they must initially attempt to contact the Respondent to resolve the complaint. They can do so by utilising the Respondent's internal or external whistleblowing and/or dispute resolution procedures, if available.

If such resolution does not prove possible then complaints are initially considered by the Chairman who will determine, if appropriate in consultation with the Complainant and/or Respondent, whether there is a case to answer.

Anonymous complaints (where the Complainant does not wish to disclose their identity to the Panel or Chairman) may be accepted at the discretion of the Chairman, however, the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed. Further detail regarding anonymous complaints is set out in Section [12.5] hereunder.

Confidential complaints (where the Complainant does disclose their identity to the Panel or Chairman but requests, whether at the outset or during the course of the complaint that their identity remains confidential) will be accepted from non-members. Where confidential complaints are received, the Panel and Chairman will endeavour not to disclose the Complainant's identity, save to the extent disclosure is required by Irish law, governmental or regulatory authority or by a court or other authority of this jurisdiction. However, Complainants wishing to make a confidential complaint should note that the ability of the Respondent to properly respond to information or matters put to them and therefore the Panel's ability to properly adjudicate on any particular complaint, may be adversely affected if the identity of the Complainant is kept confidential. In such circumstances the identity of the Complainant may be required to be disclosed to the Respondent but only with the Complainant's prior permission. If, in these circumstances, the Complainant does not grant permission to disclose their identity, it may not be possible for such a complaint to proceed. Confidential complaints will not be accepted from member companies.

12.2 Structure and Responsibilities

(a) Role of the Panel

(i) The Panel will adjudicate in situations where a complaint is made that an Irish Medtech member (or an employee of that member) is in breach of one or more of the practices laid out in the Code.

(ii) The Panel and Chairman report to Irish Medtech Board in respect of their activities and the operation and administration of this Procedure.

(iii) The Panel and Chairman will not be liable to the Complainant(s) and/or the Respondent(s) in contract, tort (including negligence and/or breach of statutory duty) or otherwise. The Panel and the Chairman will be indemnified in relation to their actions in relation to the Code and the Procedure by Irish Medtech.

(b) The Panel – Constitution and Procedure

(i) The Panel is appointed yearly by a majority vote at the Irish Medtech AGM (upon nomination by the Board of Irish Medtech) and may comprise of up to five, but not less than four independent experts. In the event that there are five, the areas of expertise should be categorised as follows: Legal, Company/ Commercial, Clinical, Patient/Research, Public/ Patient interest. In the event of less than five, they should be prioritised in the order above. The names and areas of expertise of the members of the Panel shall be published on the Irish Medtech Code of Ethical Business Practice website.

(ii) Panel members agree to serve for a minimum term of 3 years (from the date of adoption of the Procedure by the Board (12 December in 2013)) after which their position is to be filled by rotation in accordance with paragraph [12.2(b)(i)] above. From the outset two Panel members will serve for an initial period of 5 years (from the date of adoption of the Procedure by the Board (12 December in 2013)); those members to whom this pertains to be agreed amongst the Panel members, but the Chairman should be one of these. This extension to the initial period of tenure for two Panel members is required to ensure continuity of the Panel and to maximise the opportunity for rotation. In extenuating circumstances, a Panel member may resign before their term is complete by submitting their resignation in writing to the Chairman. Panel members may be nominated for a further term after the expiration of their initial term.

(iii) The Chairman shall be an independent barrister or solicitor with a minimum of 10 years post-qualification experience. A quorum of 3 Panel members is required for any Panel meeting which must include the Chairman. The Chairman has both an original and a casting vote (the casting vote only to be exercised in the event of a tie in the initial voting).

(iv) Rulings are made on the basis that a Complainant has the burden of proving their complaint on the balance of probabilities.

(v) Appointees to the Panel must treat as confidential all information with which they come in contact as members. Members of the Panel will be required to sign a Confidentiality Agreement, which will survive their tenure as members of the Panel.

(vi) Panel members are required to declare any conflict of interest with regards to any case which comes before the Panel and to excuse themselves from the case in question in the event of such a conflict. In the event that the Chairman of the Panel has a conflict, the Board of Irish Medtech will appoint another member of the Panel to act in the role of Chairman.

(vii) Panel members will be required to sign an agreement (“the Panel Agreement”) which will detail their appointment to the Panel and their duties and terms. This agreement will be counter-signed by the chairman of the Board of Irish Medtech.

(viii) The Panel may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel but have no voting

rights. Each such expert shall also be required to confirm that they have no conflict of interest in providing expert assistance on any particular case.

(ix) A complaint made under the Code and the Procedure should not be initiated, or should be suspended, in case of initiation of formal court, arbitration or other tribunal proceedings with respect to the same subject matter. Where a governmental or regulatory investigation or criminal proceedings are either initiated, or threatened, against a Complainant or a Respondent with respect to the same subject matter, that party shall notify the Chairman of the same in confidence, and the Chairman shall then have the discretion whether or not to suspend any relevant proceedings under the Procedure.

(x) At any time during a complaint handling process the Chairman or the Panel shall be entitled to refer questions of interpretation of the Code, in writing, to the [MedTech Europe Compliance Panel]. [The MedTech Europe Compliance Panel] may, at its discretion, either decline to entertain the matter if it is felt that no question of principle is at issue, or it may accept the interpretation referral and review and provide guidance on the interpretation of the Code. Where such a request has been made, the Chairman and the Panel shall be obliged to follow and apply any such guidance provided by the [MedTech Europe Compliance Panel], unless so doing would conflict with Irish law. For the avoidance of doubt the [MedTech Europe Compliance Panel] shall not rule on the merits or facts of any particular complaint but only on questions of interpretation of the Code.

12.3 Complaint Procedure

(a) Action on Complaints

(i) NOTE: Prior to lodging a formal complaint against a Respondent under the Procedure, a Complainant company shall first comply with the dispute resolution procedure outlined in paragraph [12.3(a)(ii)] below with the Respondent and, if necessary, enter into inter-company dialogue. Inter-company dialogue shall be a pre-condition before a complaint can be progressed to the Panel utilising the Procedure and any such Complainant shall adduce sufficient evidence to the Panel Administrator or the Chairman to prove such inter-company dialogue has been undertaken.

(ii) If a dispute arises between companies in connection with an alleged contravention of the Code, the Managing Directors or equivalent of the respective companies, with authority to settle the dispute will, within 14 days (or such other time as may be agreed between the parties) of a written request from one company to the other(s), meet in a good faith effort to resolve the dispute.

(iii) If the dispute is not resolved at that meeting, the companies involved will, unless otherwise agreed, attempt to settle the dispute by mediation in accordance with the Centre for Effective Dispute Resolution (“CEDR”) Model Mediation Procedure. Unless otherwise agreed between the companies, the mediator will be nominated by CEDR. To initiate the mediation a company must give notice in writing (“Mediation Notice”) to the other company to the dispute requesting mediation. The mediation will start not later than 30 days, (or such other time as may be agreed between the parties and the mediator), after the date of the Mediation Notice.

(iv) No Complainant may commence any court, arbitration or tribunal proceedings in relation to any dispute arising from the Code until it has attempted to settle the dispute by negotiation in

accordance with paragraph [12.3(a)(ii)] above and/or mediation in accordance with paragraph [12.3(a)(iii)] above and either the negotiation or the mediation has terminated or the Respondent has failed to participate in the negotiation or mediation, provided that the right to issue proceedings is not prejudiced by a delay (e.g. by the Statute of Limitations).

(v) Where the Complainant is an individual, they must initially attempt to contact the Respondent to resolve the complaint. They can do so by utilising that company's internal or external whistleblowing and/or dispute resolution procedures, if available. If no amicable resolution of the complaint can be reached through such means within a reasonable timeframe, the Complainant shall be entitled to pursue the matter further directly via this Procedure.

(vi) Any individual or company making a complaint under the Procedure that is not a member of Irish Medtech shall be required, for the duration of the Procedure, to undertake to abide by the provisions of the Procedure as a pre-condition before a complaint can be made utilising the Procedure.

(vii) A copy of the complaint (draft template available online https://www.ibec.ie/irishmedtech_ethics) to be dealt with by the Panel shall be submitted in writing, in English to the Panel Administrator (at Irish Medtech Code of Ethical Business Practice Panel Administrator, Irish Medtech Association, Ibec, 84-86 Lower Baggot Street, Dublin 2), by way of email to ciara.finlay@ibec.ie and shall include at a minimum:

(A) the name in full, description and address of the Complainant and Respondent;

(B) proof of compliance with paragraph's [12.3(a)(i)] to [12.3(a)(iii)] or if applicable, paragraph [12.3(a)(v)] above;

(C) detailed description of the nature and circumstances of the dispute giving rise to the complaint(s);

(D) reference to the provisions of the Code allegedly infringed (except in the case of an individual Complainant, where the Panel will examine the complaint and determine which clauses of the Code have been breached);

(E) detailed reasoning explaining the nature of the alleged infringement;

(F) a statement of the relief sought (except in the case of an individual Complainant, where the Panel will examine the complaint and determine the appropriate relief); and

(G) supporting documentary evidence.

(viii) Having checked that the documentation is fully complete, the Panel Administrator will forward the complaint to the Chairman in the first instance. The date of the receipt of the complaint shall be the date of confirmed receipt of the complaint by the Panel Administrator.

(ix) The Chairman shall undertake an initial review of the complaint and will determine (if appropriate, in consultation with the Complainant and/or Respondent) whether there is a prima facie case to answer. The Chairman will complete the initial review within 15 days, or such other time as may be agreed between the parties and the Chairman. When determining whether to proceed with anonymous complaints, the Chairman will follow the process set out in paragraphs [12.5(d)(i)] and [12.5(d)(ii)] below.

(x) If, in the view of the Chairman, a complaint does not show that there has been a prima facie breach of the Code, the Complainant and the Board of Irish Medtech shall be so advised. The Chairman's decision in this regard shall be final.

(xi) In the event that the Chairman determines that there is a prima facie case to answer, then the Chairman shall write to the Managing Director or equivalent of the member company

against whom the complaint has been made requesting that that member company ("the Respondent") provide a complete response to the complaint.

(xii) The Respondent shall provide a response in writing to the Chairman within 30 working days, or such other time as may be agreed between the parties and the Chairman. If no such response is provided by the Respondent within these timescales, then the Panel shall make its ruling on the basis of the information provided by the Complainant only.

(xiii) Following receipt by the Chairman of the Respondent's response, the case shall be referred to the Panel to rule whether or not there has been a breach of the Code.

(xiv) To assist member companies in ensuring that a complete response is submitted, the Chairman may suggest relevant supporting material to be supplied, although it is the responsibility of the Respondent to ensure that a full response is submitted.

(xv) In addition, the Chairman may request (whether at the suggestion of the Complainant or Respondent or at the behest of the Panel) such further clarifications or documents from either the Complainant (except in the case of anonymous complaints) or the Respondent, or any third party within such reasonable timescale as he shall deem prudent and necessary to assist the Panel in making its ruling or when assessing whether there is a prima facie case to answer in accordance with paragraph [12.3(a)(ix)] above.

(xvi) The Panel may, at its sole discretion, join several complaints into a single procedure, if the Panel decides that the subject matter of the complaints is identical or sufficiently connected.

12.4 Panel Rulings

(a) Where the Panel rules that there has been a breach of the Code, the Panel shall advise the Complainant and the Respondent, and the Board of Irish Medtech of such ruling in writing and give their reasons for the ruling. The Respondent must pay, within thirty working days, an administrative charge based on the costs incurred in respect of the Panel meetings and including the cost of expert advice (if any) as required by the Panel.

(b) The Respondent must also provide to the Panel Administrator a written undertaking within thirty days, or such other time as may be agreed between the parties and the Chairman, that the breach of the Code in question (if not already discontinued) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the Managing Director or equivalent of the Respondent and must be accompanied by details of the actions taken by the Respondent to implement the undertaking, including dates and timings and training undertaken or planned completion dates.

(c) Where the Panel rules that there is no breach of the Code, the Panel shall advise the Complainant and the Respondent, and the Board of Irish Medtech of such ruling in writing and give their reasons for the ruling.

(d) In addition to the foregoing, the Panel may impose sanctions on the Respondent (in the event of its breach of the Code) or the Complainant (in the event of no breach of the Code and the company is a member company) as appropriate in respect of any particular complaint. The Panel may:

  (i) issue a formal letter of reprimand to the member company;

  (ii) issue a formal letter of reprimand to the member company and also direct the Board of Irish Medtech to suspend that member company from membership of Irish Medtech for a specified period and/or to impose conditions for readmission;

  (iii) request the Board of Irish Medtech to expel the offender from the Association.

(e) Rulings of the Chairman or the Panel in relation to any complaint coming before him or it, and the sanctions to be imposed, shall be final and not subject to any appeal, or review, under the Code.

Note: The Panel will notify the Board of Irish Medtech of the imposition by it of any sanction under the Code.

The Board of Irish Medtech will notify the membership of Irish Medtech in the event that a member company is suspended or expelled from membership of Irish Medtech.

12.5 General Provisions

(a) Amendments to Time Periods

(i) The Chairman shall, in extenuating circumstances and at his discretion, be entitled to grant any party to this Procedure an extension in time or amend any timescales specified in this Procedure to the extent that to do so would be fair and reasonable in the circumstances.

(b) Withdrawal of Complaints

(i) A complaint may be withdrawn by a Complainant with the consent of the Respondent company up until such time as the Panel makes a ruling but not thereafter. In such case, the Complainant shall pay an appropriate administrative charge.

(c) Charges

(i) The administrative charge referred to in paragraph [12.5(b)(i)] above is determined by the Chairman based on the costs of formally convening the Panel and in dealing with the complaint.

(ii) Where two or more companies are ruled in breach of the Code in relation to a matter involving a joint activity, each company shall be separately and jointly liable to pay any administrative charge that is payable.

(iii) Failure to pay any of the administrative charges must be reported by the Panel Administrator, to the Board of Irish Medtech.

(d) Anonymous Complaints

(i) While anonymous complaints are accepted at the discretion of the Chairman, the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed. The Panel Administrator will first forward the complaint to the Chairman who will undertake an initial review to assess whether or not to accept the complaint. This will involve assessing whether there is a prima facie case to answer and if there is enough evidence and/or information available to fully adjudicate on the complaint. The process set out in Paragraphs [12.3(a)(viii)] to [12.3(a)(xvi)] will also apply to anonymous complaints.

(ii) The Chairman will consider the following factors when determining whether to accept an anonymous complaint:

(A) the significance/seriousness of the complaint;

(B) whether sufficient information has been provided to assess the anonymous complaint and respond appropriately;

(C) the potential to obtain independent information; and

(D) the potential for ongoing risk if the anonymous complaint is not assessed.

(iii) Anonymous Complainants do not have the right to challenge the outcome of either the Chairman or the Panel's decision or be kept informed of the progress of the Complaint.

(A) Amendments to the Code and the Procedure and Governing Law

(B) The Code and the Procedure may be amended by a simple majority of those present and voting at a Board meeting of Irish Medtech.

(C) The Chairman and/or the Panel may, in the light of their experience, make recommendations for amendment of the Code and the Procedure.

(D) The Code and the Procedure are governed by, and subject to, the laws of the Republic of Ireland.

13. Disclosure Guidelines

13.1 Preamble

Under the Code, Member Companies are not permitted to pay registration fees, travel or hospitality expenses directly to individual Healthcare Professionals for their participation in educational conferences organised by third parties as of 1st January 2018.

Medical Education may be supported through the provision of Educational Grants to Healthcare Organisations in compliance with the rules set out in the Code. To prevent abuses, specific safeguards when providing Educational Grants have been developed, including the obligation to disclose these Educational Grants.

Section [5.3] of Chapter 4 of the Code states that Member Companies shall document and publicly disclose all Educational Grants in accordance with these Disclosure Guidelines. These Disclosure Guidelines are therefore an integral part of the Code and need to be interpreted as such.

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

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

13.2 Chapter 1: Applicability and Scope

(a) Scope

These Disclosure Guidelines apply to Member Companies in their interactions with Healthcare Organisations based or registered in the MedTech Europe Geographic Area.

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

Transfers of value that are not included in the definition of Educational Grants (as described in Chapter 4, Section [5.3] of the Code) and that consequently cannot be allocated to any of the categories set forth in Section [13.3(b)] Aggregate Disclosure are not within the scope of these Disclosure Guidelines.

(b) Applicability of these Disclosure Guidelines

Member Companies need not report the same information twice due to being bound by national laws, regulations or professional codes imposing disclosure obligations regarding Educational Grants (as described in Chapter 4, section [5.3] of the Code) equivalent to the ones imposed by these Disclosure Guidelines.

(c) Applicability to Non-Member Companies

Non-member companies may implement these Disclosure Guidelines provided they are committed to ethical standards equivalent to those enshrined in the Code. Non-member companies may prove this commitment by obtaining the MedTech Europe Ethical Business Logo.[5]

5. The MedTech Europe Ethical Business logo is a symbol displayed by medical technology companies, distributors and other healthcare organisations to visibly demonstrate their commitment embracing and transcending the principles enshrined in the MedTech Europe Code for Ethical Business Practice.

(d) Q&As

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

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

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

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

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

Where a national code imposes disclosure obligations regarding Educational Grants (as regulated in Chapter 4, Section [5.3] of the Code) to the same extent as regulated by these Guidelines, Corporate Members, who are not a member of the National Association responsible for that national code, may choose either:

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

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

- To disclose only on the national platform or
- To disclose both on the MedTech Europe platform and the national platform. This selected option shall be included in the Methodology Note.

(iv) ***Q4 Who will decide if a national law, regulation or code imposes disclosure obligations regarding Educational Grants equivalent to the ones imposed by the Disclosure Guidelines?***

The MedTech Europe Secretariat shall conduct a yearly assessment of the equivalence of national laws, regulations and/or professional codes imposing disclosure obligations with the MedTech Europe Transparency Obligations (as regulated in Chapter 4, Section [5.3] of the Code).

Members can at any time submit any information or documentation they possess that could be relevant for this assessment to the Secretariat.

The MedTech Europe Secretariat shall submit its assessment to the MedTech Europe Transparency Task Force, who will analyse the proposal. If the MedTech Europe Transparency Task Force agrees with the proposal, it will be submitted for approval to the MedTech Europe Compliance Network. If the disclosure obligations imposed by a national law, regulation or professional code are deemed equivalent to the ones imposed by the Disclosure Guidelines, the assessment will be made public on the MedTech Europe Transparency website. This selected option shall be included in the Methodology.

13.3 Chapter 2: Disclosure Obligation

(a) General Obligation

Subject to the terms of these Disclosure Guidelines, each Member Company shall document and disclose all payments related to Educational Grants (as described in Chapter 4, section [5.3] of the Code) that it makes to a Healthcare Organisation based or registered in Europe, without limitation of value.

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

(b) Aggregate Disclosure

Educational Grants shall be disclosed on an aggregate basis. Each Affiliate of a Member Company shall disclose, for each clearly identifiable and separate recipient, the amounts paid as Educational Grants to such recipient in each Reporting Period[6] which can be reasonably allocated to one of the categories set out below. Such amounts will be aggregated on a category-by-category basis, but itemised disclosure shall be made available upon request by the Member Company, as deemed necessary, to (i) the relevant recipient, and/or (ii) the relevant authorities.

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

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

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

(c) Optional Object Specification

If desired, Member Companies may indicate the object of the Educational Grants disclosed for one or both categories set forth in Section [13.3(b)] Aggregate Disclosure.

(d) Methodology

Each Member Company shall create a note summarising the methodologies used by it in preparing the disclosures and identifying Educational Grants for each category described in Section [13.3(b)] Aggregate Disclosure. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Educational Grants for purposes of these Disclosure Guidelines, as applicable. This methodology note shall be made available upon request by an interested party.

(e) Q&As

(i) Q5 Which Affiliate should disclose a particular Educational Grant?

To facilitate the tracking of Educational Grants made to individual Healthcare Organisations, it is recommended that the Affiliate making the payment in relation to a particular Educational Grant is the one disclosing the Educational Grant, but this is an internal decision of each Member Company.

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

(ii) Q6 When should a Methodology Note be made available?

Member Companies should create a comprehensive Methodology Note that would allow any Healthcare Organisation directly affected by a disclosure to understand how the amount disclosed was aggregated. The Methodology Note

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

should therefore be made available upon specific request to Healthcare Organisations concerned about a particular disclosure that directly affects them. See Annex [IV].

(iii) Q7 What is a "unique country local identifier"?

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

13.4 Chapter 3: Form of Disclosure

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

(b) Time of Disclosure
Disclosures shall be made by each Member Company within 6 months after the end of the relevant Reporting Period.

(c) Time of Publication
The disclosures shall be made public at the time of publication. The time of publication is the 31 August of the year of the relevant time disclosure

(d) Template and Language of Disclosure
For consistency purposes, disclosures made pursuant to these Disclosure Guidelines shall be made in English using the template set forth in the Annex.

(e) Platform of Disclosure
Disclosures shall be made on the Ethical MedTech website[7] unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Section [13.2(b)] Applicability of these Disclosure Guidelines. Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, MedTech Europe shall not be held liable for (i) maintaining, correcting, deleting the published data nor (ii) for the storage of data after the three years period of disclosure in the public domain.

(f) Retention and Modification of Disclosure
Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication.

The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

(g) Enquiries Regarding Reported Disclosures
Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication.

Member Companies shall make available to Healthcare Organizations upon request any data concerning their common contractual relations published in accordance with these Disclosure Guidelines at any time while the disclosed information remains in the public domain as stated in Section [13.4(c)] Time of Publication.

(h) Q&As

(i) Q8 When will the first Reporting Period start?

The first Reporting Period is the calendar year starting with the AGM 3 March 2026, and ending on with the AGM in 2027.

(ii) Q9 In what currency should the amounts paid be disclosed?

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

7. www.ethicalmedtech.org

Part 3: Glossary and Definitions

14. 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 Irish Medtech Association Code of Ethical Business Practice (including the incorporated Questions and Answers), the Disclosure Guidelines and the Complaints Procedure and Panel Constitution.

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 member companies of the Irish Medtech Association.

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 affect 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.

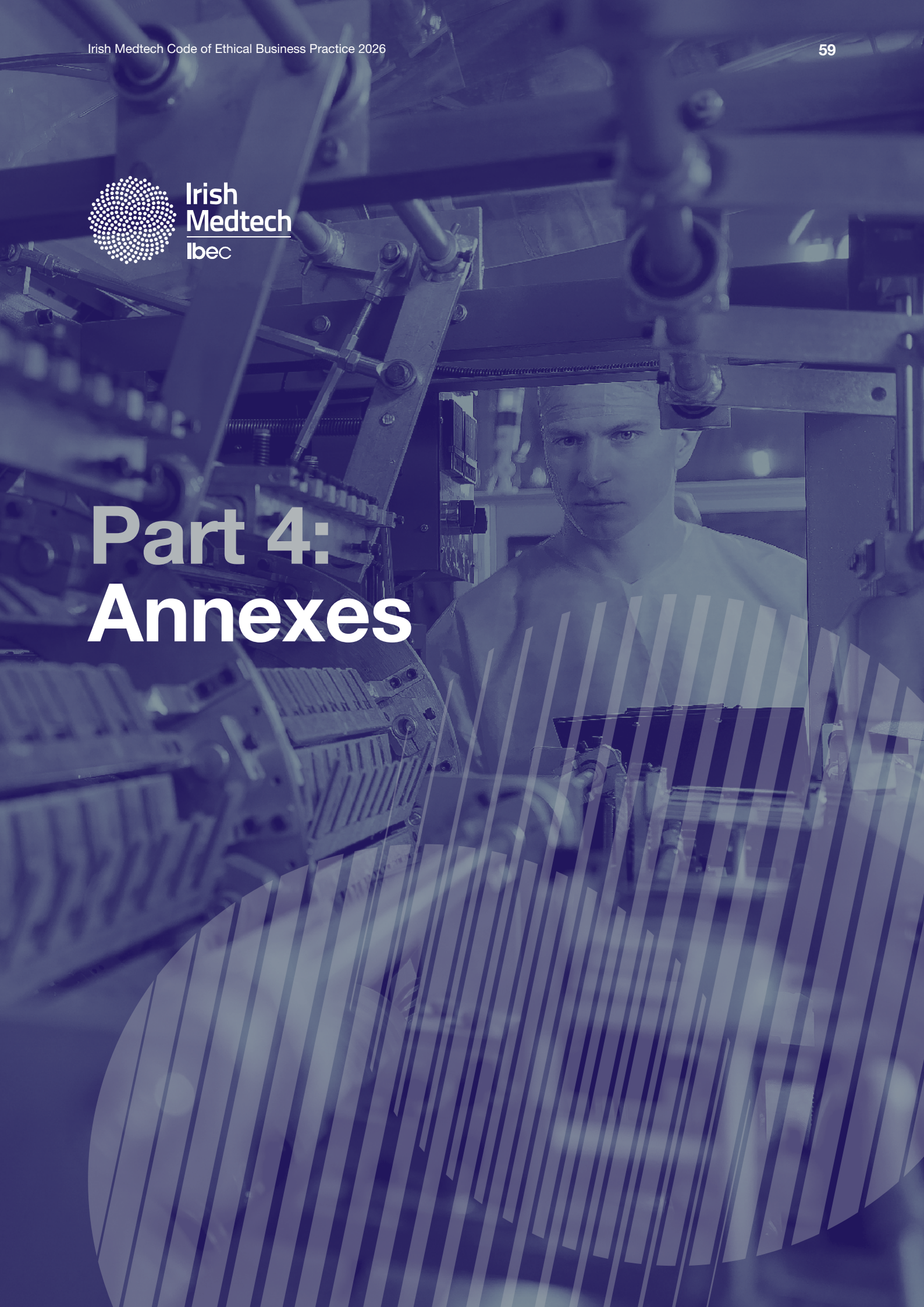
Third Party Organised Educational Conferences: means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and is 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), patient 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.



Part 4: Annexes

Annex I

14.1 CVS Scope: When are CVS assessments required?

PRIOR CVS SUBMISSION					
In Medtech Europe Geographic Area			Outside Medtech Europe Geographic Area		
Which type of support can member companies provide to which third party organised educational events?		**National** (Third Party Organised Educational Events attended by delegates which are local HCPs only)	**International** (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area)	**International** (Third Party Organised Educational Events attended by delegates who are Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area	**International** (Third Party Organised Educational Events to which no Healthcare Professionals registered and practicing in the MedTech Europe Geographic Area attend, neither as speakers or delegates)
Educational grants provided to support a third party organised conference	Educational Grant to support the general running of a conference	Allowed	Subject to CVS decision	Allowed. Not subject to CVS decision	Out of scope of the application of the Code
	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

Annex II

14.2 MedTech Europe Geographical Area

The MedTech Europe Geographic Area currently includes

(a) Countries with National Associations:

(i) Austria
(ii) Belgium
(iii) Bulgaria
(iv) Croatia
(v) Cyprus
(vi) Czech Republic
(vii) Denmark
(viii) Estonia
(ix) Finland
(x) France
(xi) Germany
(xii) Hungary
(xiii) Ireland
(xiv) Italy
(xv) Latvia
(xvi) Lithuania
(xvii) The Netherlands
(xviii) Norway
(xix) Poland
(xx) Portugal
(xxi) Romania
(xxii) Russia
(xxiii) Slovakia
(xxiv) Slovenia
(xxv) Spain
(xxvi) Sweden
(xxvii) Switzerland
(xxviii) Turkey
(xxix) The United Kingdom

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

(i) Iceland
(ii) Liechtenstein
(iii) Luxembourg
(iv) Malta

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

Annex III

14.3 Calculating the Value of In-Kind Educational Grants

(a) What is an In-Kind Educational Grant?

Please note that the Glossary includes a definition of Educational Grant and Chapter [5.3] 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.

(b) 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.

(c) Value of In-Kind Educational Grant

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	In-Kind Category
Third Party Services	Contractual value of 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)

In-Kind Category	In-Kind Category
Goods (whether third party or Member Company-produced)	• Provision of used goods – Fair Market Value – Company book value • Provision of new goods – For third party goods, the listing price – Contractual value of Fair Market Value – Internal costs, whether relating to cost of manufacture or transfer price • Loaned goods – Rental equivalent based on depreciation – Rental equivalent to highest-volume rate – NOTE: Rent cannot exceed accepted values if the equipment were to be donated or sold ■ Exception: if single used products are bundled, they should be separated and valued as a donation of equipment
Materials, technological infrastructure, components	• Fair Market Value
Licenses	• FMV for Member Company-owned licenses • For licenses acquired from third parties for HCO's use in the educational project, the cost.
Software	• Copying costs • Licensing costs • Software technical support costs
Use of Facilities	• Internal costs for use of facilities with specialized equipment

In-Kind Educational Grants 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 [7]: Research)*.

Annex IV

14.4 Methodology Note Example

Structure
Introduction

Executive summary of the methodologies used for disclosure purposes and countries specificities
Definition
- (i) Recipients
- (ii) Types of Educational Grants

Disclosure scope and timelines

Disclosures in case of partial performance or cancellation

Cross-border activities

Specific considerations:
- (a) Multi-year agreements

- (b) Consent management (please note that some jurisdictions may require the legal entity's consent for publication of data)
  - (i) Consent collection
  - (ii) Management of recipient consent withdrawal
  - (iii) Management of recipient's request
  - (iv) Partial consent

Disclosure Form

- (c) Date of submission

- (d) Currency in case of aggregated payments made in different currencies

- (e) 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 [13.3(d)] Methodology.*

Annex V

14.5 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:

(a) 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.

(b) 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)

(c) Grant provided in a form of a Scholarship or Fellowship:
- Activity records of the educational programme
- Certification of enrolment 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 VI

14.6 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 [3.3(e)]			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	Not allowed
		Taking place at or about the same time as a **Third Party Organised Educational Event**	Allowed	Not allowed (except for demonstration of non-portable equipment)
	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:

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

(b) **Satellite Symposium:** Common elements of Satellite Symposia are:

- It takes place at a Third Party Organised Event and it is part of the Third Party Organised Event 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.

(c) **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 Third Party Organised Event; 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 Third Party Organised Event or a Company Event, the following aspects should be taken into account:

- Open events (not only Company's customers) are typical of a Third Party Organised Event, and in this case, it is a Third Party who 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 Third Party Organised Event;
- Third Party Organised Events generally have a broader focus than one or only a few products;
- Single-sponsored events are often Company Events.

Annex VII

14.7 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 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 either:

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

This exception is to be narrowly interpreted.

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

Criteria for Third Party Organised Procedure Trainings Determination

(a) Programme:

Practical and hands-on activities must comprise the majority of the programme of Third Party Organised Procedure Trainings (unlike Third-Party Organised Educational Conferences which are theoretical in nature). Third Party Organised Procedure Trainings 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 Third Party Organised Procedure Trainings, 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 Third Party Organised Procedure Trainings programme.

The following will be considered as examples of practical sessions:

- Hands-on sessions in which all attendees to the Third Party Organised Procedure Trainings participate actively. In these sessions, attendees perform specific procedures on settings and environments appropriate for the practice of the relevant procedure. Examples of hands-on sessions may include surgery simulations where the technologies relevant to the specialty are practiced on cadavers, skin models, synthetic bones, cath labs; etc. To ensure that attendants are able to fully benefit from the active aspects of hands-on sessions, no “station” (model, cadaver, table, etc.) can in principle have more than four participants. For ethical considerations, when human cadavers are used, up to eight participants may share a “station”.

- Streaming (e.g. video, 3D-rendering software, augmented reality) or demonstrations of live surgeries.
- Case study sessions when the trainees learn about procedure preparations and best practices from specialty expert(s). These sessions must be interactive and based on pictures, videos, animations, 3D rending software, augmented reality, etc.

(b) Venue:
Third Party Organised Procedure Trainings' 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.

(c) Stand-alone event:
Third Party Organised Procedure Trainings 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 Third Party Organised Procedure Trainings as defined in the Code.

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

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